

**EFFECT OF QUIET TIME IMPLEMENTATION
ON SLEEP-WAKE STATES OF PREMATURE INFANTS
IN THE NEONATAL INTENSIVE CARE UNIT**

The seal of Mahidol University is a circular emblem. It features a central blue circle containing a golden Thai-style stupa or chedi. The stupa is topped with a flame-like finial and has intricate carvings. The blue circle is surrounded by a wide yellow ring. Inside this ring, the Thai text "จุฬาลงกรณ์มหาวิทยาลัย" (Mahidol University) is written in a circular path. There are also small golden floral motifs on the left and right sides of the yellow ring.

SAKUNTALA SUDSANEHA

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OF THE REQUIREMENTS FOR
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(PEDIATRIC NURSING)
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Thesis
Entitled

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IN THE NEONATAL INTENSIVE CARE UNIT**



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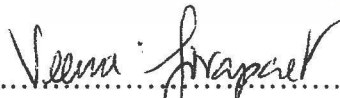
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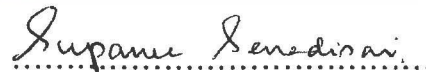
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Sakuntala Sudsaneha

EFFECT OF QUIET TIME IMPLEMENTATION ON SLEEP-WAKE STATES OF PREMATURE INFANTS IN THE NEONATAL INTENSIVE CARE UNIT

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ABSTRACT

This quasi-experimental research examined the effect of quiet time implementation on sleep-wake states of premature infants in the neonatal intensive care unit (NICU). The conceptual framework was based on developmental care and the synactive theory of development. Twenty-four premature infants, who were admitted to the NICU, Ramathibodi Hospital during August 2003 and February 2004, were selected as test subjects by purposive sampling. All subjects were used in control and experimental periods for data collection. During the control period (non-quiet time), the premature infants received conventional routine nursing care, but received conventional routine nursing care with quiet time implementation during the experimental period (quiet time). The NICU environment (sound levels, light levels, and handling scores) and sleep-wake states of premature infants were recorded by the research assistants. Data were analyzed using a powerful statistical analysis program, SPSS for Windows version 11.5.

According to the Wilcoxon signed rank test for matched paired difference, the results revealed that the mean score of sleep-wake states of premature infants during the experimental period was statistically significantly lower than during the control period in all shifts as well as total ($p < .001$). Frequency of the quiet sleep-related state during the experimental period was more than the control period with 23.3 percent increase. Moreover, frequency of the crying-related state during the experimental period was 10.9 percent less than during the control period.

These findings provide information that quiet time implementation can be used as a guideline for improving the nursing care to promote both quality and quantity of sleep of the premature infants in the NICU.

KEY WORDS: NICU ENVIRONMENT / POSITIONING /
DEVELOPMENTAL CARE / QUIET TIME /
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ผลของการจัดช่วงเวลาสงบต่อภาวะการหลับตื่นของทารกเกิดก่อนกำหนดในหออภิบาลทารกแรกเกิด

(EFFECT OF QUIET TIME IMPLEMENTATION ON SLEEP-WAKE STATES OF
PREMATURE INFANTS IN THE NEONATAL INTENSIVE CARE UNIT)

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บทคัดย่อ

การวิจัยกึ่งทดลองครั้งนี้ ศึกษาผลของการจัดช่วงเวลาสงบต่อภาวะการหลับตื่นของทารกเกิดก่อนกำหนดในหออภิบาลทารกแรกเกิด โดยใช้หลักการดูแลเพื่อส่งเสริมพัฒนาการทารกเกิดก่อนกำหนดเป็นกรอบแนวคิดในการศึกษา กลุ่มตัวอย่างเป็นทารกเกิดก่อนกำหนดที่เข้ารับการรักษาในหออภิบาลทารกแรกเกิด โรงพยาบาลรามาธิบดี ระหว่างเดือนสิงหาคม พ.ศ. 2546 ถึง เดือนกุมภาพันธ์ พ.ศ. 2547 เลือกลุ่มตัวอย่างแบบเฉพาะเจาะจงตามคุณสมบัติที่กำหนดไว้ทั้งหมด 24 ราย ทารกเหล่านี้ได้ถูกใช้ในกลุ่มตัวอย่างทั้งในช่วงเวลาควบคุม (ช่วงเวลาปกติ) และช่วงเวลาทดลอง (ช่วงเวลาสงบ) โดยในช่วงเวลาควบคุมทารกเกิดก่อนกำหนดเหล่านี้ได้รับการพยาบาลตามปกติ ส่วนในช่วงเวลาทดลองได้รับการพยาบาลตามปกติร่วมกับการจัดช่วงเวลาสงบเพื่อส่งเสริมคุณภาพการนอนหลับจากผู้วิจัยตามรูปแบบที่สร้างขึ้น โดยมีผู้ช่วยวิจัยเป็นผู้ดำเนินการเก็บข้อมูล ซึ่งได้แก่ ระดับเสียง ระดับแสง คะแนนการถูกจับต้องที่ทารกได้รับ และระยะการหลับตื่นของทารกเกิดก่อนกำหนด วิเคราะห์ข้อมูลโดยใช้โปรแกรมสำเร็จรูปทางสถิติ

ผลการศึกษา พบว่า ค่าเฉลี่ยของคะแนนการหลับตื่นของทารกเกิดก่อนกำหนดในช่วงเวลาสงบมีค่าต่ำกว่าช่วงเวลาปกติ อย่างมีนัยสำคัญทางสถิติที่ระดับ .001 โดยในช่วงเวลาสงบทารกเกิดก่อนกำหนดอยู่ในระยะหลับลึกมากกว่าช่วงเวลาปกติเพิ่มขึ้น ร้อยละ 23.3 และในช่วงเวลาสงบทารกเกิดก่อนกำหนดอยู่ในระยะร้องไห้ลดลงร้อยละ 10.9 เมื่อเปรียบเทียบกับช่วงเวลาปกติ

ดังนั้น ผลการศึกษานี้สามารถนำการจัดช่วงเวลาสงบไปใช้เป็นแนวทางในการพัฒนาการพยาบาล โดยควบคุมสภาพแวดล้อมในหออภิบาลทารกแรกเกิด เพื่อส่งเสริมทั้งปริมาณและคุณภาพการนอนหลับของทารกเกิดก่อนกำหนดได้

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CHAPTER I

INTRODUCTION

Background and Rationale

The quality of sleep plays important role in physical growth and recovery of premature infants. Schibler and Fay (1990) indicated that sleep was one of the basic needs of all kind of human being. Secretion of cortisol and adrenaline is inhibited during sleep. Growth hormone increases protein synthesis and mobilization of free fatty acids for energy use. Thus, sleep facilitates healing (Glass, 1994: 78). In infants, the sleep is a natural requirement, which promotes growth, development, and function of the body especially the central nervous system (CNS). The sleep pattern of a newborn infant is strongly related to the maturity of the central nervous system. The quality of sleep is usually indicated in two distinct states: active sleep and quiet sleep. *Active sleep* is generally defined as a wide awake asleep because of the level of brain activity similar to the awake state. During active sleep, information is processed and entered into memory as well as changing in protein synthesis increases. Thus, active sleep is thought to be related to learning and restructuring of synapses. *Quiet sleep* is restorative and anabolic. An increase in cell mitosis and replication occurs and oxygen consumption reaches the lowest levels during this state, which may be beneficial for the infants with respiratory problems. Moreover, the release of growth hormone is associated with quiet sleep. In brief, both states are necessary for optimal mental and physical functioning (Balsmeyer, 1990: 447; Blackburn & Loper, 1992: 560-564; Catelett & Holditch-Davis, 1990: 21, Holditch-Davis, 1998: 924-927; Wong & Whaley, 1991: 129).

Newborn infants spend about two third of their time asleep in order to promote growth and development during the early phase of life. The length of a normal sleep cycle and the amount of quiet and active sleep are normally changed with maturation of the CNS, which generally varies with age. Newborns spend a greater proportion of their total sleep in active sleep than adults do. Term infants spend 50 % of their sleep

time in active sleep stage. In utero, the fetus is in quiet sleep, approximately 80 % of the sleep time with very few interruptions. In contrast, preterm infants in the neonatal intensive care unit (NICU) spend as much as 60 to 70 % (about 80 % of the sleep time) of the day in active sleep, which is further increased during acute illness. Improper proportion between quiet and active sleep during acutely ill period may affect physical growth and wound healing of the preterm infants. (Brazelton, 1999: 324; Glass, 1994: 78; Kohyama, 1998: 73; Lawhon, 1988 cited in Strauch et al., 1993: 31; Schibler & Fay, 1990: 285-286; Strauch et al., 1993: 31-35)

The intrauterine environment is recognized as the optimal environment to foster growth and development of the fetus. In the other hand, birth represents an obligatory change of environment. For high-risk premature infants, their new environment becomes NICU. These infants are transported into a world of bright lights, sudden and loud noises, and rapid temperature changes. Consequently, the infants are exposed to painful and aversive experiences. There is often irregular pattern of handling and absence of handling in response to the infants' emerging behavioral organization. These noxious stimuli disrupt sleep and can have biological consequences for the neonates (Blackburn & Vadenberg, 1998: 945; Glass, 1999: 91-92). Four most commonly identified sources of stress, which may alter the sleep of the premature infants in the NICU environment, are (1) vestibular stimulation-inappropriate position, (2) auditory stimulation -noise pollution, (3) visual stimulation-ambient and bright light exposure, and (4) tactile stimulation-frequent aversive procedures or excessive handling.

How premature infants are positioned is important factor in their growth and development. Generally, the physiological flexion develops in the last trimester of pregnancy in response to decrease space in uterus and as an active process in neurological development. Therefore, infants born prematurely do not have opportunity to develop physiological flexion (Moore, 1966 cited in Creger, 1993: 430). Because of that, the physical positioning of the infants is a part of the NICU tactile-vestibular experience. Prone positioning in the NICU has been strongly supported physiologically. The current NICU dilemma is that the prone sleep position is contrary to the recommendation given by the American Academy of Pediatrics (AAP), which now supports supine positioning due to the fact that epidemiologic data

associates supine positioning with lower rate of sudden infant death syndrome (SIDS). Corff and colleagues (1995) documented that generalized motoric containment of an infant's arms and legs close to the infant's body while in a side-lying or supine position resulted in significantly lower mean heart rates, shorter mean crying and sleep disruption times, and fewer sleep-state changes after a painful heelstick procedure than without motoric containment (Lawhon, 1986; Lawhon & Melzar, 1988 cited in Blackburn & Vandenberg, 1998: 955-966).

Noise is undesirable sound in NICU. Ambient noise levels in the NICU are noted to range from 50 to 88 dB-A and peak level of 117 dB-A inside the incubator have been reported (Gottfried & Hodgman, 1984: 292-293; Thomas, 1989: 249). AAP: Committee on Environmental Hazards (1974) recommended that sound level inside incubators and in the NICU should be reduced below 58 dB-A. Noise in the NICU can be highly arousing for premature and ill term neonates, causing agitation and crying. This in turn leads to decrease in oxygenation and increase in intracranial pressure, heart rate, and respiratory rate (Long et al., 1980: 143-145). Noise may also be disruptive to the sleep state and sleep-wake cycle and may adversely affect the neonates' recovery and growth. (Bess, et al., 1979: 105; Wachs et al., 1971 cited in Depaul & Chambers, 1995: 72). In the study of Strauch, Brandt & Edwards-Beckett (1993) regarding implementation of a quiet hour: effect on noise levels and infant sleep states indicated that the decrease of noise level can significant lead the infants to have more quiet sleep than active sleep.

The recommendation for regular office lighting is 40-50 footcandles (ft-c); in the AAP Committee in 1992, Guidelines for Perinatal Care, 60 ft-c is recommended in the NICU for adequate observation, and 100 ft-c is recommended for procedures (Jack, 2000: 16; Shogan & Schumann, 1993: 7). Modern NICUs are brightly lit environments with ambient light in exceed of the recommendation. The general range reported has been 30 to 150 ft-c; with peaks over 1,500 ft-c from sunlight (Glass, 1990; Landry et al., 1985 cited in Glass, 1999: 103). The intensity of ambient illumination for any individual infant is determined by the location of the incubator in a room, the number of overhead light units, the size, location, and compass direction of windows, the season of the year, and even the prevailing weather condition (i.e., sunny vs. hazy). Bright light in an infant's face is a source of stress. Even routine

ambient light level affects sleep and wake states in preterm infants. Lower ambient light is associated with significantly less active rapid eye movement sleep and significantly more quiet sleep among premature infants with 35 to 36 weeks postconceptional age (Haith, 1983 cited in Glass, 1999: 104).

Handling is the most direct source of stress for preterm infants in the NICU. In a study of Jariya Indhabhandhu (2001), which examined the handling received by the premature infants in NICU found that on average, preterm infants were handled 45 times per day and the total handling time per day was 3 hours 53 minutes. The rest period between handling was only 13 minutes. The main disturbers were the nursing staff (82.3 percent), while the least were parents (0.9 percent). Excessive handling has other significant physiological consequences for the sick neonate. Blood pressure changes, alterations in cerebral blood flow, and episodes of oxygen desaturation are associated with noxious procedures, handling, or crying. Importantly, when caretakers monitor the infants' level of oxygenation during procedures, the severity of hypoxemic episodes can be reduced significantly. Thus, the amount and type of handling may have direct detrimental consequences for the vulnerable neonates. (Long et al., 1980; Murdoch & Darlow, 1984; Peabody & Lewis, 1985; Perlman & Volpe, 1983; Speidel, 1978; & Volpe, 1989 cited in Glass, 1999: 93).

The birth of any infant presents a dramatic change in environment. A full-term infant is however ready for the outside world, and quickly adapts with increasing interest in it. In contrast, a preterm infant is in double jeopardy as he/she is unprepared for extra-uterine life and has to face the environment of the NICU, which is complex and generally over-stimulating. Normally, individuals and their environments are constantly changing in a process of mutual adaptation. In the case of the premature infant, however, rapid physiologic changes and immature homeostatic mechanisms limit his/her abilities to adapt to the environment. Therefore, the NICU environment must be constantly changed to support and facilitate the infant's development (Blackburn & Vandenberg, 1998: 945; Glass, 1999: 91; Reid & Freer, 2000: 24-25; White-Traut et al., 1994: 393). Four studies about factors influencing sleep pattern in the premature infants have been done in Thailand. These studies are the effects of positioning on duration of sleep among premature infants (Penjit Thanacharoenpipat, 2001), handling received by premature infants in neonatal intensive care unit (Jariya

Indhabhandhu, 2001), the sleep pattern of premature infants during an eight-hour period and examined the effects of procedure on the sleep patterns of premature infants (Charastong, 2001), and the physiological and sleep-wake behavioral responses of premature infants to the neonatal intensive care unit environment (Kurdrit, 2002). There is no mention of the benefit of sleep promotion in premature infants by using reducing stimuli in neonatal intensive care unit environment in any of above studies. This is why the researcher is interested in studying the effect of quiet time implementation, which is designed to provide age-appropriate sensory input and protect the premature infant from stressful stimulation in the neonatal intensive care unit environment.

Conceptual Framework

This research is based on the *Developmental Care and Synactive Theory of Development* to study the effect of quiet time implementation on sleep-wake states of premature infants in the neonatal intensive care unit.

The term '*developmental care*' is used to describe the interventions which support and facilitate the stabilization, recovery and development of infants and families undergoing intensive care, and beyond, in an effort to promote optimal outcome. The theoretical basis demonstrates that low birth weight infants are at increased risk of medical complications, growth deficits, neurological impairment and a range of more subtle cognitive and behavioral difficulties (Fasting, 1995; Hack et al., 1995; Powls et al., 1996; Tin et al., 1997 cited in Reid & Freer, 2000: 15). Recently, the pattern of intervention in developmental care concept has been divided into two different approaches. One theoretical approach views the infant in NICU as being over-stimulated compared to the natural uterine environment and proposes minimal handling and reduced sensory input, via the environment at large and the individual cot space. Another approach views the infant as being deprived of appropriate sensory inputs and additional stimulation is provided in an effort to improve outcome. In short, a range of possible strategies and interventions are devised to meet individual need, and to support individuals' developmental goals (Reid & Freer, 2000: 16).

The synactive theory of development was developed by Heidelise Als in 1982 (Als, 1982: 230-231; Als, 1986: 15-18). The conceptualization of development focuses

on how the individual infant appears to handle the experience of the world around him/her. This theory provides a model through which one can specify the degree of differentiation of behavior and the ability of the infant to organize and control his/her behavior. The focus is not on assessment of skills, but on the unique way each individual infant deals with the world around her or him. The synactive theory of development specifies the range of neonatal behavior as the infant matures as well as the ability of the infant to regulate behavior. This model is based on the assumption that the infant's primary route of communicating both functional stability and the limits for stress is through behavior (Blackburn & Vandenberg, 1998: 940-941; Creger, 1993: 426-430; Reid & Freer, 2000:15-21).

In this study, the researcher believes that the vulnerable premature infants with intensive care in the NICU environment as being both over-stimulated from excessive handling, bright light, and noxious sound around the clock and deprived of appropriate sensory input, which in turn lack of opportunity to develop physiological flexion in the last trimester of pregnancy. These conditions are sources of stress and anomalous sensory stimulation, both of them may affect the autonomic, motor, and state-organizational system. These stimuli disturb the rest of the premature infant. Therefore, the quiet time implementation: providing optimal position, reducing sound and light levels, and keeping handling in minimal is established to encourage a period of quiet sleep. The objective of this research is to study the effect of quiet time implementation on sleep-wake states of premature infants in the neonatal intensive care unit. The relationship between the variables of this study is shown in Figure 1.

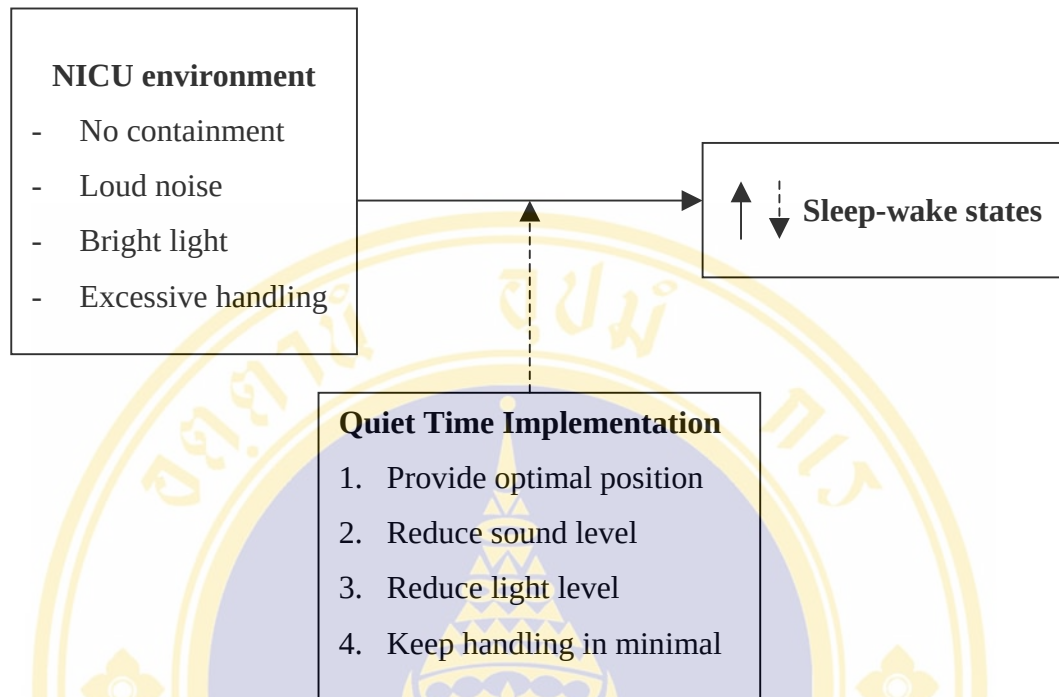


Figure 1: The relationship between the variables of the study

Research Question

Is there any difference of sleep-wake states of premature infants between non-quiet and quiet times in the neonatal intensive care unit?

Research Objective

To compare the difference of the sleep-wake states of premature infants between non-quiet and quiet times in the neonatal intensive care unit.

Research Hypothesis

The sleep-wake states mean score of premature infants during quiet time is lower than non-quiet time.

Scope of the Study

The purpose of this quasi-experimental research is to study the effect of the quiet time implementation on sleep-wake states of premature infants in the neonatal

intensive care unit. The samples used in this study are twenty-four premature infants who has been admitted to the neonatal intensive care unit, Ramathibodi Hospital, during August 2003 and February 2004.

Research Assumption

Quiet sleep is natural and basic requirement for premature infants, promoting growth, development, and functioning of their body. Being born before maturity, each premature infant faces both sensory overloading from the anomalous NICU environment and sensory deprivation from the lack of containment that contributes the negative effect on sleep-wake states.

Definition of Terms

Quiet time refers to the two-hour period during each eight-hour shift for implementing quiet time protocol to promote sleep-wake states in premature infants (12:00 am. to 2.00 pm. in day shift, 6:00 to 8:00 pm. in evening shift, and 3:00 to 5:00 am. in night shift). Quiet time protocol has four aspects of developmental care: 1) providing optimal position, 2) reducing sound levels, 3) reducing light levels, and 4) keeping handling in minimal. During quiet time protocol, the infants are placed in flexed, midline supine containment, sound and light levels are reduced, and procedures and routine activities are kept to a minimum level in which the disturbance to the rest of premature infants is well protected.

Non-quiet time refers to the rest of the time from quiet period – six hours during each eight-hour shift. The research setting in this time is set as the natural condition seen in any typical NICU. The procedures and activities given to premature infants are kept in normal routinely. They are kept warm by incubator and provide mostly in supine position.

Optimal position refers to an appropriate posture for premature infants –that is flexed, midline supine containment. This posture includes head and neck placed in neutral position or slightly extension as in midline or comfortably turn to one side, shoulders flexed forward with hands near mouth or on midline chest, hips and knees slightly flexed up toward abdomen, arms and legs in symmetrical. Also, it includes the use of nest, made with blanket roll, to provide as much flexion as possible and to

support feet by bracing it with this roll. The optimal position is provided to them only during two-hour period of quiet time in each eight-hour shift.

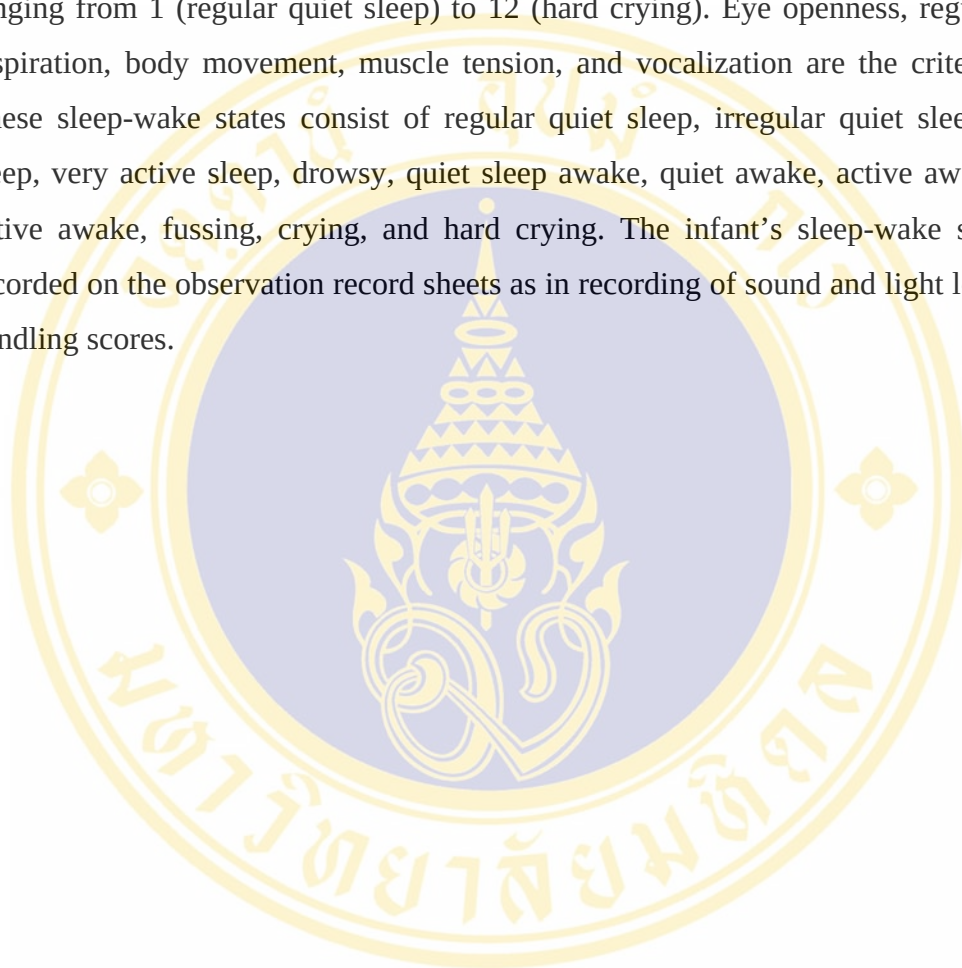
Sound level refers to the intensity or loudness of sound that generally occurs in NICU from many sources such as monitor alarms, staff conversations, medical rounds, nursing activities, intercoms and other communication devices, and grunting or crying sound from patients. The Sound Level Meter model: DS-40 providing a digital display of the decibels-A weighting (dB-A) is used to measure the sound level inside incubator. The sound levels is then recorded on the observation record sheets as a way in which two hours from non-quiet time is systematically sampled in random and two hours of quiet time are recorded for every ten minutes.

Light level refers to the intensity or illumination of light that comes from a variety of sources in NICU such as heat lamps, phototherapy lights, individual bedside lights, windows, and overhead fluorescent or incandescent lights. The Digital Lux Meter model: LX-50 providing a digital display of the lux (1 foot-candle = 10.75 lux) is used to measure the light level inside incubator. Like sound levels, the light levels are recorded on the observation record sheets as a way mentioned in sound levels recording.

Handling refers to all the touches, tactile stimuli given to premature infants by paramedics and parents in the NICU. The handling more often occurs among the critically or intermediately ill neonates due to procedures and routine activities. The handling is assessed by Assessment of Premature Infant Handling, which is developed by the researcher using renowned methods previously published in international journals. This assessment is used to measure the handling procedures received by the premature infants in the NICU for both non-quiet and quiet times. It consists of five sets of handling: no handling, comfort handling (must be received only during sleep state), disturb handling, discomfort handling, and painful handling, with the scores ranging from 0 (no handling) to 4 (painful handling), respectively. Increasing score means that the procedure is more affecting the sleep of the premature infant. Like sound and light levels, handling score has been recorded on the observation record sheets in the same way.

Sleep-wake states refer to the behavior states of a premature infant that exhibit alternation periods of sleep and wakefulness. These states are generally related to

sound levels, light levels, handling scores, and position of the premature infant in the NICU. The infant's sleep-wake states are assessed by the Anderson Behavioral State Scale (ABSS), which adapted from Parmalee and Stern (1972) to measure the behavioral state of premature infants. The ABSS consists of 12 categorical states, ranging from 1 (regular quiet sleep) to 12 (hard crying). Eye openness, regularity of respiration, body movement, muscle tension, and vocalization are the criteria used. These sleep-wake states consist of regular quiet sleep, irregular quiet sleep, active sleep, very active sleep, drowsy, quiet sleep awake, quiet awake, active awake, very active awake, fussing, crying, and hard crying. The infant's sleep-wake states are recorded on the observation record sheets as in recording of sound and light levels and handling scores.



CHAPTER II

LITERATURE REVIEW

This research studies the effect of quiet time implementation on sleep-wake states of premature infants in the neonatal intensive care unit. The review of related literature and relevant studies cover the following topics:

1. Sleep in premature infants
2. Factors influencing sleep patterns of premature infants in the NICU
3. Assessment of behavioral sleep-wake states in premature infants
4. Developmental care and synactive theory of development
5. The quiet time implementation

Sleep in Premature Infants

The behavioral state of premature infants reflects the pattern of sleep and wakefulness, and indicates their maturation of central nervous system. Body functions, health problems during neonatal period and environment around themselves, are affected by the sleep pattern of premature infants while they live in the neonatal intensive care unit. More details about these factors are described in the paragraphs bellow.

Premature infants

Premature infant is defined as a baby born before completion of 37 weeks' gestation, regardless of birth weight. The word *premature* is often used in place of *preterm*, although the two are not synonymous. After delivery, the neonate's gestational age will be estimated by assessing physical and neurologic and neuromuscular development. The rate of maturation may lag behind or forge ahead of gestational age (Joines, 1992: 1120; Peterec & Warchaw, 1999: 185; WHO, 1950 cited in Crosse, 1975: 1).

The gestational assessment is a determination of the approximate duration of fetal development, and a comparison against standardized norms of neonatal growth versus weeks of gestation, to identify those infants unusually large or small for gestational age. Various tools have been developed to facilitate estimation of

gestational age. In most widespread use are those of Lubchenco, Dobowitz, and Ballard. These assessments consist of an observation of external physical characteristics such as skin condition, ear development and an evaluation of neuromuscular development (Endo & Nishioka, 1993: 267-274).

Categories of premature infants

Premature infants can be grouped into three categories according to their status as explained in following paragraphs.

1. *Extremely premature infants* typically have gestational age between 24 and 30 weeks, with birth weights of about 500 to 1,500 grams, and represent 0.8 to 1.0 percent of live newborns. The mortality rate is high for the newborns from this category since the growth and physical development has not yet been completed.
2. *Moderately premature infants* have gestational age about 31 – 36 weeks, with birth weights in the range of 1,500 – 2,500 grams, and are spotted in 6 – 7 percent of live newborns. Many physiologic handicaps of infants born in this group can be dealt with effectively using modern therapeutic techniques.
3. *Borderline premature infants* have gestational age of 36 – 37 weeks with a birth weight ranging from 2,500 to 3,250 grams and are found among 16 percent of live newborns. The appearance of newborn infants from this group is almost identical to full-term infants.

Characteristics of premature infants

The characteristics of premature infants vary with the gestational age. They are most marked in the infants with the shortest gestational age and become less distinctive as the gestational age increases. The presence or absence of pathological conditions in the infant has a definite effect on the development of the infant, but in the following account it is assumed that the infant is healthy and has the normal characteristics of the gestational age at which it is born (Crosse, 1975: 1-12).

1. *Length.* The length of the infant is generally measured from vertex to heel. After the 28th week, the infant measures of approximately $1\frac{1}{4} \times$ weeks of gestational age in cm ($\frac{1}{2} \times$ weeks of gestational age in inch).
2. *Weight.* The mean birth weight at different gestational age varies in different countries, and even in different districts, because the birth weight is influenced by many factors.

3. *General proportions.* The premature infant has a large head in proportion to the size of its body. The chest is relatively small in the premature infant, while the abdomen is relatively large; the head circumference usually exceeds the circumference of the chest (nipple line) by 3.75 cm or more.

4. *Activity.* The lower the gestational age of the infant, the less is its. The shorter the gestational age of the infant, the weaker and less frequent the cry.

5. *Temperature control.* The body temperature tends to be subnormal because of the poor heat production, increased heat loss, and lacked of ability to regulate the body temperature.

6. *Respiratory system.* The development of the lungs depends on the length of gestation. The lower the gestational age the less blood flows through the lungs; the remainder being shunted through the ductus arteriosus. Respiration is largely diaphragmatic, and tends to be irregular in rhythm and depth. The cough reflex is absent in the smallest premature infants, making the danger of inhalation of regurgitated fluids a very real one. The nasal passages are extremely narrow, and the mucous membrane is easily injured.

7. *Circulatory system.* The heart is relatively large at birth. The peripheral circulation is often poor. The walls of the blood vessels are weak, especially those of the intracranial vessels, and this probably accounts for the special tendency to intracranial hemorrhage appeared in premature infants.

8. *Digestive system.* The smaller infants have poor powers of suction and swallowing. These reflexes become progressively feebler and the smallest infants are unable to feed effectually.

9. *Urinary system.* Urination is scanty and infrequent for a few days after birth due to the small amount of fluid taken. The kidneys may be easily palpable, being relatively lower during fetal life.

10. *Genital system.* In female, the labia minora are not covered by the labia majora until almost at term. In male, the testicles may be in the abdomen, inguinal canal or scrotum, according to the gestational age, but they may be found in the scrotum as early as 28 week's gestation.

11. *Nervous system.* The development of the nervous system depends on the length of gestation. Those with the shortest gestational age tend to lie quietly unless

disturbed; only waking at intervals for feeding. The shorter the gestational age the less good is the muscle tone. The centers controlling the vital functions, e.g. respiration, control of body temperature, are poorly developed, and so also are the centers controlling the vital reflexes, e.g. coughing, swallowing and sucking.

12. *Eyes.* By gestational age of 24 weeks, the retinal vessels have grown about 6 mm from the optic nerve. Between 24 and 30 weeks no further growth occurs ('immature fundus') but after this time growth recommences ('transitional fundus') and by about 34 weeks the fundus is usually mature.

13. *Skin, hair, and nails.* The skin is red and shiny, and little subcutaneous fat is present in infants up to 28 weeks' gestation; but after this the skin becomes paler and subcutaneous fat begins to appear. In the smallest infants, the nipples are flat pigmented areas and it is only after 36 weeks gestation that they rise above the surrounding skin. Lanugo is plentiful up to 28 weeks, and then becomes less in amount; the back, the face and extensor surfaces of the limbs being most commonly affected. Hair is short and scanty and eyebrows are often absent. The nails are softer than at term.

Health problems during neonatal period

Premature birth deprives the neonate of the complete benefits of intrauterine life. Consequently, the response of a premature infant to extra-uterine life is different from that of a term infant. Due to immaturity, many health problems the premature infant facing during neonatal period includes inadequate respiratory function, cardiovascular disorder, temperature instability, fluid and electrolyte imbalance, gastrointestinal disorder, endocrine and metabolic disorder, hematological disorder, infection disease, and neurological problem. Health care of premature infant is assessed at birth and resuscitation performed if indicated. Stabilization of respiration and thermoregulation take priority over all other types of care. Besides, the special needs of the premature infant are composed of nutritional care, close observation, position and skin care. As a result of many health problems and special needs during neonatal period, thus the premature infants may spend up to 3 months or more in the NICU (Joines, 1992: 1125-1129; Papageorgiou & Bardin, 1999: 451-458; Peterec & Warchaw, 1999: 189-194; Thompson & Ashwill, 1992: 111-117).

Sleep

Sleep is a natural, recurring state of altered consciousness that provides rest for the body, mind, and spirit, and is terminated by intrinsic or extrinsic stimuli. It is a complex process consisting of several stages governed by the interaction of neurochemical systems and endogenous circadian and ultradian pacemakers (Barndt-Maglio, 1986 cited in Schibler & Fay, 1990: 285; Cohen & Merritt, 1992: 109). Sleep is a phenomenon that is common to all humans and it begins before birth as a part of intrauterine existence and continues until the time of death. It is an integral part of the human experience, omnipresent throughout the life cycle (Renual, 1996: 27; Webster & Thompson, 1986: 447).

Sleep-wake states

After birth, the infant exhibits alternating periods of sleep and wakefulness. Sleep in neonates and infants exhibit differences from that of the adult. As a result, sleep is not well defined and definitions are less precise than in the adult. Consequently, neonatal and infant sleep is described in terms of state, which is a group of physiologic and behavioral characteristics that regularly recurring together (Blackburn, 1983 cited in Blackburn & Loper, 1992: 560). Sleeping and waking states are clusters of behaviors that tend to occur together and represent the level of arousal of the individual, the individual's responsiveness to external stimulation, and the underlying activation of the CNS (Ashton, 1973 cited in Holditch-Davis, 1998: 921). Three states have been identified in adult: wakefulness, non-REM (rapid eye movement) sleep, and REM sleep. In infants, it is also possible to identify states within waking and states that are transitional between waking and sleeping because infants are less able to make rapid changes between states than are adults. Because the electrophysiological patterns associated with sleeping and waking states in infants are somewhat different from those in adults (Anders et al., 1971 cited in Holditch-Davis, 1998: 921), the sleep states are usually designated active and quiet sleep, rather than REM or non-REM sleep.

The major difference between conventional definitions of sleep-wake states of infants is the number of types of states and therefore the specificity and precision of the various states. Generally, the more immature neonate according to gestational and postconceptional age, the grosser or less precise the definitions of state and

consistency among indicators. Six categories of behavioral states have been described, which include: non-REM or quiet or deep sleep, REM or active or light sleep, drowsy, awake or quiet alert, active alert or considerable motor activity, and crying.

1. *Quiet (non-REM) sleep* is deep, restful sleep with the eyes closed, little body or facial movement, except for an occasional startle or twitch, regular respiration and heart rate, and no movement of the eyes. Quiet sleep is restorative and anabolic. An increase in cell mitosis and replication occurs during this stage. Oxygen consumption reaches the lowest levels during quiet sleep that is oxygenation is higher during this sleep state; thus, quiet sleep may be beneficial for infants with respiratory problems.

2. *Active (REM) sleep*. During this state the eyes are closed but there are movements of the extremities and face, mouthing, grimacing, and sucking movements. Respiration and heart rate are irregular. Active bouts of REM occur in association with dreaming; the fine, rapid movement of the eyes can be observed beneath the lid. Information is processed during active sleep and entered to memory; thus, active sleep has been linked to learning and restructuring of synapses and changes in protein synthesis increase during active sleep. However, in as much as respiratory patterns are relatively unstable in active sleep and transcutaneous oxygen values are lower and more variable.

3. *Drowsy*. During the drowsy state, the neonate or infant seems partially awake and partially asleep. Drowsiness usually indicates a state transition between awake and sleep states.

4. *Quiet alert*. In this state, the neonate or infant is awake, the eyes are open, and there is little motor movement. The neonate or infant is alert and shows interest or attention by focusing on visual stimulation. The quiet alert state is sometimes referred to as awake alert, emphasizing the limited motion and activity associated with the infant attending to sensory information.

5. *Active alert*. The neonate or infant's motor activity escalates in the active awake state. The eyes may have a hyper alert appearance. There may be spitting up or hiccoughing. Respiration often becomes increased and irregular, and skin color changes may occur. The active alert state often precedes crying.

6. *Crying.* In healthy infants crying is easily recognizable. Crying behaviors include closed eyes with facial characteristics and the vocalization of cry sounds. In preterm infants the motor actions associated with cry sounds are evident, but because of the infant's immaturity and weakness, the sounds may not be produced.

The ability to clearly differentiate these states is dependent on the infant's postconceptional age. The proportion of time spent in each of these states also varies with postconceptional age. The mean duration and frequency of episodes of each state also changes over the preterm period: quiet waking, active waking, and sleep-wake transition episodes occurred more frequently, and active waking and quiet sleep bout length increased over age (Brazelton, 1973; Holditch-Davis, 1998: 921-927; Reid & Freer, 2000: 20-24; Wolff, 1996 cited in Blackburn & Loper, 1992: 561).

Development of sleep-wake patterns

In neonate, sleeping and waking states represent the level of maturity and intactness of the central nervous system (CNS), the infant's relationship with the external environment and his or her ability to regulate and stabilize underlying internal systems (Reid & Freer, 2000: 20). Fetal activity records document fluctuating periods of activity and quiescence, seen as early as 21 weeks' gestation (Serman, 1972 cited in Blackburn & Loper, 1992: 560). At a gestational age of 24 weeks, cycling between sleeping and waking can be identified by electroencephalogram (EEG) in some infants and by 28 weeks, infants clearly exhibit distinct sleeping and waking states. However prior to 30 weeks', the various behaviors associated with sleep and waking – eye movements, body movements, respiration, and muscle tone – are not well coordinated; not until at least 36 weeks' GA do preterm infants exhibit the same degree of correlation between these parameters as do full-term infants.

The development of sleep patterns change occur from neonate to adult. The most substantial change is the ratio of active to quiet sleep. Active sleep predominates in the immature infant and declines with maturation. Thus, sleep begins with active state during early life and gradually changes to quiet as the first sleep state (Anders & Keener, 1983 cited in Schibler & Fay, 1990: 286-287). Neonates and infants spend a large portion of the 24-hour day sleeping.

Newborns depend on an adequate amount of sleep to meet the needs of their rapid growth. They sleep approximately 16 to 18 hours of every 24-hour period. The

length of a normal sleep cycle and the amount of active and quiet sleep vary with age. The length of each sleep cycle is shorter in young infant than in old infant. The length of sleep cycle in preterm infant is about 30 to 40 minutes, in full-term infant is about 50 to 60 minutes, and in adult is about 90 to 100 minutes. Full-term infants spend 50 percent of sleep time in active sleep. However, premature infants spend more time in active sleep approximately 80 percent of the sleep time. Periods of sleep are short, typically not extending beyond 3 or 4 hours. Since arousal occurs most easily when the sleeper emerges from quiet to active sleep, the infant has more periods of being vulnerable to awakening than the older child or adult (Blackburn & Loper, 1992: 560-654; Ferber, 1985b cited in Balsmeyer, 1990: 447; Holditch-Davis, 1998: 924-927; Kick, 1996: 247; Schibler & Fay, 1990: 285-288; Sears, 1985 cited in Balsmeyer, 1990: 447).

Central nervous system (CNS) development determines the ability to prolong periods of sleep and wakefulness in infancy. With increasing age, time spent in each stage of sleep changes. As the CNS matures, REM stages are shortened and NREM periods and periods of wakefulness lengthen (Faranoff & Martin, 1987; Ferber, 1985b cited in Balsmeyer, 1990:447). Sleep-wake pattern change with CNS maturation and sleep is required for brain development.

Differences in sleep-wake patterns reflect differences in neurological development and the infant's ability to modulate state. State modulation refers to the infant's ability to make smooth transitions between states, arouse when appropriate, and sustain sleep states. By modulating or regulating state, the infant can control sensory input to some extent and the response to the environment (Brazelton, 1984 and Gorski, Lewkiwicz, & Huntington, 1987 cited in Blackburn & Loper, 1992: 563). In addition, the infant can use state behaviors to guide caregiving and to modify social interactions. State modulation is therefore an asset in the infant's adaptation to the environment. Infant factors influencing state modulation include immaturity, pain, stress, maternal substance abuse, and illness. Environmental factors that affect state regulation and interfere with the infant's sleep-wake pattern include noise, light, temperature, and caregiver actions (Blackburn & Loper, 1992: 563-654).

Factors Influencing Sleep-wake States of Premature Infants in the NICU

The birth of infants presents a dramatic change in environment with leaving the fetal environment: consistent temperature, containment, gravitational support, attenuated light and noise and subtle nutritional, hormonal and psychological influences. However, a full-term infant is ready for the outside world, and quickly adapts with increasing interest in it. Normally, individuals and their environments are constantly changing in a process of mutual adaptation. But birth before term, a premature infant is unprepared for new environment of the NICU, which is totally different from the uterus. The highly technological NICU has been found to be physiologically stressful to the premature infant and disturb his/her sleep-wake state. Factors influencing sleep-wake states of premature infant in the NICU are expressed in this section.

Physical environments

Noise: noise is undesirable sound. The intensity of sound is measured in decibel A-weighting (dB-A). Noise originates from four sources in NICU: the environment itself (such as outside sound, traffic noise), patient care equipments (such as monitor alarms, operating sound), caregivers (such as conversation, rounds, radios, intercoms and other communication devices), and patients (such as grunting or crying sound). AAP: Committee on Environmental Hazards (1974) recommends that sound levels in incubators and in the NICU should be reduced below 58 dB-A. Ambient noise levels in the NICU are noted to range from 50 to 80 dB-A and inside the incubator, measurements from 55 to 88 dB-A, with peak levels of 117, have been reported (Gottfried & Hodgman, 1984: 292-293; Thomas, 1989: 249). Noise in the NICU can be highly arousing for premature and ill term neonates, causing agitation and crying. This in turn leads to decrease in oxygenation and increase in intracranial pressure, heart rate, and respiratory rate (Long et al., 1980: 143-145). Noise also may be disruptive to the sleep state and sleep-wake cycle and may adversely affect the neonate's recovery and growth. The sensory overload resulting from environmental NICU noise may have long-term developmental effects. High-intensity stimulation and prolonged noise exposure from which an infant cannot escape has been proposed to be correlated with lower levels of cognitive development and sensorineural hearing impairment (Bess, et al., 1979: 105; Wachs et al., 1971 cited in Depaul & Chambers, 1995: 72). In the study of Strauch, Brandt & Edwards-Beckett (1993) implementation of

a quiet hour: effect on noise levels and infant sleep states, indicated that the decrease of noise levels can lead the infants to quiet sleep more than active sleep significantly.

Light: the recommendation for regular office lighting is 40-50 foot-candles (ft-c); in the AAP Committee in 1992, Guidelines for Perinatal Care, 60 ft-c is recommended in the NICU for adequate observation, and 100 ft-c is recommended for procedures (Jack, 2000: 16; Shogan & Schumann, 1993: 7). Modern NICUs are brightly lit environments with ambient light in exceed of the recommendation. The general range reported has been 30 to 150 ft-c; with peaks over 1,500 ft-c from sunlight (Glass, 1990; Landry et al., 1985 cited in Glass, 1999: 103). The intensity of ambient illumination for any individual infant is determined by the location of the incubator in a room, the number of overhead light units, the size, location, and compass direction of windows, the season of the year, and even the prevailing weather condition (i.e., sunny vs. hazy). NICU lighting was bright and continuous throughout the 24-hour day. In a study of the effects of cycled lighting on preterm, Blackburn & Patterson (1991) found that infants who were exposed to lower light levels during certain periods of the day had lower heart rates and activity levels during those periods. In addition, Mann and associates (1986) reported that infants exposed to day-night light and sound cycles experienced greater weight gain and spent more time sleeping and less time feeding than infants who were not exposed to cyclical stimulation (Gray et al., 1998: 34). Bright light in an infant's face is a source of stress. Even routine ambient light level affects sleep and wake states in preterm infants. Lower ambient light is associated with significantly less active rapid eye movement sleep and significantly more quiet sleep among preterm infants at 35 to 36 weeks postconcepal age (Haith, 1983 cited in Glass, 1999: 104). Shogan and Schumann examined the effects of environmental lighting on premature infants in relation to oxygen saturation. Although no statistically significant difference was found in oxygen saturation when the light level was decreased from 100 ft-c to 5 ft-c, 22 percent of the study group showed a statistically significant decrease in oxygen saturation when the light level was abruptly increased from 5 ft-c to 100 ft-c (Shogan & Schumann, 1993: 7-13).

Temperature: infants have a limited capability to behaviorally manipulate their thermal environment. Thus, an increase in environmental temperature can increase

both the frequency and duration of apneic pauses in premature infants (McKenna et al, 1993: 16 cited in Charastong, 2001: 33-34). Ambient and core temperatures influence sleep cycle. Core temperature, for instance, has a strong effect on sleep architecture. Temperature changes affect respiratory control systems in the immature central nervous system. Elevation of ambient and core temperatures not only increases apneic episodes, but also increases the amount of active sleep or changes the number of transitions into active sleep (Scher et al., 1994: 191-194 cited in Charastong, 2001: 34).

Handling

Handling is the most direct source of stress for preterm infants in the NICU. On average, the preterm infants in NICU are handled 45 times per day and the total handling time per day is 3 hours 53 minutes. The rest periods between handling are only 13 minutes. The main disturbers are the nursing staff (82.3 %), while the least are parents (0.9 %) (Jariya Indhabhandhu, 2001: 45-50). Excessive handling has other significant physiologic consequences for the sick neonate. Blood pressure changes, alterations in cerebral blood flow, and episodes of oxygen desaturation are associated with noxious procedures, handling, or crying. Importantly, when caretakers monitor the infants' level of oxygenation during procedures, the severity of hypoxemic episodes can be reduced significantly. Thus, the amount and type of handling may have direct detrimental consequences for the vulnerable neonate (Long et al., 1980; Murdoch & Darlow, 1984; Peabody & Lewis, 1985; Perlman & Volpe, 1983; Speidel, 1978; & Volpe, 1989 cited in Glass, 1999: 93).

Body posture

The physical position of an infant is part of the NICU tactile-vestibular experience. Prone positioning in the NICU has been strongly supported physiologically. The current NICU dilemma is that the prone sleep position is contrary to the recommendation by the American Academy of Pediatrics (AAP), which now supports supine positioning because epidemiologic data associate supine positioning with a lower rate of sudden infant death syndrome (SIDS). Covering, swaddling, and placing blanket rolls around the infant help her or him maintain the desired posture and prevent loss of control of the flexed position. The use of these rolls provides containment and boundaries for the infant, promoting feelings of security, quiescence, and energy conservation. Nesting is often an effective way of reducing agitation

(Lawhon, 1986; Lawhon & Melzar, 1988 cited in Blackburn & Vandenberg, 1998: 955-966). Corff and associates (1995) documented that generalized motoric containment of an infant's arms and legs close to the infant's body while in a side-lying or supine position resulted in significantly lower mean heart rates, shorter mean crying and sleep disruption times, and fewer sleep-state changes after a painful heel stick procedure than without motoric containment (Lotas & Walden, 1996: 683).

Age

Age is the most powerful determinant of a person's sleep behavior. Specific physiological parameters of sleep change with maturation, and contribute to differences in neonatal sleep organization between preterm and term infants in accordance with postconceptional term age. Age-related changes in behavioral state, expression and organization take place from 28 to 36 weeks postconceptual age. With increasing age, quiet sleep increases and active sleep decreases. Age has an effect on the behavioral responses to care giving. Older infants, 30 to 33 weeks postconceptual age, more often express wakeful and fussy/crying behavior when compared to younger infants (McCain, Donovan, & Gartside, 1999: 463-467; Scher et al., 1995: 316; Webster & Thompson, 1986: 450 cited in Charastong, 2001: 29-30).

Circulatory system

Sleeping and waking states affect the infant's circulatory system. Overall, heart rate is higher in waking states than sleeping states and particularly during crying. Mean heart rates in the two sleep states are very similar, but heart rate is more variable in active sleep. This difference in variability is large enough that it is possible to differentiate between the two sleep states on the basis of heart rate variability (Holditch-Davis, 1998: 927-278).

Respiratory system

The effect of sleeping and waking states on the respiratory system is even greater than on the circulatory system. The nervous system controls of breathing are different in different states. During wakefulness, breathing is regulated by metabolic controls, general stimulation from the reticular activating system, and voluntary activities. In quiet sleep, metabolic controls predominate, and maintaining acid-base and oxygen homeostasis is the primary stimulus for breathing. Medullar respiratory center activity varies during active sleep depending on whether the infant is

experiencing rapid eye movements and motor activity (phasic active sleep) or not (tonic active sleep), indicating that these two types of active sleep include different controls on breathing. Infants exhibit higher respiratory rates and lower tidal volumes in phasic active sleep than in tonic active sleep (Holditch-Davis, 1998: 278).

Neurological problems

The sleep-wake patterns of infants with neurological insults differ markedly from healthy infants. At term, premature infants with IVH have been found to have lower arousal than healthy full-term infants (Anderson et al., 1989 cited in Holditch-Davis, 1998: 927). Full-term infants with hyperbilirubinemia show decreased amounts of wakefulness as compared with full-term infants with only mild bilirubin elevations (Prechtl et al., 1973 cited in Holditch-Davis, 1998: 927). Moreover, infants exposed prenatal to drugs (marijuana, methadone, and cocaine) or alcohol or nicotine exhibit abnormalities in their sleep-wake patterns possibly as the result of neurological insults. Infants with central nervous system disorders, such as Down's syndrome, mental retardation, and cerebral palsy, often have disturbed sleep patterns exhibited by disordered sleep-wake rhythm, sleep apnea, delirium, insomnia, or hypersomnia. These symptoms are attributed to dysfunction or destruction of specific areas of brain responsible for generating sleep and sleep-wake patterns (Ferber, 1985; Okawa & Sasaki, 1987 cited in Schibler & Fay, 1990: 291-292).

Feeding and sucking

Feeding times and hunger are known to have a great influence on the patterns of sleep and wakefulness in newborn infants. Quiet wakefulness is most often found after feeding (Karch et al, 1982: 40). A study of Medoff-Cooper and associates (2000) found that the preterm infants had increasing ability to maintain quiet alertness from 34 weeks PCA to term.

Medications

Sleep pattern disturbance is a frequent side effect of drugs prescribed for pain relief. Barbiturates, which are commonly used for sedation and pain relief in postoperative patients, tend to decrease active sleep and morphine, meperidine, and diazepam decrease active sleep too. In addition, chloral hydrate is a useful sedative because it facilitates relaxation and eases sleep stage transitions with minimal effect on

active sleep (Barndt-Maglio, 1986; Kales & Kales, 1970; Kleitman, 1972; Schmitt, 1985 cited in Schibler & Fay, 1990: 291).

Miscellaneous

Sleep difficulties may be more common in selected populations, such as children with juvenile rheumatoid arthritis, who awaken frequently because of the pain experienced when changing sleep positions. Postoperatively, children may have difficulty falling asleep because of pain and stiffness (Barndt-Maglio, 1986 cited in Schibler & Fay, 1990: 291). Further, the incision may inhibit them from assuming their normal position. Newborn infants with jaundice and those born with diabetic mothers have been noted to sleep significantly more than normal infants (Duxbury et al., 1984 cited in Schibler & Fay, 1990: 291).

Although many parameters found to be affecting the sleep-wake states of premature infants, four most commonly identified sources of stress which may alter the sleep of the premature infant in the NICU environment are inappropriate position, noise pollution, bright light exposure, and excessive handling. To support and facilitate the premature infants' health improvement, the NICU environment must be constantly adjusted with modifying the most stressful parameters to be in optimal as required by the premature infants. For this reason, the researcher is strongly interested in finding optimal use of these factors to promote the sleep of the premature infants.

Assessment of Behavioral Sleep-Wake States in Premature Infants

In adult, sleeping and waking states are usually scored by electroencephalography (EEG). However, because of the neurological immaturity of infants, EEG is less reliable and needs to be combined with observation. When EEG and behavioral scoring of states in preterm infants are compared, there is a high degree of agreement (Sahni et al., 1995 cited in Holditch-Davis, 1998: 921). Thus, sleeping and waking states in newborn infants, whether full-term or preterm, can be validly scored by directly observing the infant and identifying global categories that are made up of a number of specific behaviors that tend to occur together and reflect a similar level of arousal and responsiveness to the environment (Holditch-Davis, 1998: 921). Variables observed when studying the sleep patterns of infants include facial and body movement, respiratory patterns, heart rate, and electro-oculogram (EOG) (Kick, 1996: 247).

Currently, five standardized systems for use to scoring behavioral observations of neonatal sleep-wake states. These systems define states in very similar ways and are probably equally useful for clinical purposes which eye openness, rapid eye movement, face movement, body movement, muscle tension, regularity of respiration, and vocalization were the criteria used. These systems were developed by Brazelton (1984), Als (1982), Anderson (Gill et al., 1988), Thoman (1990), and Reid (2000). Measurement of sleep-wake states in the newborn can be described as follows (Blackburn & Vandenberg, 1998: 942-943; Brazelton, 1999: 321-325; Chang et al., 2002: 161-169; Creger, 1993: 428-429; Holditch-Davis, 1998: 921-925; Reid & Freer, 2000: 21-23).

The revised Neonatal Behavioral Assessment Scale

T. Berry Brazelton revised the Neonatal Behavioral Assessment Scale (NBAS) in 1984. He developed his first state scoring system in 1973. The NBAS is used to measure the coping capacities and the adaptive strategies of full-term healthy infants from 36 to 44 week's gestation that emerge during recovery from the stresses of labor and delivery and adjustment to the demands of the extra-uterine environment. This scale consists of 6 states: quiet sleep, active sleep with rapid eye movements, drowsy, alert inactivity, fussing, and crying. It has the advantage that is easy to learn because the differences between the states are fairly obvious and there are only six states; therefore, it has been widely used in research and clinical practice. However, owing to the small number of states described, it is not always sensitive enough to identify indeterminate and transitory qualities of premature infant behavioral states.

The Assessment of Preterm Infants' Behavior

The Assessment of Preterm Infants' Behavior (APIB) was developed by Heidelise Als in 1982. The APIB was a modification of the original NBAS (Brazelton, 1973) that based on the synative theory of development. Recently, it is a component of the neonatal individualized developmental care and assessment program (NIDCAP). It is used to determine organization of the CNS and how infants cope with the intense environment of the NICU. It is particularly useful for the preterm and full-term high risk infant from birth to 44 weeks' postconceptual age. The state scale from the NBAS has been expanded into a 13-state system by subdividing each of the 6 states so that the immature and unclear sleeping and waking states of premature infants can be more

adequately described. This scale consists of 13 states: very still deep sleep, deep sleep, light sleep, noisy light sleep, drowsy with more activity, drowsy, awake and quiet, hyperalert, bright alert, active, considerable activity, crying, and lusty crying. The advantage of this system is that it also assesses autonomic and motor function as part of a holistic assessment and care-planning program, where state functioning is an important consideration. However, a 13-state system is difficult to assess because of the subtle definitions described; consequently, training and supervision in its use are essential.

The Anderson Behavioral State Scale

The Anderson Behavioral State Scale (ABSS) was developed by Gene Cranston Anderson. She developed a 12 categorical states scale from Parmelee and Stern (1972) to be used with preterm infants based on her own observations of these infants and on the work of Parmelee and Stern. The ABSS used to determine the behavioral state of an infant by noting his/her respiratory regularity, eye movement, degree of limb and trunk involvement, activity, and intensity of crying. This scale consists of 12 states: regular quiet sleep, irregular quiet sleep, active sleep, very active sleep, drowsy, quiet alert awake, quiet awake, active awake, very active awake, fussing, crying, and hard crying and it can also be collapsed when an investigator does not need such fine discriminations. Although the ABSS is difficult to learn because of the complexity of 12 states and it emphasizes quantitative differences among the states which is different theoretical basis than the other state scoring systems that differentiate among states based on qualitatively different aspects of the infant's behavior. However, Anderson has recently emphasized qualitative differences between states and it has increasing of the inter-rater reliability in the present. Also, it was designed for use with premature infants and can be used in the infant with postconceptual age at least 26 weeks.

The Thoman's revised State Scoring System

The Thoman's revised State Scoring System was developed by Evelyn B. Thoman in 1990. She developed her first state scoring system in 1975 based on the work of Woff (1966) and Korner (1972). This state scoring system consists of 10 states: quiet sleep, active-quiet transitional sleep, active sleep, sleep-wake transition, drowsy, daze, alert, non-alert waking, fuss, and crying and it can also be combined

when an investigator does not need such fine discriminations. The sleeping and waking states are differentiated enough that they can be used with premature infants to infants older than one month after term who's had perinatal complication. It has been shown to have predictive validity with later developmental outcome; also, it is more sensitive that has inter-rater and test-retest reliability with premature infants. However, this system is more difficult to learn and training is not readily available.

The Modified Sleep-Wake Assessment

The Modified Sleep-Wake Assessment was developed by Tilly Reid (formerly Padden) in 2000. This modified sleep-wake assessment consists of 9 states: very quiet sleep, quiet sleep, restless sleep, drowsy, quiet awake, restless awake, hyper alert, fussing, and crying. This scale can be readily utilized in general practice with minimal training and supervision. It has practical validity and 85 percent inter-rater reliability with experienced nurse in three units; furthermore, it has been shown to be a useful instrument in supporting the change process and promoting developmentally focused care in seconding units. However, it is less sensitive than other premature sleep-wake assessment and because this scale is the newest tool, there is no research report have been published by using this scale.

This research will use the Anderson Behavioral State Scale (ABSS) to determine the behavioral state of an infant by noting his/her eye openness, regularity of respiration, body movement, muscle tension, activity, and vocalization. The ABSS was designed for use with premature infants and can be used in the infant with postconceptual age at least 26 weeks. Because of the large number of states described, it is always sensitive enough to identify indeterminate and transitory qualities of premature infant behavioral states. In this study, it is appropriate tool for the characteristic of the subjects- that is premature infant with post-conceptual age between 28 – 36 weeks. The first used of this scale is to describe the effect of nonnutritive sucking on behavioral state in preterm infants before feedings by Gill et al. in 1988. Inter-rater reliability for seven observers was established by calculating kappa agreement for each pair of observers and then obtaining an average. The average across seven observers was 0.71. Recently, the ABSS has demonstrated the increasing in the inter-rater reliability: 0.85, 0.95, and 0.94 – 0.95 in the study of Zahr

(1998), Change et al. (2002), and Kurdrit (2002), respectively (Chang et al., 2002: 161-169; Gill et al., 1988: 347-350; Kurdrit, 2002: Zahr, 1998: 28-36).

Developmental Care and the Synactive Theory of Development

Developmental care

The term '*developmental care*' is used to describe the interventions or process which support and facilitate the stabilization, recovery and development of the delicate, immature central nervous system of premature and ill infants, and families undergoing intensive care, and beyond, in an effort to promote optimal outcome (Lefrak & Lund, 2001: 224; Reid & Freer, 2000: 15). The theoretical basis for current understanding begins with the wide body of evidence that demonstrates that LBW infants are at increased risk of medical complications, growth deficits, neurological impairment and a range of more subtle cognitive and behavioral difficulties (Fasting, 1995; Hack et al., 1995; Powls et al., 1996; Tin et al., 1997 cited in Reid & Freer, 2000: 15). Whilst the incidence of major handicap is reducing and the survival of VLBW infants is steadily improving, there remains an urgent need to explore strategies which have the potential to ameliorate the side-effects of treatments necessary for life support.

During the last trimester of pregnancy, the fetal brain develops at a greater rate than at any other stage of life. This critical growth process consists of neuronal migration, synaptogenesis and arborisation, and myelinisation (Volpe, 1995 cited in Reid & Freer, 2000: 15). Healthy brain development depends upon subtle influences from the ecologically appropriate uterine experience; therefore the prematurely extra uterine fetal infant is vulnerable to abnormal influences from the NICU environment. This frequently results in poorly modulated behaviors in the autonomic, motor and state systems, which manifest themselves through unstable, delayed or abnormal systems development. Illness and extreme prematurity exacerbate the infant's vulnerabilities, however deficits in neurobehavioral performance at term age are noted in healthy preterm infants as well as those requiring prolonged intensive care (Huppi et al., 1996 cited in Reid & Freer, 2000: 15).

Irrespective of illness and treatments, the environment of care is itself a source of stress for preterm infants and their families, who are particularly vulnerable to the

adverse conditions facing them (Miles et al., 1991; Gardner et al., 1993; Padden & Glenn, 1997 cited in Reid & Freer, 2000: 15). Parent – infant relationships can be influenced by supportive interventions which will have an impact on outcome beyond the events of the neonatal period, and which could be seen as crucial to the success of neonatal intensive care. Thus developmental care is viewed as an expansion of neonatology in which evolving infant and family systems interface with the biological, environmental and psychoemotional risks of preterm birth.

Developmental support programs have been guided by different theoretical models, summarized by Wolke (1991) thus:

- Programs that counteract neonatal sensory overload or deprivation.
- Programs that aim to prevent faulty maternal – infant attachment.
- Programs that aim to help parents to resolve the emotional crisis of preterm delivery.
- Programs that help parents to be more sensitive and responsive to their infant's cues and improve maternal – infant interaction.
- Compensatory programs which are aimed at infants with developmental deficit or chronic illness.

More recently, current strategies based on the synactive theory of development (Als, 1982 & 1986) promote systematic assessment of infant behavior with an increasing emphasis on parent teaching and support based on infant individuality (Als & Gilkerson, 1997 cited in Reid & Freer, 2000: 16). A range of possible strategies and interventions are devised to meet individual need, and to support individuals' developmental goals.

One theoretical approach views the infant in NICU as being over – stimulated compared to the natural uterine environment and propose minimal handling and reduced sensory input, via the environment at large and the individual cot space. Another approach views the infant as being deprived of appropriate sensory input, and additional stimulation is provided in an effort to improve outcome. Some studies have used a single intervention – auditory (maternal voice, heartbeat sounds), tactile (massage, stroking), visual (mobiles, facial presentation), vestibular (oscillating cot, waterbed, rocking) – whilst others have implemented multi – modal interventions using a combination of strategies in an effort to emulate the fetal environment. Other

studies have investigated the impact of environmental manipulation, postural support, therapeutic touch, parent – infant interaction coaching and various models of psychoemotional support (Reid & Freer, 2000: 16).

Synactive theory of development

The synactive theory of development developed by Heidelise Als in 1982 & 1986. The conceptualization of development focuses on how the individual infant appears to handle the experience of the world around him/her. This theory provides a model through which one can specify the degree of differentiation of behavior and the ability of infants to organize and control their behavior. The focus is not on assessment of skills, but on the unique way each individual infant deals with the world around her or him. The synactive theory of development specifies the range of neonatal behavior as the infant matures as well as the ability of the infant to regulate behavior. This model is based on the assumption that the infant's primary route of communicating both functional stability and the limits for stress is through behavior. Infants are seen as being in continual interaction with their environment via five subsystems: the autonomic system, the motor system, the state organizational system, the attention and interaction system, and the regulatory balancing system (Als, 1982: 230-231; Als, 1986: 15-18; Blackburn & Vandenberg, 1998: 940-941; Creger, 1993: 426-430; Miller & Quinn-Hurst, 1994: 506-507; Reid & Freer, 2000:15-21).

1. The autonomic system

The autonomic system is behaviorally observable in the pattern of respiration, color change, tremulousness, and visceral signals such as bowel movements, gagging, hiccoughing, etc. This system is unlikely to have reached a level of robustness to enable stable functioning without support, and this stability is likely to be under duress when challenged by handling, environment disturbance, pain and illness.

2. The motor system

The motor system, behaviorally demonstrable through muscle tone, posture and movements, is the second emerging subsystem. Preterm infants have reduced muscle bulk and power, and an immature central nervous system, which results in poor mobility and an inability to counteract gravity in order to support their own developmental needs. The term infant's flexed rounded posture and organized, purposeful movements are in stark contrast with the preterm infant.

3. The state organizational system

The state organizational system is behaviorally observable in the kind and range of states of consciousness available to the organism (from asleep to aroused states), in the pattern of state transitions exhibited, and in the clarity, robustness and definedness of the states. Sleeping and waking states represent the level of maturity and intactness of the central nervous system, the infant's relationship with the external environment and his or her ability to regulate and stabilize underlying internal systems.

4. The attention and interaction system

The attention and interaction system is exemplified in the organism's ability to come to an alert, attentive state and to use this state to take in cognitive and social-emotional information from the environment and in turn elicit and modify these inputs from the environment.

5. The regulatory balancing system

The regulatory system is behaviorally exemplified in the observable strategies the organism uses to maintain a balanced, relatively stable and relaxed state of subsystem integration or to return to such a state of balance and relaxation. If the infant's own regulatory capacity is exceeded momentarily and the infant is unable to return to an integrated, balanced subsystem state, another parameter of functioning is identifiable in the kind and amount of facilitation from the environment that is useful to the infant to aid the infant's return to balance. Regulation is an assessment of the infant's success in achievement of a balance in the other subsystems.

Each subsystem can be described independently, but it is the processes of subsystems interaction, or synaction combined with the infant's interaction with his or her environment, which completes the developmental theory. This model describes a hierarchical continuum of stability, organization and development in the underlying subsystems which enables the infant to achieve more complex tasks as stability is achieved, helped by resolving illness, maturity and contingent handling. The loss of integrity in one subsystem can influence the organization of other subsystems in response to environmental demands. In preterm, less organized infant, the systems interplay, continuously influencing each other; in addition, less mature infants tend to be able to tolerate only one activity at a time and may easily lose control if required to

do more. An important consideration within this framework is the recognition that the preterm infant is not a dysfunctional term infant but is competent for his or her stage of development within the uterine environment.

The Quiet Time Implementation

The intrauterine environment, with few exceptions, is recognized as the optimal environment to foster the growth and development of the fetus. This environment provides a variety of stimuli to the fetus while modifying the intensity and nature of the sensory input. In the other hand, birth represents an obligatory change of environment. For high-risk infants, this new environment is the NICU. The infant is thrust into a world of bright lights, sudden and loud noises, and rapid temperature changes, an environment without the containment and movement of the uterus. The infant is exposed to painful and aversive experiences. There is often an irregular pattern of handling and an absence handling in response to the infant's emerging behavioral organization. Immaturity and health status make the high-risk infant both dependent on and vulnerable to this environment to maintain vital functions, promote growth and development, and provide opportunities for the development and organization of the infant's state and behavior. These noxious stimuli disrupt sleep and can have biological consequences for the neonate (Blackburn & Vadenberg, 1998: 945; Glass, 1999: 91-92).

In Thailand, a study of Kurdrid (2002) that is the physiological and sleep-wake behavioral responses of premature infants to the neonatal intensive care unit environment found that the sound level was range from 35.8 - 87.3 dB and the light level was range from 7-468 lux. Both physical environments were measured inside incubator. The observed caregiving activities showed the premature infant was interrupted range from 14-18 times per shift. The results of the study showed the heart rate of premature infants had a statistically significant positive correlation with noise level and caregiving activities. Moreover, the sleep-wake states of premature infants had a statistically significant positive correlation with noise levels, light levels, and caregiving activities. Thus, the NICU environment has an effect on responses of premature infants.

The premature infant is in double jeopardy as he or she is unprepared for extrauterine life and has to face the environment of the NICU, which is complex and generally over-stimulating. Problems with state modulation may emanate from the infant or environment. Infant factors influencing state modulation include immaturity, pain, stress, maternal substance abuse, and illness. Environmental factors that affect state regulation and interfere with the infant's sleep-wake pattern include noise, light, temperature, and caregiver actions (Blackburn & Loper, 1992: 563-654).

Gray and associates (1998) implemented three aspects of developmental care: lower noise levels, decreased light levels, and flexed, midline positioning. This study is a research utilization project. The developmental care interventions were implemented on a daily basis for two hours of quiet time during each eight-hour shift. The results found that mean light levels and mean noise levels decreased during quiet time on all three shifts during the project. Optimal positioning was achieved 78 percent of the time during the project period observations.

A study of Strauch, Brandt, & Edwards-Beckett (1993), the implementation of a quiet hour in developmental units, which purpose of the study, was to decrease the noise levels and promote sleep states in infants on the unit. Intervention was implemented for two weeks. Light was turn off and caregiving activities was rearranged to minimize infant disturbances during quiet hour period. The results found that noise levels decreased significantly during on two of the three shifts. Fewer infants were crying during the quiet hour than the control period and more were in deep or light sleep. This study demonstrates that noise levels in developmental units can be significantly decreased, and that decreased noise levels positively impact infant state.

In summary, the four most commonly identified sources of stress which may alter the sleep of the premature infants in the NICU environment are (1) vestibular stimulation - inappropriate position, (2) auditory stimulation - noise pollution, (3) visual stimulation - ambient and bright light exposure, and (4) tactile stimulation - frequent aversive procedures or excess handling. The NICU environment must be constantly changed to support and facilitate the infant's sleep-wake states. Therefore, the 'Quiet Time implementation' was conducted to promote sleep of premature infants in the NICU. Quiet time implementation is an intervention for developmentally supportive care to promote quality of sleep in premature infants. This protocol was

developed by the researcher based on the research works of Gray & associates (1998) and Strauch & associates (1993). This protocol which covered four aspects of developmental care: provide optimal position, reduce sound levels, reduce light levels, and keep handling in minimal, was developed as a guideline for nursing care.

Observation time was fixed at two hours for every eight-hour shift. Specific observation time, set up from 12:00 am. to 2.00 pm. in day shift, 6:00 to 8:00 pm. in evening shift, and 3:00 to 5:00 am. in night shift, varied with shifts for getting optimal time which both maximizes the comfort of infants and minimizes the medical interventions as much as possible. All of above times were appropriate for the premature infant to rest since the medical rounds and routine cares were completed before these periods. Before starting the implementation, the quiet time signs, which serve as a reminder to anyone moving close to incubator, were clearly display on the entrance door and in front of the test subjects' incubator. Four steps of the quiet time protocol are as follows:

I. Providing optimal position

The physical position of an infant is part of the NICU vestibular experience. The vestibular system responds to movement as well as directional changes in gravity and is situated in the non-auditory labyrinth of the inner ear. Vestibular stimulation affects level of alertness. Slow, rhythmic, and continuous movement induce sleep. Periodic or higher amplitude swing increases arousal. Initial vestibular development is concurrent with auditory development, emanating from the same otocyst early in gestation. The three semicircular canals begin to form before 8 weeks of gestation, reaching morphologic maturity by 14 weeks, and full size by week 20. The vestibular sacs probably develop at the same time. Response to vestibular stimulation has been observed by 25 weeks of gestation. The traditional vertex presentation of the fetus at term gestation is thought to occur from fetal activity in response to vestibular input.

Premature infants are at risk for alterations in postural and motor development because of their weak muscle tone and inability to maintain flexion on their own. The physiological flexion develops in the last trimester of pregnancy in response to decreased space in uterus and as an active process in neurological development. Therefore, infants born prematurely do not have opportunity to develop physiological flexion (Moore, 1966 cited in Creger, 1993: 430).

To providing the optimal position that is encouragement an infant's position as much flexed as possible. It could be done by the steps were as follows:

1. Position an infant into flexed, midline supine position with following process:
 - 1.1 Place a small-soft roll under the head and neck to tuck the head in neutral position or slightly extension.
 - 1.2 Provide a nest, which surrounds the infant with walls of a big-soft roll and supports the feet by bracing them with it. This containment prevents retraction of shoulders and external rotation of hips and extremities.
 - 1.3 Bring the hands to midline across the chest or near the mouth as well.
2. Elevate the mattress to 15 – 30 degrees.

II. Reducing sound levels

The noise exposure is a part of auditory experience of premature infant in the NICU. The auditory system is composed of both peripheral and central components. Development of the auditory system begins around 3 to 6 weeks of gestation. Both cortical auditory evoked responses and brainstem auditory evoked responses can be elicited by 25 to 28 weeks. A blink response to vibroacoustic stimulation has been obtained in human fetuses of 24 to 25 weeks of gestational age. A more complex behavioral response to sound occurs at least by 28 weeks, but readily fatigues. The maximum rate of eletrophyiologic change occurs in the cortical auditory evoked response and brainstem auditory evoked response between 28 to 34 weeks of gestation. Orienting behavior to soft sound can be elicited by this time.

Maturation of the fetal auditory system is marked by an increase in spectral sensitivity, in both lower and higher frequencies, and a decrease in auditory threshold. The range of auditory sensitivity initially is fairly restricted: from 500 to 1,000 Hz in the third trimester compared to around 500 to 4,000 Hz at term and an adult range of 30 to 20,000 Hz. Changes in auditory threshold are related to maturation of both peripheral and central components. Auditory thresholds in a preterm infant ad 25 weeks of gestation have been obtained with a 65-dB stimulus compared to 25 dB-A at term.

To reduce sound levels could be done by the eight steps as follows:

1. Place the sign “Quiet Time” on the incubator while the quiet time protocol is applied.
2. Reduce the voice to a minimal when talking near the baby.
3. Decrease the telephone ringing volume and the equipment alarm to a minimum level in which observers could be easily alerted.
4. Physician rounds are avoided.
5. Avoid large equipment entering the unit.
6. Make special effort not to slam doors, drawers, trash cans, and incubator doors as well as not to drag chairs.
7. Forward all phone calls to the main desk.
8. Respond rapidly to monitoring alarms or crying infants.

III. Reducing light levels

The light exposure is a part of visual experience of premature infant in the NICU. The visual system, the eye is an outgrowth of the brain from the early embryonic stage. By 24 weeks of gestation, gross anatomic structures are in place and the visual pathway is complete. As early as 24 to 28 weeks of gestation, a visual evoked response to bright light can be obtained, but it consists of a long-latency negative wave that readily fatigues. Between 30 to 34 weeks of gestation, the morphology of the visual evoked response becomes more complex. The pupillary reflex is more efficient. A bright light will cause immediate lid closure, and the response sustains. The eyes may open spontaneously, and the infant may even briefly fixate. This has been described as the beginning of attention. By 36 weeks, the visual evoked response resembles that of a full-term infant. Spontaneous eye opening, even in utero, has been observed on ultrasound. Although alertness still is less sustained than at term, the preterm infant now shows a spontaneous orientation toward a soft light and can track an object horizontally and vertically. The visual system development is continuing over the next 6 months.

To reducing light levels could be done by the two steps were as follows:

1. Cover the top, left, right, and back sides of the incubator with a cloth.
2. After complete this intervention, open the cloth gradually side by side.

IV. Keeping minimum handling

Handling is a part of tactile experience of premature infant in the NICU. The cutaneous system includes sensation of pressure, pain, and temperature. The tactile sense develops early in fetal life and is thought to play a particularly pervasive role in the early development of the organism. Receptor cells are present in the perioral region in the fetus by the 8th week of gestation and spread to all skin and mucosal surfaces by the 20th week. The cortical pathway is intact by 20 to 24 weeks of gestation, and some myelin is already present. Response to tactile stimulation has been observed by ultrasound as early as 8 weeks of conceptional age. Response to stroking in the lip region occurs first, followed by a response to stimulation of the palms. Most of the body is sensitive to touch by 15 weeks. Infants less than 32 weeks PCA respond to repeated stimulation with sensitization and a diffuse behavioral response.

To keeping handling in minimal could be done by the two steps were as follows:

1. Wear diaper during the quiet time.
2. Make special effort not to handling the infant and reschedule caregiving activities during quiet time implementation for minimal disturbance.

CHAPTER III

MATERIALS AND METHODS

Research Design

This quasi-experimental research was performed to study the effect of quiet time implementation on sleep-wake states of premature infants in a neonatal intensive care unit.

Population and Sample

In this study, the population has been assigned with a group of test subjects, premature infants, who were admitted to the neonatal intensive care unit (NICU), Faculty of Medicine, Ramathibodi Hospital, Mahidol University.

Twenty-four subjects were recruited by using purposive sampling technique, and have been used both control and experimental periods, which have inclusion criteria as follow:

1. Having post conceptual age (PCA) between 28–36 weeks as determined by a doctor using the Ballard score assessment and postnatal age between 1 – 28 days;
2. Warming with incubator and have range of body temperature between 36.5°C and 37.5°C at the day that the case is selected and the data are collected;
3. Having stable haemodynamic status;
4. Free from congenital heart disease (except PDA), major congenital anomaly, orthopedic problem, and neurological problems;
5. Not using high frequency ventilator;
6. Not participating phototherapy;
7. Not receiving sedative and/or antihistamine drugs and/or paralyzing agents;
8. Receiving written informed consent from parents for participating in this research.

The test subjects are then excluded from the study if they could not participate in all three continuous shifts in one day.

Setting

This research was conducted in the NICU, Faculty of Medicine, Ramathibodi Hospital, Mahidol University. The observed NICU unit was situated inside a large rectangular-shape hall with rooms belonging to administration personals and patients settled in each side of longer walls. The area belongs to the patients was in the side that bright sunshine was being able to pass through the glass windows in daytime. The patients' area was partitioned into four rooms in which each room had distinct purpose. First room situated in a corner, was specifically designed as a closed environment for infectious patients. Second room next to the room belongs to the infectious patients was for the patients with critical condition and it was placed directly in front of the counter where nurses generally sit so that the patients in this room was under watchful eyes of the nurses for 24 hours. Third room, which is next to the critical room, was semi-critical room for patients with less critical condition. There was not much difference between the critical and semi-critical room regarding health status of patient since no interchanging occurs between them. The patients getting better in the critical room still has to settle in it unless full recovery. The similar situation goes to the semi-critical room so there is no visible difference between the critical and semi-critical room regarding condition of patients. The last room situated in one corner of the hall was for recovered patients who were going to be transferred to another place such as another special care unit or return home with parents. Every room except critical room was assigned with a nurse to closely monitor the condition of the patients. The whole area was artificially lit by overhead fluorescent lamps, arranged in long banks, and opened around the clock.

Total capacity of this unit was ten beds in which each bed was equipped with modern life supporting equipments according to the needs of the patients. Total of four beds belongs to the recovery room were equipped with basic supporting equipments such as incubator, pulse oximeter, photo lamp, infusion pump, syringe pump, and oxygen supplier and some incubators were covered with blankets. Other six beds equipped with more advance equipments such as high frequency ventilator were placed in other rooms for the patients with more severe condition. The environment and approach existed in the observed NICU was similar to the care-giving activities, light and sound condition experienced in any other typical intensive care unit. Day to

day process of this unit was taken care by the group of staffs, which comprises of registered nurses and nursing students, medical specialists, medical interns and medical students.

The test subjects were the premature infants who admitted in the area, which includes recovery room, semi-critical and critical rooms. This area accommodated a patient population of mixed acuity, ranging from recovered premature infants to critically ill infants requiring mechanical ventilation. Due to utilization of ventilator or umbilical catheter, the position available for the infants was sometime limited to supine position.

Research Instruments

The instruments used in this research could broadly be divided into two groups regarding their utilization. The instruments belong to first group was represented as guide line and supporting instruments in implementation of this research work while second group was classified as instruments utilized in data collection process. The broader explanation about instruments belongs to two groups is seen as follow:

1. Instruments for intervention:

1.1 Quiet time protocol. Quiet time implementation is an intervention which uses developmentally supportive care to promote quality of sleep in premature infants. This protocol was developed by the researcher, based on the research works of Gray & associates (1998) and Strauch & associates (1993). Its content were validated by experts, three pediatric nursing educators, a neonatologist, and a registered nurse who has master degree in pediatric nursing and fourteen years of work experience in neonatology (Appendix D). Quiet time protocol has been revised according to the recommendations given by the above experts then tried out on the premature infants that near the test subject criteria.

Quiet time protocol which covered four aspects of developmental care: provide optimal position, reduce sound levels, reduce light levels, and keep handling in minimal, was developed as a guideline for nursing care. Observation time was fixed at two hours for every eight-hour shift. Specific observation time, set up from 12:00 am. to 2.00 pm. in day shift, 6:00 to 8:00 pm. in evening shift, and 3:00 to 5:00 am. in night shift, varied with shifts for getting optimal time which both maximizes the

comfort of infants and minimizes the medical interventions as much as possible. All of above times were appropriate for the premature infant to rest since the medical rounds and routine cares were completed before these periods. Before starting the implementation, the quiet time signs, which serve as a reminder to anyone moving close to incubator, were clearly display on the entrance door and in front of the test subjects' incubator. Four steps of the quiet time protocol are as follows:

Step I Provide optimal position

1. Position an infant into flexed, midline supine position with following process:
 - 1.1 Place a small-soft roll under the head and neck to tuck the head in neutral position or slightly extension.
 - 1.2 Provide a nest, which surrounds the infant with walls of a big-soft roll and supports the feet by bracing them with it. This containment prevents retraction of shoulders and external rotation of hips and extremities.
 - 1.3 Bring the hands to midline across the chest or near the mouth as well.
2. Elevate the mattress to 15 – 30 degrees.

Step II Reduce sound levels

1. Place the sign “Quiet Time” on the incubator while the quiet time protocol is applied.
2. Reduce the voice to a minimal when talking near the baby.
3. Decrease the telephone ringing volume and the equipment alarm to a minimum level in which observers could be easily alerted.
4. Physician rounds are avoided.
5. Avoid large equipment entering the unit.
6. Make special effort not to slam doors, drawers, trash cans, and incubator doors as well as not to drag chairs.
7. Forward all phone calls to the main desk.
8. Respond rapidly to monitoring alarms or crying infants.

Step III Reduce light levels

1. Cover the top, left, right, and back sides of the incubator with a cloth.
2. After complete this intervention, open the cloth gradually side by side.

Step IV Keep handling in minimal

1. Wear diaper during the quiet time.
2. Make special effort not to handling the infant and reschedule caregiving activities during quiet time implementation for minimal disturbance.

1.2 Equipment for positioning the infant and covering the incubator

- A small cotton-blankets for supporting neck and shoulder.
- A large cotton blanket for making a nest.
- Incubator covering sheet.

2. Instruments for data collection:

2.1 Sound level meter model: DS-40. The sound level meter is a small, battery operated, electric condenser microphone, which can be used as a meter for measuring sound ranging between 35 and 130 dB-A. The sound measuring procedure is to place this instrument near the noise source and point the microphone to it. Then, the intensity value of noise will be display in screen of equipment by digital numbers in unit of decibels-A weighting (dB-A).

The sound level meter was calibrated by an officer of the Industrial Metrology and Testing Service Centre (a division of the Thailand Institute of Scientific and Technological Research, TISTR, which is a nonprofit state enterprise under the Ministry of Science and Technology, MOSTE). This centre is recognized as the first accredited calibration laboratory of Thailand conforming to ISO/IEC 17025. The validity and reliability of this equipment can be verified using the calibrated result shown in Appendix D.

2.2 Digital lux meter model: LX-50. The lux meter is small battery operated equipment, which measures the intensity of light. It is used in measuring light by placing the instrument at the required point. The illuminant value will be displayed in monitor of equipment by digital numbers in unit of lux.

The lux meter was also calibrated by the officer of the Industrial Metrology and Testing Service Centre. The validity and reliability of this equipment can be verified using the calibrated result shown in Appendix D.

2.3 Demographic data form (Appendix C). It was a data form used in collecting data which includes gender, post-natal age, date and time of birth,

gestational age, birth weight, type of delivery and indication, current weight, post-conceptual age, diagnosis, and health problem and treatment.

2.4 Assessment of Premature Infant Handling (Appendix C). This tool was developed by the researcher based on research works observed in international journals. The assessment tool was used in evaluating handling scores received by premature infants in NICU during non-quiet and quiet times. The evaluation process determine the five level of handling received by infant: no handling, comfort handling (which must be received only during sleep states), disturb handling, discomfort handling, and painful handling, with the scores ranging from 0 (no handling) to 4 (painful handling), respectively. Increasing score indicates the higher level of disturbance in the sleep of the premature infant. Following is the definition of handling scores:

Score 0: No handling

Score 1: Comfort handling (which must be received only during sleep states) such as gently touching the infant after received painful medical procedures, or placing hands to his/her mouth.

Score 2: Disturb handling such as checking body temperature via axillary, changing diaper, or physical examination using stethoscope.

Score 3: Discomfort handling such as changing bed sheet, weighting, or checking body temperature via rectum.

Score 4: Painful handling such as direct medication injection via skin directly, suctioning via endotracheal tube, or lumbar puncture.

2.5 The Anderson Behavioral State Scale (ABSS) (Appendix C). This instrument was developed by Gene Cranston Anderson and translated into Thai by Supreeda Kurdrit (2002). The ABSS process, which adopted the study of Parmalee and Stern (1972), consisted of 12 categories for measuring the behavioral state of preterm infants. Eye openness, regularity of respiration, body movement, muscle tension, and vocalization were used as the major criteria in determining the behavior state of the infant, which was defined with value ranging from 1 (regular quiet sleep) to 12 (hard crying). The research assistant closely observed the infants' behavior for 30 seconds before making any conclusion. Following is the definition of behavioral states:

- State 1:* Regular quiet sleep- closed eyes; regular respiration; faint or no mouthing; (movement of fingers and toes).
- State 2:* Irregular quiet sleep- closed eyes; irregular respiration; no movement or slight slow movement of face, hand, foot, head, forearm, or lower leg; (brief apnea).
- State 3:* Active sleep- closed eyes; irregular respiration; whole limb movement; (rapid eye movement; facial grimaces).
- State 4:* Very active sleep- closed eyes; total body movement; twisting trunk.
- State 5:* Drowsy- opening and closing eyes; quiet or some movement; dull glazed appearance to eyes.
- State 6:* Quiet alert awake- opened eyes, luminous, fixated, and/or following; no movement or slight slow movement of face, hand, foot, head, forearm, or lower, leg; (eye contact).
- State 7:* Quiet awake- opened eyes; not fixated and/or following; no movement or slight slow movement of face, hand, foot, head, forearm, or lower, leg.
- State 8:* Active awake- opened eyes; whole limb movement.
- State 9:* Very active awake- opened eyes; total body movement; twisting or lifting trunk.
- State10:* Fussing- opened or closed eyes; normal color; slightly prolonged exhalation; whimpers; (precry grimace; snorts).
- State11:* Crying- opened or closed eyes; red face; prolonged exhalation; audible or silent cry; general body tension.
- State 12:* Hard crying- opened or closed eyes; very red face; clenched fists; very prolonged exhalation; audible or silent cry; entire body very tense.

Rules:

1. Score the highest number that occurs during a 30-second observation interval.
2. If the baby has eye patches on, assume that the eyes are closed unless they are seen to be open.
3. If someone is working with the infant, wait until 1 minute after the intervention; the score arousal for 30 seconds.

4. If one eye is open and one is closed, score this as state 5.

5. Items in parentheses need not be present.

The ABSS was translated and validated by Supreeda Kurdrut (2002). The content validity in the Thai version was tested by seven experts in this field: four pediatrics-nursing educators, a physiologist, and two registered nurses having twenty-one years and ten years of work experience in the NICU.

For reliability, this tool demonstrated moderate to high inter-rater reliability (0.85 – 0.95) (Chang et al., 2002: 164; Kurdrut, 2002: 46; Zahr, 1998: 32). The data used in the behavioral states was collected by six reliable research assistants who had the inter-rater reliability between 0.83 and 1.0 according to the reliability check performed in every three months (Appendix D).

2.6 The observation record sheets (Appendix C). These sheets were created with five columns for documenting the collected data, which includes period, sound levels, light levels, handling, and sleep-wake states. Sound levels, light levels, handling, and sleep-wake states from two hours of non-quiet time were collected using systematic random sampling process while same data set was recorded for every ten minutes during two hours of quiet time. For equal probability of selection in the non-quiet time period, the observation record sheet was divided into six sets (set I – VI), each set started to record from day to night shift.

The implementation of the observation record sheet as well as the definition and utilization of its six sets for achieving equal probability of selection in non-quiet time period are as follow. The 24 subjects are placed into 6 sets according to the random selection process utilized by the researcher. It is simple but effective randomization process for distributing subjects into 6 sets uniformly. Numbers ranging between 1 and 6 is written on six pieces of papers one after another without repeating and folded them carefully. Each subject from the first 6 subjects among 24 total subjects takes the turn to pick the folded paper to determine which set he/she belongs to. With this approach, 6 subjects is being able to be individually placed into 6 different sets such as subject number one goes to set number 2, subject number two goes to set number 3 and so on. This process is repeated for next 6 subjects until the last 6 subjects finished taking their turn.

After finishing random sampling process, the 24 test subjects were uniformly distributed into 6 sets in which 4 subjects belong to each set. Then, the data related to non-quiet time and quiet time were then recorded according to the set arrangement. In case of quiet time, the observation time was 2 hours and the data of subjects belong to every set was recorded for every 10 minutes during observation. During both non-quiet time and quiet time period, total of 12 data sets from a test subjects was recorded during one shift, making number of observation for 24 subjects during one shift became 288 for one data type and total number of observation stand at 864 as well. The process became more complicated in non-quiet time due to 6 hours observation time. To achieve the uniformly distributed data of 2 hours from 6 hours observation time, the time for data collection was set on different 2 hours duration during 8 hour shift for different set with every 2 sets overlapping one hour between them. The detail arrangement of observation time setting of different sets is seen in table 1 With this arrangement, uniformly distributed 2 hours data from non-quiet time implementation within 6 hours observation time, which is equivalent of 2 hours data from quiet time approach, was achieved and recorded in the observation sheets.

Table 1 Systematic Random Sampling of Non-quiet Time Period

Set	Day shift						Evening shift						Night shift														
	7-8 am	8-9 am	9-10am	10-11 am	11-12 am	12am-1pm	1-2 pm	2-3 pm	3-4 pm	4-5 pm	5-6 pm	6-7 pm	7-8 pm	8-9 pm	9-10 pm	10-11 pm	11-12 pm	12pm-1am	1-2 am	2-3 am	3-4 am	4-5 am	5-6 am	6-7 am			
I	X	X				Quiet Time			X	X		Quiet Time					X	X			Quiet Time						
II		X	X							X	X								X	X							
III			X	X							X				X					X		X					
IV				X	X										X	X						X				X	
V					X			X								X	X									X	X
VI	X							X	X								X	X									X

X = Non-Quiet Time

Training of the Research Assistants

To reduce a possibility of data bias on the measurement regarding research assistants, six research assistants, having 2 - 6 years experiences as a neonatal nurse in the NICU, were trained for determining sound levels, light levels, handling scales, and sleep-wake states correctly and accurately, and recording it in the data collection sheets. The training process was first conducted by the researcher with detail explanation of the research procedure including scoring methods of the ABSS and giving practice for observation skills. Then, both the researcher and research assistants have accessed the behavioral state of the premature infants in the NICU and reliability assessment of each research assistant has been evaluated according to his/her performance. The inter-rater reliability between the researcher and the research assistants is between 0.83 and 10 according to the reliability check performed in every three months (Appendix D).

Protection of Human Subjects

The data collection procedure in this study was encompassed by the protection of human subjects. Permission to conduct the study was requested to the Ethical Clearance Committee on Human Rights Related to Researches Involving Human Subjects, Faculty of Medicine, Ramathibodi Hospital, Mahidol University. The researcher began to collect data after permission was obtained to conduct the study and it was performed based on the protection of human subjects. In the process of selecting test subjects, the researcher introduced herself to the parents of the premature infants and informed them about the research work including objective, process, benefits, and right to refuse to participate in the study. The parents of the test subjects were then given the right to request information from the researcher at any time if they did not understand well about the study as well as right to cancel their participation at any time without affecting the nursing and medical care received during perioperative period. The parents of the test subjects who agree to participate in this study were again informed and assured that the data would be kept confidential and only reported as group data. Finally, the data collection process started after the consent forms (Appendix C) were signed by the parents.

Data Collection

Data collection started after permission was secured from the Faculty of Graduate Studies, Mahidol University, according to the following steps:

1. Asking for permission to collect the data with submitting the Documentary Proof of Ethical Clearance Committee on Human Rights Related to Researches Involving Human Subjects, Faculty of Medicine, Ramathibodi Hospital, Mahidol University.
2. Asking for permission from the head neonatologist of Department of Pediatrics and the head nurse of the NICU, Ramathibodi Hospital to conduct this research work and letting them inform the staffs about the research procedure.
3. Informing the health care providers who work in the NICU about the process of this research and its significance before collecting the data.
4. Quiet Time protocol procedure was visibly displayed on a bulletin board since the time the research was started and the Quiet Time signs were shown on the door and in front of the incubators of the test subjects whenever quiet time process was in use.
5. Then, the test subjects were selected according to the outcome of the purposive criteria implication to medical records of premature infants in the NICU.
6. Afterward, the researcher contacted the parents to introduce the purposes and objectives of her research and requested their approval.
7. Researcher then filled in a demographic data form with the data received from test subjects.
8. Furthermore, the setting of Quiet Time protocol was arranged by the researcher to twenty-four test subjects starting continue from day to night shift.
9. Moreover, research assistants measured sound levels, and light levels through instruments, and evaluated sleep-wake states through judgment for both non-quiet time and quiet time and recorded it on the data forms correspondingly.
10. Then, absolutions of the data for statistical analysis.

Data Analysis

Computerized data analysis was made by using a powerful statistical analysis program, SPSS for windows version 11.5, with following procedure:

1. Demographic data of the test subjects was statistically analyzed, and frequencies, percentage, range, and mean values were then utilized in displaying personal characteristic of the test subjects.
2. Sound levels, light levels, and handling scores during the non-quiet and quiet time was analyzed with statistical approach and range, mean, and standard deviation values were separately processed for each of the three shifts and total.
3. Wilcoxon signed rank test for matched paired difference was made to highlight the different level of sleep-wake states occurred in premature infants between the non-quiet and quiet time.

CHAPTER IV

RESULTS

This quasi-experimental study was conducted to examine the effect of quiet time implementation on sleep-wake states of premature infants in the Neonatal Intensive Care Unit (NICU). Totals of twenty-four test subjects were selected according to the purposive sampling criteria mentioned in the methodology section. Each subject was then used as a sample in both control (non-quiet time) and experimental (quiet time) periods. The control period generally received typical routine nursing care, while the experimental period received typical routine nursing care with quiet time implementation as a bonus. The results of the data analysis of this study were then divided into three parts according to their characteristic as follows:

Part I: Demographic characteristics of the samples

Part II: Description of NICU environment during control and experimental periods

Part III: Results from hypothesis testing

Part I: Demographic characteristics of the samples

The samples of this study were premature infants who were admitted in the NICU, Ramathibodi Hospital and their data were collected during August 2003 and February 2004. Although twenty-six premature infants who met the selection criteria in initial stage were first approached, two were later excluded from the study due to the reason that they could not meet the criteria that requires three continuous shifts participation in a day. Consequently, the samples received from twenty-four premature infants were included in this study.

Demographic characteristics of the samples were shown in table 2. The data presented in table 2 highlighted the general characteristic of the premature infants who participated in this study. According to the gender, the test subjects comprised of 14

subjects being boys, which is 58.3 percent of total, and 10 subjects being girls, which is 41.7 percent as well. Their ages were in the range of 2 to 28 days and the mean age was 11.92 days with standard deviation of 7.57 days. The percentage distributions of the test subjects belong to early neonatal period, which is defined as the age of the test subjects being less than 7 days, and late neonatal period, which is defined as the age of the test subjects being between 7 and 28 days, were 25 and 75 percent respectively. In case of gestational age (GA), the percentage distribution became 54.2 percent for moderate premature infants, whose GA is ranging between 31 weeks and 36 weeks, while 45.8 percents were from extremely premature infants with GA ranging between 27 and 31 weeks. The mean GA of the test subjects was 30.54 weeks and the standard deviation was 1.89 weeks. Regarding postconceptional age (PCA), the percentage distribution became 83.3 percent for moderate premature infants, whose PCA is ranging between 31 weeks to 36 weeks, while 16.7 percent came from extremely premature infants with PCA ranging from 29 to 31 weeks. The mean PCA of test subjects was 32.21 weeks and the standard deviation was 1.77 weeks. The birth weights of premature infants were ranging from 620 to 2170 grams with the mean weight and the standard deviation weight were 1258.54 grams and 338.28 grams respectively. By the date of observation, the current weights of the premature infants were ranging from 830 to 2210 grams and the mean weight and the standard deviation weight were recorded 1314.58 grams and 349.49 grams respectively. Regarding weight, birth and current weight of the premature infants were recorded into three separate levels; low weight, very low weight and extremely low weight. Extremely low weight status are assigned to the group of the premature infants weighing below 1000 grams while very low weight and low weight status were labeled to the infants weighing between 1000 and 1500 grams, and 1500 and 2500 grams respectively. The percentage distributions of different level of the birth weights were 16.6, 54.2, and 29.2 percent respectively, and 20.8, 50.0, and 29.0 percent respectively for different level of current weights. Twelve premature infants, 50 percent of total subjects, resided in semi-critical area, eight premature infants, which is 33.3 percent, were in the critical area, and four premature infants, 16.7 percent of total, were in the recovery area.

Table 2 Demographic characteristics of the sample (N = 24)

Characteristics	Frequency	Percentage
Gender		
Girl	10	41.70
Boy	14	58.30
Age (days) (Min = 2, Max = 28, Mean = 11.92, SD = 7.57)		
< 7 (early neonatal period)	6	25.00
7 – 28 (late neonatal period)	18	75.00
GA (weeks) (Min = 27, Max = 34, Mean = 30.54, SD = 1.89)		
< 31 (extremely premature infant)	11	45.80
31 – 36 (moderately premature infant)	13	54.20
PCA (weeks) (Min = 29, Max = 35, Mean = 32.21, SD = 1.77)		
< 31 (extremely premature infant)	4	16.70
31 – 36 (moderately premature infant)	20	83.30
Birth weight (grams) (Min = 620, Max = 2170, Mean = 1258.54, SD = 338.28)		
< 1,000 (extremely low birth weight)	4	16.60
1,000 – 1,499 (very low birth weight)	13	54.20
1,500 – 2,499 (low birth weight)	7	29.20
Current weight (grams) (Min = 830, Max = 2210, Mean = 1314.58, SD = 349.49)		
< 1,000 (extremely low weight)	5	20.80
1,000 – 1,499 (very low weight)	12	50.00
1,500 – 2,499 (low weight)	7	29.20
Test subjects distribution in NICU		
Critical area	8	33.30
Semi-critical area	12	50.00
Recovery area	4	16.70

Part II: Description of NICU environment during control and experimental periods

The important parameters affecting the environment existing in the NICU are sound levels, light levels, and handling techniques. These parameters are mentioned detail in this part. To represent the NICU environment in detail, the sound levels, light levels, and the handling scores were recorded to the observation record sheets every ten minutes during both non-quiet and quiet times. Total of 288 data sets in which 12 data sets belong to one test subject with 24 test subjects participating in this study were recorded for one type of parameter in each period under each shift. In one day, 864 data sets were recorded for each parameter in each period in which 8-hour 3 shifts rotate around the clock.

The level of the sounds appeared in the NICU were shown in table 3. The sound levels during non-quiet time (n = 864 observations) was ranging from 46.80 to 87.00 dB-A, having the mean value of 55.01 dB-A and standard deviation of 5.50 dB-A. In case of quiet time period, the range of sound levels recorded was between 44.80 and 68.50 dB-A with the mean value and standard deviation of 51.47 and 3.34 dB-A respectively. The mean sound level was highest in day shift and lowest in night shift for both non-quiet and quiet times.

Table 3 Min-max, mean, and standard deviation of sound levels (dB-A) as measured in NICU between non-quiet and quiet times, shown by shift and total

Shift	n	Non-quiet Time			Quiet Time		
		Min-max	Mean	SD	Min-max	Mean	SD
Day	288	46.90-87.00	55.97	6.06	46.20-68.50	51.89	3.16
Evening	288	46.80-86.70	55.17	5.54	44.80-68.20	51.53	3.42
Night	288	47.00-70.00	53.90	4.61	46.00-58.00	51.00	3.39
Total	864	46.80-87.00	55.01	5.50	44.80-68.50	51.47	3.34

Based on the data patterns that shown in table 3, following conclusions can be made.

- Through out the day irrespective of any shift, the experimental period (quiet time) is lower than the control period (non-quiet time) as such it satisfies with the objectives of this research.

- The sound levels in experimental period remain considerably lower than 58 dB-A; the maximum recommended sound level recommended by the American Academy of Pediatrics.

As the mean sound level during control period (non-quiet time) was not greater than 58 dB-A, it was decided to further analyze these behaviors with additional peak sound levels and they are shown below in table 4. During the control period (non-quiet time) there were 196 observations (22.68 percent) where the minimum sound level was greater than 58 dB-A. However during the experimental period there were only 4 such instances (0.46 percent). It was a positive result to have only 4 instances with such sound levels.

Table 4 Frequency, percentage, and min-max of peak sound levels (58 dB-A) as measured in NICU between non-quiet and quiet times, shown by shift and total

Shift	n	Non-quiet Time		Quiet Time	
		Frequency	Percentage	Frequency	Percentage
Day	288	72	25.00	2	0.69
Evening	288	69	23.95	2	0.69
Night	288	55	19.09	-	-
Total	864	196	22.68	4	0.46

The illumination status inside the NICU is displayed in table 5. The light levels during non-quiet time (n = 864 observations) was between 3 and 661 lux with the mean value and standard deviation of 136.67 and 86.95 respectively. For quiet time, the range of light levels was between 2 and 84 lux, having the mean value and standard deviation of 19.29 and 12 lux respectively. Like sound level, the mean light level was highest in day shift and the lowest in night shift for both non-quiet and quiet times.

Table 5 Min-max, mean, and standard deviation of light levels (lux) as measured in NICU between non-quiet and quiet times, shown by shift and total

Shift	n	Non-quiet Time			Quiet Time		
		Min-max	Mean	SD	Min-max	Mean	SD
Day	288	3.00-661.00	148.84	91.93	4.00-52.00	22.28	11.60
Evening	288	6.00-328.00	143.83	82.99	2.00-84.00	20.99	13.30
Night	288	5.00-454.00	117.32	82.58	3.00-46.00	14.59	9.37
Total	864	3.00-661.00	136.67	86.95	2.00-84.00	19.29	12.00

According to the handling evaluation process, the handling score ranging from 0 to 4 was assigned to the handling states, between no handling and painful handling, whenever the observation was made to the test subject. The frequency of handling scores during the non-quiet and quiet times are shown in table 6. According to the result regarding non-quiet time period, the handling state most observed is no handling with 83.6 percent of total handling observation pointing to this state. The total frequency of handling states belongs to some level of physical handling is only at 16.4 percent, which includes disturbance handling (6.9 percent), discomfort handling (6.6 percent) and painful handling (2.9 percent). Regarding total handling observed during quiet time, no handling state occurred at 98.7 percent, indicating that the lower percentage of handling score happened due to the quiet time protocol. Combination of other handling states with some physical handling was merely 1.3 percent, which includes comfort handling (0.1 percent) and disturbance handling (1.2 percent).

Regarding percentage distribution of state with some level of physical handling, the most frequent handling received by premature infants during non-quiet time occurred in day shift with 25.4 percent, which comes from disturbance handling (10.1 percent), discomfort handling (9.7 percent) and painful handling (5.6 percent) while the lowest observation was happened in night shift with 10.4 percent during non-quiet time, which came from disturbance handling (5.6 percent), discomfort handling (4.5 percent) and painful handling (0.3 percent). In case of quiet time, the highest frequency of handling was done in day time with both day shift (disturbance handling, 1.7 percent) and evening shift (comfort handling, 0.3 percent and disturbance handling, 1.4 percent) presenting same disturbance level at 1.7 percent each and the lowest frequency of handling was occurred in night shift with 0.3 percent of disturbance handling.

Table 6 Frequency, percentage, mean, and standard deviation of handling scores between non-quiet and quiet times, shown by shift and total

	Non-quiet Time		Quiet Time	
	Frequency	Percentage	Frequency	Percentage
Day shift (n = 288)	(Mean = 0.72, SD = 1.29)		(Mean = 0.03, SD = 0.26)	
0 = no handling	215	74.6	283	98.3
1 = comfort	-	-	-	-
2 = disturbance	29	10.1	5	1.7
3 = discomfort	28	9.7	-	-
4 = pain	16	5.6	-	-
Evening shift (n = 288)	(Mean = 0.38, SD = 0.01)		(Mean = 0.03, SD = 0.24)	
0 = no handling	249	86.4	283	98.3
1 = comfort	-	-	1	0.3
2 = disturbance	15	5.2	4	1.4
3 = discomfort	16	5.6	-	-
4 = pain	8	2.8	-	-
Night shift (n = 288)	(Mean = 0.26, SD = 0.79)		(Mean = 0.01, SD = 0.12)	
0 = no handling	258	89.6	287	99.7
1 = comfort	-	-	-	-
2 = disturbance	16	5.6	1	0.3
3 = discomfort	13	4.5	-	-
4 = pain	1	0.3	-	-
Total (n = 864)	(Mean = 0.45, SD = 1.06)		(Mean = 0.02, SD = 0.22)	
0 = no handling	722	83.6	853	98.7
1 = comfort	-	-	1	0.1
2 = disturbance	60	6.9	10	1.2
3 = discomfort	57	6.6	-	-
4 = pain	25	2.9	-	-

Part III: Result of hypothesis testing

Hypothesis stated that “The mean score of sleep-wake states of premature infants during the experimental period (quiet time) is lower than the control period (non-quiet time).”

The result regarding total frequency of sleep-wake states of premature infants is displayed in table 7. For comparison reason, the states were combined according to their similarity in characteristic, forming 3 broader states: sleep related state, drowsy state, and awake-related state. According to the results regarding control period, the state that occurs in highest frequency, is sleep-related state, with 52.2 percent of total observation (10.60 percent from quiet sleep and 41.60 percent from active sleep) while the frequencies of awake-related state is at 39.3 percent (15.40 percent from quiet awake, 11.40 percent from active awake and 12.50 percent from crying), and drowsy state stands at 8.5 percent. For the experimental period, the state occurred in highest frequency is sleep-related state with 79.7 percent of total observation (33.90 percent from quiet sleep and 45.80 percent from active sleep) while the frequencies of awake-related state is at 14.0 percent (7.80 percent from quiet awake, 4.60 percent from active awake, and 1.60 percent from crying), and drowsy state is at 6.3 percent. The significant result that is seen in the experimental period with quiet-sleep related state representing 33.9 percent of total observation, hefty 23.30 percentage jump from 10.60 percent recorded during the control period. Moreover, crying state is decreased by 10.9 percent, from 12.50 percent recorded in the control period to just 1.60 percent in the experimental period.

Table 7 Frequency and percentage of sleep-wake states of the 24 infants between non-quiet and quiet times, shown by total.

Sleep-wake States	Non-quiet Time		Quiet Time	
	Frequency	Percentage	Frequency	Percentage
Sleep				
Quiet sleep	92	10.60	293	33.90
Regular quiet sleep	7	0.80	64	7.40
Irregular quiet sleep	85	9.80	229	26.50
Active sleep	359	41.60	395	45.80
Active sleep	221	25.60	290	33.60
Very active sleep	138	16.00	105	12.20
Drowsy				
Drowsy	74	8.50	54	6.30
Drowsy	74	8.50	54	6.30
Awake				
Quiet awake	133	15.40	68	7.80
Quiet alert awake	12	1.40	8	0.90
Quiet awake	121	14.00	60	6.90
Active awake	98	11.40	40	4.60
Active awake	49	5.70	27	3.10
Very active awake	49	5.70	13	1.50
Crying	108	12.50	14	1.60
Fussing	41	4.70	4	0.50
Crying	36	4.20	7	0.80
Hard crying	31	3.60	3	0.30
Total	864	100.00	864	100.00

The overall comparison between the control and experimental periods are shown in table 8. The total mean scores of sleep-wake state of premature infants (n = 864 observations) reduces to 3.51 (SD = 2.05) during the experimental period, while it (n = 864 observations) is 5.43 (SD = 2.91) during the control period. The score received from the experimental period was lower than the score received from the control period. Outcome from comparison analysis made by using Wilcoxon signed rank test for matched paired difference indicates that the total different mean scores of sleep-wake state of premature infants between two periods are statistically significant different ($z = -14.717$, $p < .001$).

Table 8 Comparison mean scores of sleep-wake states of the 24 premature infants between non-quiet and quiet times, shown by shift and total, by Wilcoxon signed rank test for matched paired difference.

Shift	n	Non-quiet Time			Quiet Time			Z
		Min-max	Mean	SD	Min-max	Mean	SD	
Day	288	1-12	5.55	2.98	1-12	3.53	2.01	-8.757*
Evening	288	2-12	5.40	3.00	1-12	3.58	2.21	-7.954*
Night	288	2-12	5.35	2.75	1-12	3.44	1.93	-8.820*
Total	864	1-12	5.43	2.91	1-12	3.51	2.05	-14.717*

* $p < .001$

CHAPTER V

DISCUSSION

This study was designed to determine the effect of quiet time implementation on sleep-wake states of premature infants in the neonatal intensive care unit (NICU). Totals of 24 test subjects were selected according to the purposive sampling criteria mentioned in the methodology section. Each test subject was then used as a sample in both control (non-quiet time) and experimental (quiet time) periods. The control period received typical routine nursing care, while the experimental period received typical routine nursing care with quiet time implementation as a bonus. In this chapter the detail discussion of findings are presented regarding the demographic characteristics of the test subjects, the NICU environment, and outcome from the comparison of the sleep-wake state scores between two periods.

Demographic Characteristics of the Sample

The test subjects participated in this study are almost equally distributed regarding gender with 58.3 percent belongs to male and 41.7 percent for female. Although gender has no significant effect on this study, the closer to equal distribution of the test subjects validates the usability and reliability of findings from this study to the real world where gender distribution is almost equal.

The age distribution of the test subjects is in the range of 26 days in which youngest and oldest ones are 2 days and 28 days old respectively. Even though the distribution of the test subjects regarding early neonatal and late neonatal period are 25 and 75 percent respectively, the average age of the test subjects, 11.92 days, indicates that the distribution of general population is in the vicinity of the borderline value, 7 days, that separates the neonatal periods. The fact that the average age of the test subjects participating in this research closer to the early neonatal period signify the effect of the result received from this study. Lack of adaptability and vulnerability of the premature infants in early age highlight the importance of test subjects regarding their age.

In case of gestational age of the test subjects at the time of birth, the population is divided into two groups with 45.8 percent belonging to extremely premature infants while 54.2 percent goes to moderately premature infants. The mean gestational age, 30.54 weeks, is below the upper limit of the extremely preterm period, indicating the extreme preterm situation of the observed infants at birth. The distribution of postconceptual age indicates that 83.3 percent of the test subjects are in the moderate preterm period at the time of observation. The fact that the mean postconceptional age, 32.21 weeks, is in close proximity to the borderline value, 31 weeks, that separates the extremely and moderate premature state, and low standard deviation value, 1.89 weeks, verify that the test subjects participating in this study were highly reliant on the environment they were in. This finding emphasizes that the test subjects were not well prepared for extra-uterine life. After birth, rapid physiologic changes and immature homeostatic mechanisms limit their abilities to adapt to NICU environment.

Similar pattern is noticed in the distribution of weight status of the test subjects at the time of birth and current. As of three levels defined for weight level, low weight level has the same distribution value, 29.2 percent, in both birth weight and current weight of the test subjects. The difference is seen in the extremely low weight and very low weight level in which the distribution was 16.7 and 54.1 percent respectively at the time of birth but has been changed to 20.8 and 50 percent at the time of observation. The explanation for this situation is that the interchanging happened between the test subjects belonging to very low weight level and extremely low weight. The reason is that the preterm infants usually lose weight in the first few days of birth (Crosse, 1975: 2) and started gaining weight after two weeks of age. Two of the preterm infants with age below two weeks and having very low birth weight were losing weight since the time they were born and dropped into extremely low weight level when the observation was made. Other preterm infant with age above two weeks and having extremely low birth weight was gaining weight and moved back to very low weight level.

The distribution of the population was also recorded according to the condition of the preterm infants. Half of the population was situated in semi-critical area while 33.3 percent was in critical area. The large numbers of the test subjects with severe conditions presented in this study signify the effect of the results received from this study.

NICU Environment during the Control and Experimental Periods

The aim of this study is to determine the impact of quiet time application in the NICU environment. Detail setting of the environment at the NICU that includes sound levels, light levels, and handling approaches, in the control period, which applied non-quiet time approach, and in the experimental period, which utilized quiet time protocol, are discussed as follow.

Sound

The environment of the NICU for the control period was set as the typical environment seen in any conventional NICU. The minimum noise levels recorded in this normal environment have very little difference among shifts with the lowest occurred in evening shift with 46.8 dB-A. The significant difference is seen in maximum noise level in which the highest value is 87.0 dB-A, which occurred at day shift while the maximum noise level at night shift is just 70 dB-A. According to the mean noise score, the noisiest shift happens to be the day shift with average of 55.97 dB-A while the quietest shift is the night shift with average of 53.9 dB-A. Above finding of noise level from the NICU is in line with general knowledge that daytime is the noisiest and nighttime is the quietest. (Gray et al., 1998: 36; Kurdrit, 2002: 52-53).

The minimum noise levels recorded in this improved environment have very little difference among shifts with the lowest occurred in evening shift with 44.8 dB-A. The maximum noise level in which the highest value is 68.5 dB-A, occurred at day shift while the maximum noise level at night shift decreases 10 dB-A comparing with day shift. This maximum noise level was recorded when one of the test subjects expressed his discomfort from eliminating feces with crying. American Academy of Pediatric (AAP): Committee on Environmental Hazards (1974) recommends that sound levels inside incubators and in the NICU should be reduced below 58 dB-A. Comparing it with the results from this study, there are four data of noise levels recorded over 58 dB-A but all of them related with crying states of the premature infants. No sound level that over 58 dB-A came from the staffs or equipments. Although the noisiest time still belongs to the day shift with average of 51.89 dB-A and the quietest time is in the night shift with average of 51.00 dB-A, the difference between the mean sound score among shifts is hardly seen due to the extra afford given for controlling noise. Therefore, these results are still consistent with previous

reports mentioning the quietest time is in the night shift (Gray & associates, 1998 and Strauch & associates 1993). When we compare the noise level of this improved environment with base case, which is the conventional NICU environment, the highest noise level were dramatically decreased from 87.00 to 68.50 dB-A, with 21.26 percent noise deduction was achieved during quiet time implementation. In case of the mean sound level comparison between two periods, 6.44 percent noise deduction was achieved with the quiet time protocol in line with the noise deduction achieved in highest noise level (from 55.01 to 51.47 dB-A). Since noise comes from many different sources at unexpected time, it is almost impossible to reduce the noise level beyond certain level without advance installation and equipments (Gottfried & Hodgman, 1984: 292-293; Thomas, 1989: 249). Although, the mean sound level in the control period was 55.01 dB-A and it was not over than 58 dB-A but there are 196 observations (22.68 percent) of peak sound levels (over 58 dB-A) were recorded. In the experimental period, there are only 4 peak sound levels (0.46 percent) occurred while the quiet time was implemented. When we considering the total mean sounds between two periods, the mean sound level in the control period was 55.01 dB-A and became to 51.47 dB-A in experimental period. Considering the mean sound level between two periods, although it was 3.54 dB-A deduction but when the statistical analysis by Mann-Whitney U test was made, there are significantly different between two periods ($p < .001$) (Appendix A). Therefore, the reduction of sound plays an important role in enhancing the sleeping level of the premature infants.

Light

In case of light level, the highest and lowest illuminations recorded during the control period in the NICU are 661 and 3 lux respectively, both happening to be in day shift. Regarding with the lowest illumination, which is 3 lux, this data came from the test subject who was placed in recovery room at the time the data were collecting. It showed that data contamination was occurred during data collection process between the control and experimental periods regarding light levels. According to the mean illumination score, the brightest shift is the day shift with average of 148.84 lux while the night shift is lowest, which has average of 117.32 lux. The difference appeared between day shift and night shift is due to the fact that the daytime received the extra illumination from sunlight, which generally comes through the glass windows.

During quiet time, the highest and lowest illuminations were recorded with 84 and 2 lux respectively, both in evening shift. Regarding the mean illumination score, the brightest shift is the day shift with average of 22.28 lux while the night shift has average of 14.59 lux. The difference among the mean light level between shifts is dramatically reduced in the improved environment. The staggering illumination deduction is seen when the comparison is made between two periods. In case of highest illumination comparison, the light levels were decreased to 84 from 661 with a new approach, which controls the light level. For the mean comparison, the light levels were dramatically decreased to 19.29 from 136.67 lux with reduction of 85.88 percent were achieved from the conventional NICU environment. Since the environment the test subject existed was easy to control for lighting, the illumination level of the experimental period was being able to be reduced to the required level. Strauch & associates (1993) found that the mean light levels decreased during quiet time in all three shifts and the lowest illumination was occurred in night shift similar to this study. Based on these data, it is possible to conclude that the infants had more enhanced sleep level during the experimental period than the control period with the reduced light levels.

Handling

In case of handling process, it is generally divided into two broad categories, no handling and handling for better representation. The most frequent handling occurred in day shift with 25.4 percent of total observation while the level of handling reduced to 13.5 percent and 10.4 percent in evening and night shift respectively. The reason that higher level of handling occurred in day shift is due to the extra activities which can only be performed in daytime such as routine medication and cleaning as described by Kurdrit (2002).

Under the improved environment with quiet time protocol, the handling was restricted to the essential situation. With the help of this restriction, the most frequent handling occurred in daytime with just 1.7 percent of total observation while the frequency of handling reduced to almost zero in night shift (0.3 percent). Considering total handling received by the 24 test subjects between the two periods, during the quiet time, handling was less occurred than during the non-quiet time with 15.1 percent deduction (from 16.4 percent to 1.3 percent). When the statistical analysis by

Mann-Whitney U test was made, there are significantly different of the mean score between the two periods ($p < .001$). The observed result indicates that the stress occurred in the preterm infants due to excessive handling can be reduced with imposing restriction on handling. Based on the above data, it is concluded that minimal amount of handling is needed to enhance the sleep of an infant because of handling received by the premature infant is a kind of tactile stimulation, which is direct effect of sleep of the premature infant.

Position

In this study, the sample was the moderately premature infants (mean PCA = 32.21 weeks). Because of born before completion of 36 weeks' gestational that the physiological flexion will developed in response of decrease space in the uterus and as an active process in neurological completely development in the last trimester of pregnancy. Therefore, they have a physiological muscle hypotonia. The position of the 24 test subjects were flexed, midline supine containment and assumed as unchanged during quiet time implementation instead of recording the actual position of the test subjects at the time of observation.

The improved environment of the experimental period was developed with the quiet time protocol application to the conventional NICU.

Sleep-wake States of Premature Infants between the Control and Experimental Periods

The result of this study revealed that the sleep-wake states of the premature infants between control period and experimental period were statistically significant different ($z = -14.717$, $p < .001$). It is noticed that the premature infants were more frequent in the state of quiet sleep during the experimental period than during the control period. Similar situation is seen in crying state with the test subjects appeared less frequent in it during the experimental period than during the control period.

For comparison reason, the states are combined according to their similar characteristic, forming 3 broader states: sleep-related state, drowsy state, and awake-related state, which is transition state between sleep and awake. According to the result regarding non-quiet time, the state occurred with highest frequency is sleep-related state with representing 52.2 percent of total observation while the frequencies of awake-related and drowsy states are at 39.3 and 8.5 percent respectively. During

quiet time, the state occurred with highest frequency is still sleep-related state but the occurrence is dramatically increased to 79.7 percent while the frequency of awake-related and drowsy states are represented at 14.0 and 6.3 percent respectively. It is obvious that the observed frequency of the sleep-related state is increased 23.3 percent, while the awake-related state is decreased 25.3 percent due to the implementation of the quiet time protocol. The significant result is also seen in the experimental period with quiet-sleep related state representing 33.9 percent of total observation, 23.30 percent increased from 10.60 percent at the time of control period. Moreover, statistically significant different ($p < .001$) was achieved with statistical analysis made between the two periods. The increase level of sleep due to quiet time protocol has positive effect on the preterm infants since sleep promotes growth, development and function of infants' body (Balsmeyer, 1990: 447; Blackburn & Loper, 1992: 560-564; Catelett & Holditch-Davis, 1990: 21, Holditch-Davis, 1998: 924-927).

When we look deeper into the sleep-related state, we can see another significant result regarding quality of sleep. Although the quiet-related states, regular and irregular quiet sleep, possessed 10.6 percent of total observation in the control period, it was dramatically increased to 33.9 percent in the experimental period. This observation indicates that the sleep of the preterm infants is improved due to quiet time implementation not only in quantity but also in quality. In case of awake-related states, the significant result is seen in the most severe awake state, crying state, with the frequency reduced to 1.6 percent from 12.5 percent with quiet time implementation. This finding expresses that the stress level of premature infants are significantly reduced with quiet time implementation. These results are consistent with previous reports. The study of Strauch & associates (1993), the implementation of a quiet hour: effect on noise levels and infant sleep, found that fewer infants were crying during the quiet hour than the control period, and more were in deep or light sleep. Panita Nakklinkul (2003) examined the effects of the quiet hour provision on duration of sleep among preterm infants and found that both the duration of deep sleep and the total duration of sleep in the quiet hour were statistically significantly more than the normal hour ($p < .001$) and the average duration of active sleep in the quiet hour was less than in normal hour at the level ($p < .05$).

Limitations

Since the subjects used in this study were recruited from one setting, it could not be able to represent the whole population.



CHAPTER VI

CONCLUSION

The quasi-experimental research was developed to study the effect of quiet time implementation on sleep-wake states of premature infants in the neonatal intensive care unit. In addition, the detail research on the environment of the NICU was made to study the characteristics of the conventional NICU, and to find the feasible solution that promotes the new environment suited for the requirement of the preterm infants as well as the sleep improvement of the preterm infants. This study was based on developmental care and synactive theory of development for the premature infants.

The instruments used in this research could broadly be divided into two groups regarding their utilization. The instruments belong to first group was represented as a guideline of quiet time protocol, which was developed by the research, and were validated by five experts in neonatology, and supporting instruments such as nesting clothes in implementation of this research work. The instruments belong to second group were classified as instruments utilized in data collection process such as the demographic data collection form, observation record sheets, assessment of premature infant handling, the Anderson Behavioral State Scale, digital lux meter, and sound level meter. The data used in the behavioral states of premature babies were collected by six reliable research assistants who had the inter-rater reliability between 0.83 and 1.0 according to the reliability check performed in every three months.

The data collection procedure in this study was encompassed by the protection of human subjects. First, permission to conduct the study was requested to the Ethical Clearance Committee on Human Rights Related to Researches Involving Human Subjects, Faculty of Medicine, Ramathibodi Hospital, Mahidol University. Afterward, total of 24 test subjects who were premature infants admitted to the NICU during August 2003 and February 2004, Ramathibodi Hospital, were selected according to the purposive sampling criteria mentioned in the methodology section after receiving written inform

consent from the parents. Each test subject was then used as a sample in both control and experimental periods. The control period generally receives typical routine nursing care, while the experimental period receives typical routine nursing care as well as quiet time implementation, which includes providing optimal position (flexed, midline supine containment), reducing sound level, reducing light level, and keeping handling in minimal.

The demographic data of the test subjects was statistically analyzed, and frequency, percentage, range, and mean values were then utilized in displaying personal characteristic of the test subjects. The division of gender of test subjects participating in this study was almost equal between female and male. The mean age of the test subjects was 11.92 days with the average PCA of 32.21 weeks. Half of them were born with very low weight and average weight became 1,314.58 grams at the time of observation. Regarding with condition of the premature infants, 16.7 percent of population was in recovery condition while others were severe condition with 50 percent and 33.3 percent admitted in semi-critical and critical area respectively.

All data were analyzed by using a powerful statistical analysis program, SPSS for Windows version 11.5 with statistical approach. The findings of the study are as follow:

1. The mean sound level inside incubator measured in the NICU during the quiet time is lower than during the non-quiet time and frequency of peak sounds that occurred during the quiet time is less than during the non-quiet time.
2. The mean light level inside incubator measured in the NICU during the quiet time is lower than during the non-quiet time.
3. Frequency of handling received by the premature infants in the NICU during the quiet time is less than during the non-quiet time and the mean handling score during the quiet time is lower than during the non-quiet time.
4. The mean score of sleep-wake states of premature infants between the control and experimental period was statistically significant different ($p < .001$).

The Quiet Time implementation was developed based on the literature review of developmental supportive care to promote sleep of the premature infants. This protocol covers four aspects of developmental care: providing optimal position, reducing sound levels, reducing light levels, and keeping handling in minimal. During the quiet time,

mean sound levels, mean light levels, and mean handling scores were significantly lower than the same parameter receiving from during the non-quiet time in statistical way and the premature infants were in flexed, midline-containment throughout this period. This intervention depends on collaborative efforts of all health care providers within the NICU. In this study, it may be summarized that quiet time implementation can promote both quality and quantity of sleep of premature infants who are living in the NICU environment.

Recommendations

The findings of this study contain several implications for the nursing professional, including nursing practice, nursing education, and nursing research.

Implications for nursing practice

Quiet time implementation can be used as a guideline to promote both quality and quantity of sleep in premature infants, reducing the stressful stimulation in the noxious NICU environment.

Implications for nursing education

The quiet time protocol can be used in nursing education. Nursing students can learn how to save life of the premature infant in the NICU with high medical technology and how to reduce sequelae, by modifying the highly technological NICU environment. This intervention is part of developmental care, which is a holistic approach for the premature infants and their family.

Implications for nursing research

The extension of this study should be done for analysing physical parameter of premature infants such as heart rate, respiratory rate and oxygen saturation. Also, the quiet time protocol used in this study should be extended for longer period to determine the growth of preterm and length of stay in hospital.

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APPENDIX A

ADDITIONAL ANALYSIS

Table 9 Comparison of mean sound levels (dB-A) as measured in NICU between non-quiet and quiet times, shown by shift and total, by Mann-Whitney U test

Shift	n	Non-quiet Time			Quiet Time			Z
		Min-max	Mean	SD	Min-max	Mean	SD	
Day	288	46.9-87.0	55.97	6.06	46.2-68.5	51.89	3.16	-10.258*
Evening	288	46.8-86.7	55.17	5.54	44.8-68.2	51.53	3.42	-8.922*
Night	288	47.0-70.0	53.90	4.61	46.0-58.0	51.00	3.39	-8.253*
Total	864	46.8-87.0	55.01	5.50	44.8-68.5	51.47	3.34	-15.422*

* p <.001

Table 10 Comparison of mean light levels (lux) as measured in NICU between non-quiet and quiet times, shown by shift and total, by Mann-Whitney U test

Shift	n	Non-quiet Time			Quiet Time			Z
		Min-max	Mean	SD	Min-max	Mean	SD	
Day	288	3-661	148.84	91.93	4-52	22.28	11.60	-19.737*
Evening	288	6-328	143.83	82.99	2-84	20.99	13.30	-18.674*
Night	288	5-454	117.32	82.58	3-46	14.59	9.37	-19.062*
Total	864	3-661	136.67	86.95	2-84	19.29	12.00	-32.767*

* p <.001

Table 11 Comparison of handling scores as measured in NICU between non-quiet and quiet times, shown by shift and total, by Mann-Whitney U test

Shift	n	Non-quiet Time			Quiet Time			Z
		Min-max	Mean	SD	Min-max	Mean	SD	
Day	288	0-4	0.72	1.29	0-2	0.03	0.26	-8.341*
Evening	288	0-4	0.38	0.01	0-2	0.03	0.24	-5.397*
Night	288	0-4	0.26	0.79	0-2	0.01	0.12	-5.357*
Total	864	0-4	0.45	1.06	0-2	0.02	0.22	-11.171*

* p <.001

APPENDIX B

DOCUMENTARY PROOF OF ETHICAL CLEARANCE



คณะแพทยศาสตร์ โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล

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**Documentary Proof of Ethical Clearance Committee on Human Rights
Related to Researches Involving Human Subjects
Faculty of Medicine, Ramathibodi Hospital, Mahidol University**

No. 0382/2003/N₁

Title of Project

Effect of Quiet Hour Implementation on Sleep-wake States
of Premature Infants in the Neonatal Intensive Care Unit

Protocol Number

ID 07-46-16

Principal Investigator

Miss. Sakuntala Sudsaneha

Official Address

Department of Nursing
Faculty of Medicine, Ramathibodi Hospital
Mahidol University

Document reviewed

New Title:

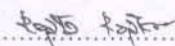
Effect of Quiet Time Implementation on Sleep-wake States
of Premature Infants in the Neonatal Intensive Care Unit

*The aforementioned documents have been reviewed and acknowledged by
Committee on Human Rights Related to Researches Involving Human Subjects, based
on the Declaration of Helsinki.*

Signature of Chairman
Committee on Human Rights Related to
Researches Involving Human Subjects


Prof. Krisada Ratana-olarn, M.D., FRCST, FICS.

Signature of Dean


Prof. Rajata Rajatanavin, M.D., F.A.C.E.

Date of Approval

April 11, 2005

INFORMED CONSENT FORM (THAI VERSION)

หนังสือยินยอมโดยได้รับการบอกกล่าวและเต็มใจ
สำหรับผู้เข้าร่วมการวิจัยที่ไม่สามารถแสดงความยินยอมได้ด้วยตนเอง

ชื่อโครงการ ผลของการจัดช่วงเวลาสงบต่อภาวะการหลับคืนของทารกเกิดก่อนกำหนดในหออภิบาลทารกแรกเกิด

ชื่อผู้วิจัย นางสาวศุภนุชดา สุดแสนหา

* ชื่อผู้เข้าร่วมการวิจัย.....

อายุ..... เลขที่เวชระเบียน.....

คำยินยอมของผู้มีอำนาจกระทำการแทนผู้เข้าร่วมการวิจัย

ข้าพเจ้า นาย/นาง/นางสาว..... ซึ่งเป็นผู้มีอำนาจกระทำการแทน นาย/นาง/นางสาว/ค.ช./ค.ญ. ในฐานะ..... ได้ทราบรายละเอียดของโครงการวิจัย ตลอดจนประโยชน์และข้อเสี่ยงที่จะเกิดขึ้นต่อผู้เข้าร่วมการวิจัยจากผู้วิจัยแล้วอย่างชัดเจน ไม่มีสิ่งใดปิดบังซ่อนเร้นและยินยอมให้ทำการวิจัยในโครงการที่มีข้อข้างต้น และข้าพเจ้ารู้ว่าถ้ามีปัญหาหรือข้อสงสัยเกิดขึ้น ข้าพเจ้าสามารถสอบถามผู้วิจัยได้ และข้าพเจ้าสามารถไม่ให้ผู้เข้าร่วมการวิจัยเข้าร่วมโครงการวิจัยนี้เมื่อใดก็ได้ โดยไม่มีผลกระทบต่อการศึกษาที่ผู้เข้าร่วมการวิจัยได้รับ นอกจากนี้ผู้วิจัยจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวผู้เข้าร่วมการวิจัยเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวผู้เข้าร่วมการวิจัยต่อหน่วยงานต่างๆ ที่เกี่ยวข้อง กระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

ลงชื่อ (ผู้มีอำนาจกระทำการแทน)

..... (พยาน)

..... (พยาน)

วันที่

คำอธิบายของผู้ทำวิจัย

ข้าพเจ้าได้อธิบายรายละเอียดของโครงการ ตลอดจนประโยชน์ของการวิจัย รวมทั้งข้อเสี่ยงที่อาจเกิดขึ้นแก่ผู้เข้าร่วมการวิจัยให้ผู้มีอำนาจกระทำการแทนทราบแล้วอย่างชัดเจนโดยไม่มีสิ่งใดปิดบังซ่อนเร้น

ลงชื่อ (ผู้วิจัย)

วันที่

* ผู้เข้าร่วมการวิจัย หมายถึง ผู้ยินยอมตนให้ทำวิจัย

PATIENT / PARTICIPANT INFORMATION SHEET (THAI VERSION)

เอกสารชี้แจงข้อมูล / คำแนะนำแก่ผู้เข้าร่วมการวิจัย

ชื่อโครงการ ผลของการจัดช่วงเวลาสงบต่อภาวะการหลับตื่นของทารกเกิดก่อนกำหนดในหออภิบาลทารกแรกเกิด

ชื่อผู้วิจัย นางสาวสกุณฑลา สุธะสนัหา

สถานที่วิจัย หออภิบาลทารกแรกเกิด (ไอ ซี ยู ทารกแรกเกิด) คณะแพทยศาสตร์ โรงพยาบาลรามาธิบดี

บุคคลและวิธีการติดต่อเมื่อมีเหตุฉุกเฉินหรือความผิดปกติที่เกี่ยวข้องกับการวิจัย

1. น.ส. สกุณฑลา สุธะสนัหา โทร. 0-1870-3064 หรือ 0-9109-5825
2. ผศ.ดร. เรณู พุกบุญมี โทร. 0-9511-3987

ความเป็นมาของโครงการ

เนื่องจากการหลับมีความจำเป็นต่อทารกเกิดก่อนกำหนดเป็นอย่างมากสำหรับการเจริญเติบโตและพัฒนาการ แต่สิ่งแวดล้อมภายในหออภิบาลทารกแรกเกิดนั้นเต็มไปด้วยสิ่งรบกวนการนอนหลับของทารก สิ่งแวดล้อมเหล่านี้ ได้แก่ เสียงดัง แสงสว่างจ้า และการถูกจับต้องที่มากเกินไป รวมทั้งทารกขาดความพร้อมในการพัฒนาของกล้ามเนื้อจากการเกิดก่อนกำหนด ทารกจะมีแขนขาอ่อนปวกเปียกและเหยียดออก ไม่สามารถออกแรงต้านแรงโน้มถ่วงได้ ก่อให้เกิดภาวะเครียดและรบกวนการหลับในทารกเกิดก่อนกำหนดได้ ดังนั้น การจัดช่วงเวลาสงบโดยการจัดท่านอนที่เหมาะสมให้กับทารก ลดระดับเสียง ลดระดับแสง และลดการจับต้อง จะสามารถส่งเสริมให้ทารกหลับ ได้มีคุณภาพมากยิ่งขึ้น

วัตถุประสงค์

เพื่อเปรียบเทียบความแตกต่างของภาวะการหลับตื่นของทารกเกิดก่อนกำหนด ระหว่างช่วงเวลาปกติและช่วงเวลาสงบ ในหออภิบาลทารกแรกเกิด

รายละเอียดที่จะปฏิบัติต่อผู้เข้าร่วมการวิจัย

ผู้วิจัยจะดำเนินการจัดช่วงเวลาสงบเป็นเวลา 2 ชั่วโมงต่อวัน ทั้งหมด 3 วันต่อวัน เริ่มตั้งแต่เช้าถึงเย็น โดยมีการปฏิบัติต่อผู้เข้าร่วมการวิจัยโดยตรง คือ การจัดทำที่เหมาะสม จะปฏิบัติ 1 ครั้งต่อวัน ครั้งละประมาณ 2-3 นาที ส่วนการลดเสียง ลดแสง และลดการจับต้องนั้น ไม่ได้ปฏิบัติต่อตัวผู้เข้าร่วมการวิจัยโดยตรง

ประโยชน์และผลข้างเคียงที่จะเกิดแก่ผู้เข้าร่วมการวิจัย

ผู้เข้าร่วมการวิจัยจะได้รับการส่งเสริมการนอนหลับ และเนื่องจากการวิจัยครั้งนี้เก็บข้อมูลโดยการสังเกตและบันทึกผล ดังนั้นจะไม่ก่อให้เกิดอันตรายใดๆ แก่ผู้เข้าร่วมการวิจัย

การเก็บข้อมูลเป็นความลับ

ข้อมูลที่ได้จากการวิจัยครั้งนี้จะนำเสนอแต่เพียงข้อมูลทางวิชาการในภาพรวม โดยจะไม่มีการเปิดเผยชื่อและภูมิปัญญาของผู้เข้าร่วมการวิจัย

ถ้าท่านมีข้อข้องใจหรือมีความกังวลเกี่ยวกับวิธีดำเนินการวิจัยของโครงการวิจัยนี้ ท่านสามารถติดต่อได้ที่
ประธานกรรมการจริยธรรมการวิจัยในคน คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี งานบริการวิชาการและวิจัย
ชั้น 5 (ห้อง 509) ศูนย์การแพทย์สิริกิติ์ โทรศัพท์ 0-2201-1541 ในเวลาราชการ

APPENDIX C

INSTRUMENTS FOR DATA COLLECTION

DEMOGRAPHIC DATA FORM

Date..... No..... Area.....

H.N. Birth Date..... Time..... Sex..... Age..... days

Type of Delivery..... Indication.....

Gestational age weeks Birth weight grams

Postconceptional age weeks Current weight grams

Diagnosis.....

Health status and Treatment

OBSERVATION RECORD SHEET

Table 12 Observation Record Sheet

Set I – Day shift

Time	Sound level (dB-A)	Light level (lux)	Handling score	Sleep-wake state	Remark
8:10 am.					
8:20 am					
8:30 am.					
8:40 am.					
8:50 am.					
9:00 am.					
9:10 am.					
9:20 am.					
9:30 am.					
9:40 am.					
9:50 am.					
10:00 am.					
12:10 pm.					
12:20 pm.					
12:30 pm					
12:40 pm.					
12:50 pm.					
13:00 pm.					
13:10 pm.					
13:20 pm.					
13:40 pm.					
13:50 pm.					
14:00 pm.					

Date..... No.....

Table 13 Observation Record Sheet**Set I – Evening shift**

Time	Sound level (dB-A)	Light level (lux)	Handling score	Sleep-wake state	Remark
16:10 pm.					
16:20 pm					
16:30 pm.					
16:40 pm.					
16:50 pm.					
17:00 pm.					
17:10 pm.					
17:20 pm.					
17:30 pm.					
17:40 pm.					
17:50 pm.					
18:00 pm.					
18:10 pm.					
18:20 pm.					
18:30 pm					
18:40 pm.					
18:50 pm.					
19:00 pm.					
19:10 pm.					
19:20 pm.					
19:40 pm.					
19:50 pm.					
20:00 pm.					

Date..... No.....

Table 14 Observation Record Sheet**Set I – Night shift**

Time	Sound level (dB-A)	Light level (lux)	Handling score	Sleep-wake state	Remark
00:10 am.					
00:20 am					
00:30 am.					
00:40 am.					
00:50 am.					
01:00 am.					
01:10 am.					
01:20 am.					
01:30 am.					
01:40 am.					
01:50 am.					
02:00 am.					
03:10 am.					
03:20 am.					
03:30 am					
03:40 am.					
03:50 am.					
04:00 am.					
04:10 am.					
04:20 am.					
04:40 am.					
04:50 am.					
05:00 am.					

Date..... No.....

ANDERSON BEHAVIORAL STATE SCALES: ABSS (THAI VERSION)

แบบประเมินพฤติกรรมระยะหลับตื่นของทารกเกิดก่อนกำหนด

คะแนน 1 – 4 เป็นพฤติกรรมระยะหลับ ของทารก (Sleep State)			
1. หลับนิ่งมาก (regular quiet sleep)	2. หลับเล็กน้อย (irregular quiet sleep)	3. หลับตื่น (active sleep)	4. หลับตื่นมาก (very active sleep)
• หลับตา • • •	• หลับตา • • •	• หลับตา • • •	• หลับตา • • •
คะแนน 5 เป็นพฤติกรรมระยะ ง่วงซึม ของทารก (Drowsy State)			
• ทารกกำลังจะหลับตาหรือกำลังจะลืมตา หรือทารกหลับตาแบบกะแฉกๆ หรือทารกเปิดตาข้างเดียวส่วนอีกข้างปิด •			
คะแนน 6 – 9 เป็นพฤติกรรมระยะตื่น ของทารก (Awake State)			
6. ตื่นไม่มีการเคลื่อนไหว (quiet alert awake)	7. ตื่นเฉื่อย (quiet awake)	8. ตื่นมีการเคลื่อนไหว (active awake)	9. ตื่นมีการเคลื่อนไหวมาก (very active awake)
• ลืมตา • •	• ลืมตา • •	• ลืมตา • •	• ลืมตา • •
คะแนน 10 – 12 เป็นพฤติกรรมระยะ ร้องไห้ ของทารก (Crying State)			
10. หงุดหงิด (fussing)	11. ร้องไห้ (crying)		12. ร้องไห้หนัก (hard crying)
• หลับตาหรือลืมตา • • • •	• หลับตาหรือลืมตา • • • •		• หลับตาหรือลืมตา • • • •

*** ให้สังเกตพฤติกรรมทารกก่อนเป็นเวลา 30 วินาที จึงทำการสรุประยะการหลับตื่นของทารกลงในแบบบันทึก (1 – 12) ***

ASSESSMENT OF PREMATURE INFANT HANDLING (THAI VERSION)

แบบประเมินประเภทการดูแลทารกเกิดก่อนกำหนด

1. การดูแลข้อต่อเพื่อการปลดปล่อย	2. การดูแลข้อต่อเพื่อให้เกิดความรำคาญ	3. การดูแลข้อต่อเพื่อให้เกิดความไม่สุขสบาย	4. การดูแลข้อต่อเพื่อให้เกิดความเจ็บปวด
การจับหรือสัมผัสเบาๆ	การเขี่ยผิวหนังระคายเคือง	การทำให้ผิวหนังบวมแดง	การดูแลเฉพาะทางหรือช่วยหายใจ

หมายเหตุ

1. คะแนน 0 หากทารกไม่ถูกจับต้อง ให้ 0 คะแนน
- 2.
- 3.

APPENDIX D

QUALITY OF THE INSTRUMENTS

LIST OF EXPERTS

There are five experts who have validated the quiet time protocol are as follows:

1. Associate Professor Fongcum Tilokskulchai, Ph.D.(Nursing)
Department of Pediatric Nursing,
Faculty of Nursing, Mahidol University.
2. Assistant Professor Jariya Witayasuporn, D.N.S.
Department of Nursing,
Faculty of Medicine, Ramathibodi Hospital, Mahidol University.
3. Assistant Professor Sarayuth Supapannachat, M.D.
Neonatal Unit,
Faculty of Medicine, Ramathibodi Hospital, Mahidol University.
4. Assistant Professor Prissana Soontornchai, M.N.S.
Department of Pediatric Nursing,
Faculty of Nursing, Chiang Mai University.
5. Miss Penjit Thanacharoenpipat, M.N.S.
Special Care Nursery
Department of Pediatrics, Sawanpracharak Hospital.

INTER-RATER RELIABILITY OF ABSS

Table 15 Inter-rater reliability test of ABSS between the researcher and the research assistants.

Research assistants	Number test			Mean
	1st	2nd	3rd	
1	1.00	0.96	1.0	0.99
2	0.92	0.96	0.92	0.93
3	0.96	0.96	0.92	0.94
4	0.88	0.83	0.88	0.86
5	0.88	0.92	0.92	0.90
6	0.96	0.92	0.92	0.93
Total	0.93	0.925	0.926	0.925

CALIBRATION CERTIFICATE OF DIGIAL LUX METER



Request No. BP-P 349 / 46

MTC No. PSL-P 194 / 46

CALIBRATION CERTIFICATE

Nomenclature : Digital Lux Meter

Serial No. : L 552583

Maker : DIGICON

Model / Type : LX - 50

Customer : MISS SAKUNTALA SUDSANEHA

Address : Faculty of Medicine, Ramathubodi Hospital, Mahidol University, Bangkok.

Date of request : 22 May 2003.

Date of calibration : 2 June 2003.

Place of calibration : Photometry Standards Laboratory, MTC (Bangpoo).

Basis of calibration : Calibrated at 0 ~ 1990 lux.

Condition of calibration : - Laboratory ambient temperature : $25 \pm 2^{\circ}\text{C}$.

- Laboratory relative humidity : $60 \pm 10\%$.

Reference Standard : Working Standard Luminous Intensity Lamp at color temperature 2856 K, Serial No.: SB50142C, which was calibrated on 5 July 2002, can be traceable to Australian National Standard Maintained at National Measurement Laboratory (NML), CSIRO Division of Applied Physics, Australia.

Support Equipment :
1. Photometric bench, 3.0 meter long.
2. DC. power supply.
3. Digital multimeter, Model : R 6551, S/N : 42040037 and 42040048.

Calibration Procedure : The Unit Under Calibration (UUC) was measured to illuminance obtained from The Working Standard Luminous Intensity Lamp at calibration points.

The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor $k=2$, providing a level of confidence of approximately 95 %.

The results of calibration are attached here-with.

page 1 of 2

The above results are valid exclusively for the tested/analysed sample(s)/calibrated item(s) as mentioned in this report/certificate.
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Amphoe Muang, Samutprakan 10280
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Fax. (66) 0 2323 9165

CALIBRATION CERTIFICATE OF SOUND LEVEL METER



Request No. EE. 413/46

MTC No. EEL. BP. 38/0546

CALIBRATION CERTIFICATE

Submitted by : Miss Sakuntala Sudsaneha

Address : Dormitory of Mahidol University, Tambon Salaya, Amphoe Phutthamonthon, Nakhon Phathom

Calibrated at : Electrical and Electronic Standards Laboratory, Industrial Metrology and Testing Service Center

Instrument Calibrated :

Ambient Environment

Description : Sound Level Meter

Temperature : $(23 \pm 3) ^\circ\text{C}$

Manufacturer : Digicon

Relative Humidity : $(55 \pm 15) \%$

Model : DS-40

Ambient Pressure : $(1\,008 \pm 5) \text{ hPa}$

Serial No. : M114235

Microphone No. : -

Preamplifier No. : -

Standards used :

1. Multifunction Acoustic Calibrator Brüel&Kjær 4226 S/N 2295571
with Coupler UA0915 S/N 2295571

Calibration Procedure : This procedure is developed by Electrical and Electronic Standards Laboratory based on ;

1. IEC 651(1979) Standard for Sound Level Meters
2. International Recommendation OIML R 58(1998) for Sound Level Meters

This instrument has been calibrated against standards maintained at Electrical and Electronic Standards Laboratory (EEL), which are traceable to ;

- Brüel&Kjær UK Ltd.

Accredited by : UKAS, United Kingdom

Accreditation No. : 0174

Date of Receipt : 22 May 2003

Date of Calibration : 2 Jun. 2003

1 / 3

fmm/h

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BIOGRAPHY



NAME	Miss Sakuntala Sudsaneha
DATE OF BIRTH	August 25, 1975
PLACE OF BIRTH	Chachoengsao, Thailand
INSTITUTE ATTENDED	Boromrajonani College of Nursing Chonburi, Chonburi, Thailand, 1993 – 1997: Diploma in Nursing Science Mahidol University, Bangkok, Thailand, 2001 – 2005: Master of Nursing Science (Pediatric Nursing)
POSITION & OFFICE	1997 – Present Special Care Nursery Chachoengsao Hospital Chachoengsao, Thailand Position: Registered Nurse