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Interventions to Reduce the Effects of NICU Noise in Preterm Neonates

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INTERVENTIONS TO REDUCE THE EFFECTS OF NICU NOISE IN PRETERM
NEONATES

By

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A thesis submitted in partial fulfillment of the requirements
for Honors in the Major Program in Nursing
in the College of Nursing
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Abstract

Exposure to excessive noise during a neonates stay in the neonatal intensive care unit (NICU) can create both immediate and long term health problems such as, hearing loss, neurological deficits, and sleep pattern disturbances. The use of earmuffs or earplugs to decrease the neonate's exposure to noise can create a more stable environment to facilitate improved growth and development. The purpose of this research was to examine the use of earmuffs or earplugs to reduce the impact of noise on neonates. A systematic review of literature was conducted using online databases including CINAHL, ERIC, Ebsco Host, Medline, and PsychINFO. The search included a combination of the following terms: 'preterm', 'neonate', 'NICU', 'noise', 'earplugs', and 'earmuffs'. Peer reviewed, articles published in the English language were examined that tested noise reduction devices in the NICU setting, hearing screening of neonates, and the effect of noise reduction interventions on physiologic changes in the preterm infant receiving care in the NICU. Results yielded 8 articles between the years of 1995 to 2017 which were synthesized for review. The results indicated that the use of earmuffs or earplugs in the NICU may offer a viable solution to reducing the effects of excessive noise on neonate's growth and development. The use of earmuffs or earplugs has been shown to positively improve vital signs, increase growth, improve physiological and motor development, and improve sleep efficiency. Further research on larger sample sizes is needed in order to validate the findings and offer substantial evidence for its use in the clinical setting.

Dedication

To all the NICU nurses who have dedicated their time to providing the best possible care to such a delicate population.

For all of the parents who have been faced with the uncertainty of their infants future.

And finally, for my amazing mentor, Dr. Leslee D'Amato-Kubiet for supporting me and encouraging me to achieve my goals.

Acknowledgments

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To Christopher Bridegroom, thank you for your help with the initial research and encouraging me to complete this thesis.

Above all, I would like to thank my committee chair, Dr. Leslee D’Amato-Kubiet, for your support and encouragement throughout this journey. Without you this thesis would not be possible.

Finally, to my friends and family, thank you for your never-ending support and understanding.

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Introduction

The neonatal intensive care unit (NICU) serves as home to preterm infants for a range of weeks to months after birth. According to the CDC, within the last 5 years in the United States (US), one in every ten neonates born was preterm. Preterm infants in the NICU are at an increased risk for overstimulation due to the abundant amount of activity and noise produced during daily activities. Sensory overstimulation, specifically auditory overstimulation, can create a negative impact on the overall growth and development of the neonate, and can damage the immature neurologic system in preterm populations.

Noise is the most concerning overstimulation effect to the sensory system for newborn infants in the NICU and can lead to hearing loss and neurological deficits later in life. Current practice in the NICU exposes preterm infants to excessive noise, subjecting the neonate to potentially long term consequences which are not fully realized until later in life. Interventions to reduce the amount of sensory stimulation, particularly auditory stimulation, can be used to reduce the insult to the developing neurologic system and to improve growth and development rates in preterm infants that are admitted to the NICU.

Problem

Noise levels above the recommend level of 45 decibels are routinely present in the NICU which places additional stress on the neonate's immature body systems. Excess sound pollution and additional stress puts the infant at a disadvantage for proper growth and development. There has always been a concern over the amount of sound produced around neonates in the critical care setting, and recently, with advances in medical technology, the NICU has become an even noisier environment.

Multiple studies suggest there is a need to identify noise reducing interventions in the NICU. However, very few studies have actually been conducted to identify any type of intervention to reduce exposure to noise in a neonatal population. Noise pollution in the NICU can impact the development of the cardiovascular, respiratory, auditory and nervous systems of the neonate. This can have immediate effects that cause distress to the infant and lasting effects that cause overall developmental problems. Since nurses act as key participants in monitoring and maintaining the stability of the infant's physiologic development in the NICU, it is imperative that evidenced based practice supports methods to safeguard the neonate from environmental stressors, such as noise.

Background

A premature or preterm infant is described as an infant born before 37 weeks of gestational age. While the mortality rate of preterm infants has declined over the years the likelihood of nervous system disturbances has increased, particularly due to overstimulation during time spent in the NICU. (Abdeyazdan, Ghassemi, & Marofi, 2014)

Auditory development is a slow process and begins early during pregnancy with completion of the major brain structures occurring between 23 and 25 weeks of gestational age (GA). The cochlea develops from low-to-high frequency during 26 to 30 weeks of GA. The intrauterine environment is able to facilitate this development by protecting the fetus from overexposure to noise. As the fetus grows the uterine wall thins allowing the fetus to be exposed to more high frequency sounds which allows for further development of the auditory system. The uterine wall thinning occurs gradually from 26 to about 33 weeks of gestational age. The auditory system becomes developed enough to distinguish between different sounds by 30 weeks GA. (Lahav & Skoe, 2014)

While in utero the mother's abdominal wall and the contents in between the uterus and abdominal wall provides the infant with necessary protection from overstimulation. In terms of auditory stimulation, the uterine structures as well as the amniotic fluid serve to protect developing fetuses from excessive, high frequency sounds. Preterm infants are forced to adapt to an extra uterine environment before having the chance to fully mature and the lack of

auditory protection during the final stages of development may have a negative impact of development.

Preterm infants spend an average of approximately 80 days in the NICU. During this time the neonate undergoes developmental changes which are essential to health during later years in life (Lee, Bennett, Shulman & Gould, 2013). These changes can be negatively impacted when exposed to excess noise. According to the American Academy of Pediatrics the noise level in the neonatal intensive care unit should not exceed 45 decibels. However, studies have shown that many NICU's are unable to maintain noise at this level. Life-saving equipment are needed to monitor and treat preterm infants, such as incubators, ventilators, and heart monitors. The average noise level inside a typical incubator is around 65 decibels, which is 20 decibels above the recommended average. The equipment sounds are also amplified because the infant is in an isolette (Marik, Fuller, Levitov & Moll, 2012).

Noise is defined as any undesirable sounds. Levels of sound are measured in decibels (dB), the higher the decibel the louder the noise. Research has shown that loud noise has been known to create irregular, neurogenic focused conditions in infants in the NICU, including high blood pressure, increased or abnormal heart rate, and difficulty sleeping. Prolonged exposure to sounds that are greater than 85 dB has been linked to permanent hearing loss. While current recommendations state noise should not exceed 45 decibels currently practices expose the infants to levels way above the recommended level.

Current practice has incorporated a variety of methods to attempt to limit sound exposure on neonates in the NICU. One method frequently utilized involves clustering of care activities with the neonate to avoid overstimulation. This means the registered nurse will attend to all of the infants needs at regular intervals including diaper changes, feeding, medication administration, and other interventions that may need to be performed. While this is effective in limiting overstimulation in some aspects it is not very effective in terms of auditory overstimulation. Education is another practice that is being utilized currently; the staff is informed about the danger of auditory overstimulation during the neonate's time in the NICU. They are taught to limit talking in normal voice tones while working with the infants and to monitor the overall noise level in the NICU periodically. While these methods do have some effect on the amount of noise exposure to the infant in the NICU, research has shown care providers are still unable to maintain an environment below the recommended 45 decibels.

Studies have been done on a variety of ways to reduce the effects of sound on infants, one of which proposed the idea of changing the layout of the NICU. (Szymczak & Shellhaas, 2014) However, much easier and more cost effective ways are available including the use of earmuffs and earplugs. When used correctly earplugs and earmuffs can reduce noise by 15 to 30 decibels. (Noise, n.d.) Along with adequate staff education on the proper use and the importance of maintaining noise levels below 45 decibels, these interventions may be effective in reducing the negative effects of noise on preterm infants.

Purpose

The purpose of this integrated review of literature was to determine how the use of earmuffs or earplugs decreases the effects of sound exposure in preterm neonates. The outcome of this review is expected to provide evidence that decreased noise exposure positively influences physiologic development in preterm infants and minimizes growth and developmental delays. Further examination of this topic is needed to fully discover the implications of noise reduction interventions and the efficacy for their use in preterm infants in the NICU.

Methods

A search of relevant databases focused on research articles that evaluated the use of earplugs and/or earmuffs on preterm neonates to reduce the effects of noise stimulation. The literature search spanned the years of 2000-2016 and was limited to post-millennial works due to the evolution of the concept in healthcare research and the need to find the most current definition and use of the concept in NICU care of preterm infants. A source from 1995 was used as a seminal study to highlight the foundations of the research. Databases that were used to search for articles included: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Education Resources Information Center (ERIC), Elton B. Stephens Company, Medical Literature On-Line (Medline), and PsychINFO. Searches used combinations of the following key terms: 'preterm', 'neonate', 'NICU', 'noise', 'earplugs', and ' earmuffs'. The resulting articles were reviewed against the inclusion criteria of: 1) results of primary research published in English, 2) tested noise reduction devices in the NICU setting, and 3) identified screening for hearing and the effect on physiologic changes in the preterm infant receiving care in the NICU.

Each article was evaluated and individually critiqued for relevance to the topic and application to the use of noise reduction devices used for neonates in the NICU. In the appendices, Table 3 summarizes the findings for each article that was reviewed for this thesis. Subsequently, all the critiqued articles were synthesized by the researcher and key findings were extracted along with consistent and inconsistent findings and gaps in the literature. Limitations of the study and recommendations for future research also were noted.

Results

Out of the sixteen articles reviewed, eight met the inclusion criteria and were relevant to the use of noise reduction for neonates in the NICU. Of the eight studies reviewed, one used earplugs to reduce sound while the remaining seven utilized earmuffs. Each study used different measurements to examine the effectiveness of earmuffs and earplugs on preterm neonates; this information is summarized with the findings of each study in Table 1.

Four of the eight articles compared physiological responses including heart rate, respiration rate, and oxygen levels. Two of the eight articles compared weight gain, both of which noted an increased weight gain in neonates who wore earmuffs. One article observed pain response during a heel lance using the interventions of earmuffs and eye shields which showed no significant reduction in pain response, however, several limitations were also noted in the study and further investigation was recommended. Two of the eight articles compared motor responses by observing for tremor, twitch, and startle reflex through observation; both noted a decrease in motor response while neonates were wearing earmuffs. One article compared the amount of days the neonates required the using of oxygen. Two of the eight articles used surveys to obtain the nurses response to using earmuffs. Two articles measured and compared behavioral responses using the Anderson Behavioral State Scale (ABSS). One article observed for adverse effects caused by the earmuffs such as skin breakdown.

While each study utilized different measures, all but two of the studies found that the use of earmuffs or earplugs positively impacted preterm neonate's growth and development.

The results of each measurement will be further discussed in subsequent sections of this literature review. All of the studies recommended further research with larger sample sizes to verify results and examine the long term effects of the use of earmuffs and earplugs.

Table 1: Measurements Used to Examine the Effectiveness of Earmuffs/Earplugs

| Measurements | Articles | Total Articles |
|---|--|----------------|
| Physiological responses (Heart Rate, Respiration Rate, and Oxygen Saturation) | (Zahra Abdeyazdan, Ghassemi, & Marofi, 2014), (Abujarir, Salama, Greer, Al Thani, & Visda, 2012), (Duran et al., 2012), (Zahr & de Traversay, 1995), (Khalesi, Khosravi, Ranjbar, Godarzi, & Karimi, 2017) | 5 |
| Weight Gain | (Z. Abdeyazdan, Ghasemi, Marofi, & Berjis, 2014), (Abou Turk, Williams, & Lasky, 2009) | 2 |
| Motor Responses | (Z. Abdeyazdan et al., 2014), (Z. Abdeyazdan, Ghasemi, Marofi, & Berjis, 2014) | 2 |
| Nurse Response | (Zahra Abdeyazdan et al., 2014), (Abou Turk et al., 2009) | 2 |
| Pain | (Aita, Goulet, Oberlander, Snider, & Johnston, 2015) | 1 |
| Behavior | (Duran et al., 2012), (Zahr & de Traversay, 1995), (Khalesi et al., 2017) | 3 |
| Days of Oxygen Requirement | (Abujarir et al., 2012) | 1 |
| Adverse Effects | (Abou Turk et al., 2009) | 1 |

Physiological Responses

Physiological responses are automatic responses to stimuli such as heart rate, respiratory rate, and oxygen saturation. A literature review of 8 articles examined preterm neonatal response to auditory overstimulation and automatic responses to measure the effectiveness of earmuffs and earplugs. Five of the studies found fewer fluctuations in heart rate, respiratory rate, and oxygen saturation in the group of participant neonates that were wearing earmuffs or earplugs. This indicates that during this time, the neonates were physiologically stable, and the quiet environment allowed the neonates to focus their energy on growth and development. Although the findings in some studies were not statistically significant the designs in several of the studies were not consistently rigorous.

Weight Gain

Weight gain is a commonly used indicator of neonatal growth. For this reason, two of the studies utilized growth as a measurement to determine the effectiveness of their interventions. The first study (N=34) used silicone earplugs to reduce the effects of noise and found no significant difference in weight between the two groups. Although it was not significant, the study did suggest more weight gain in the earplug group compared to the control group (Abou Turk, Williams, & Lasky, 2009). The second study (N =96) examined weight gain in neonates wearing earmuffs, with a 'silence' group, and with a control group that received no noise reduction interventions during the study time period. The silence group

included neonates that were cared for by nurses that were trained in noise reduction. The findings indicated that neonatal weight during the 10 day intervention showed an increase in the group wearing earmuffs when compared to the 'silence' group and the control group, although this increase was not significant. Further investigation showed that the neonates who wore earmuffs demonstrated an average of 44g increase in weight, while the 'silence' group had a weight reduction of 45g, and the control group a reduction of 42g (Z. Abdeyazdan, Ghasemi, Marofi, & Berjis, 2014).

Motor Response

Neurologic motor response can be disturbing to neonatal sleep. Increased motor response due to NICU noise can lead to decreased sleep time and can negatively affect the growth and development of preterm neonates. Many neonates in the NICU are swaddled to decrease movement stimulated by neurologic motor response and to promote quiet sleep. Two studies examined the effects that decreased noise had on stimulation of neurologic motor responses. The first study (N=96) found a significant reduction in motor responses in neonates wearing earmuffs with a p value of <0.000 (Z. Abdeyazdan et al., 2014). The second study (N = 64) had similar results, with decreased motor responses in the experimental group. The studies did not indicate if the infants were swaddled during the intervention.

Nurse Response

Nurses are the provider at bedside and they have the most hands on care with the neonates. How nurses respond to interventions can impact the results. Two articles took into

account the response of the nurses to the use of earmuffs and earplugs. The first article used a survey to obtain the responses of the all 23 nurses who had primary responsibility of the neonates wearing earplugs to mainly close ended questions about the use of earplugs. This concluded that nurses felt the earplugs were beneficial and did not interrupt their nursing care (Abou Turk et al., 2009). The second study used the same questionnaire that was developed by Abou Turk in 2009 and found similar results with 64% of the nurses agreeing that earmuffs are beneficial for neonates; however, the study did not indicate how many nurses completed the questionnaire. (Zahra Abdeyazdan et al., 2014).

Pain

Pain is a stressor for neonates that can negatively affect growth and development. Painful interventions, such as blood draw and nasogastric tube placement, are often necessary for the care of neonates. Overstimulation and repetitive pain can cause hyper excitability of the central nervous system and therefore can have long term effects on brain development in preterm infants that do not have fully developed neurologic systems at time of birth (Grunau et al., 2009). One study (N =44) examined the use of decreased stimuli to reduce the effects of painful procedures. The study used both earplugs for auditory stimuli and eye shields for visual stimuli. The pain response was measured using heart rate variability between baseline and during the procedure. The study found no significant differences in heart rate variability between the control and the experimental group (Aita, Goulet, Oberlander, Snider, & Johnston, 2015)

Behavior

A neonate's behavior can help to better understand the developing brain. "Behavioral assessment provides information about the infant's neurologic well-being and allows caregivers to design individualized, developmental care plans for hospitalized infants." A few different scales exist to rate neonatal behavior including the Brazelton's system (mainly for term neonates) and the Anderson Behavioral State Scoring System (specifically designed for use in preterm neonates). Since preterm neonates are still developing their respiratory and neurologic systems, as well as their other major body systems outside the womb, the amount of time spent in the deep sleep is essential to growth and development (Tappero & Honeyfield, 2009). Three of the studies used the Anderson Behavioral State Scoring System (ABSS) to assess the effects of reduced auditory stimulation of the neonate's behavior. The score is based on a 1 to 12 scale ranging from very quiet sleep to hard crying. A chart with each score is listed below.

Table 2: Anderson State Scoring Scale

| Anderson State Scoring Scale | |
|-------------------------------------|---------------------|
| 1 | Very Quiet Sleep |
| 2 | Quiet Sleep |
| 3 | Restless Sleep |
| 4 | Very Restless Sleep |
| 5 | Drowsy |
| 6 | Alert Inactive |
| 7 | Quite awake |
| 8 | Restless Awake |
| 9 | Very Restless Awake |
| 10 | Fussing |
| 11 | Crying |
| 12 | Hard Crying |

The first study examined neonate behavior (N=30) and was completed in 1995. It noted fewer changes in sleep state during a noisy event in the experimental group as well as significantly more time in the quiet sleep state with a p value of 0.0085 (Zahr & de Traversay, 1995). The second study (N=20) was performed in 2012 and found that infants wearing earmuffs were observed in the quiet sleep state more often than the control group. The control group contained 61.2% of neonates observed in the restless sleep state and only 29.4% in the quiet sleep state compared to the experimental group which had 11.9% in the active sleep and

87.5% in the quiet sleep. These results were statistically significant with a p value of <0.001 (Duran et al., 2012). The third study (N=36) found that 68.34% of the neonates in the intervention group were observed in the quiet state while 58.89% of the control group were observed in the active sleep state (Khalesi et al., 2017).

Days of Oxygen Requirement

Many preterm neonates in the NICU require oxygen therapy due to the immaturity and underdevelopment of the respiratory system. Over use of oxygen can result in hyperoxia which has been linked to multiple, disabling physiologic complications, such as retinopathy of prematurity (ROP), bronchopulmonary dysplasia (BPD), and longer hospital admissions (Sola, Rogido, & Deulofeut, 2007). Research has also shown that noise intensity in the post nasal space is significantly higher in neonates using CPAP which can lead to cochlear damage (Surenthiran et al., 2003). While the use of oxygen can be a life saving measure, it should be used sparingly and for the least amount of days possible. One study examined the effects of decreasing stimulation on the amount of days neonates required oxygen use. A small improvement, that was not statistically significant, was seen in the experimental group in regards to oxygen use ($p = 0.0295$) (Abujarir et al., 2012).

Adverse Reactions

Adverse reactions are a concern when any new intervention is used to treat neonates. Some concerns that are present with the use of earplugs include skin irritation/breakdown,

aspiration of the earplug, and the risk of the plug getting lodged into the nares. Only one study looked at adverse effects as a secondary outcome. This same study had examined the nurse's response to the use of earplugs and used questions related to adverse effects to determine the concerns of the nurses working with the neonates. The study found that 48% of the nurses expressed concern of earplugs falling out, 35% were concerned with the earplugs being swallowed, aspirated, or lodged into the nares, and 57% expressed concerns related to keeping the earplugs in place. The study concluded that no irritation was observed (Abou Turk et al., 2009).

Discussion

The reviewed articles suggest evidenced based interventions for reducing the effects of sound on preterm infants is potentially beneficial, although the full extent of these benefits has not yet been determined. Further research is needed to provide additional follow up of neonatal development over a longer time period that incorporated the consistent use of noise reduction devices to fully examine the long term benefits of the use of earmuff and earplugs on growth and development. None of the studies evaluated long term hearing loss or had a longitudinal design.

It is abundantly evident that overstimulation, particularly auditory, has a negative impact on the growth and development of preterm neonates. The articles examined a range of measurements including physiological responses, weight gain, motor responses, nurse's response, pain, behavior and days of oxygen use. Each article concluded that noise reduction can positively impact all of the measurements examined.

Although these articles concluded that there are positive effects with the use of earmuff and earplugs on growth and development of infants there is still a need for further research with larger sample sizes and additional follow ups. This will help to further validate the information found in these studies and to offer substantial evidence for use in a clinical setting.

The articles found limitations that could affect study results. One commonly discussed limitation that was noted was the lack of blinding in the studies, which unfortunately is unavoidable. The other limitation that was noted in all the studies was the small sample sizes.

Future studies should try to ensure that research be performed in a facility that will offer an adequate sample size in order to validate findings.

Conclusion

The purpose of this literature review was to determine if the use of earmuffs or earplugs was an adequate intervention to reduce the effects of noise on preterm neonates. Noise levels above the recommended amount of 45 decibels is routinely present in the neonatal intensive care unit. NICU noise is considered sound pollution and places additional stress on the preterm infant that is already at a disadvantage for proper growth and development. Prior concern over the amount of sound produced around neonates has been an issue in the NICU, but with the advances of medical technology, the NICU has become an even noisier environment. Multiple studies have demonstrated that there is a need to identify noise reducing interventions to aid in neonatal growth factors. However, very few studies have been conducted to identify any type of plausible, evidence-based practice interventions.

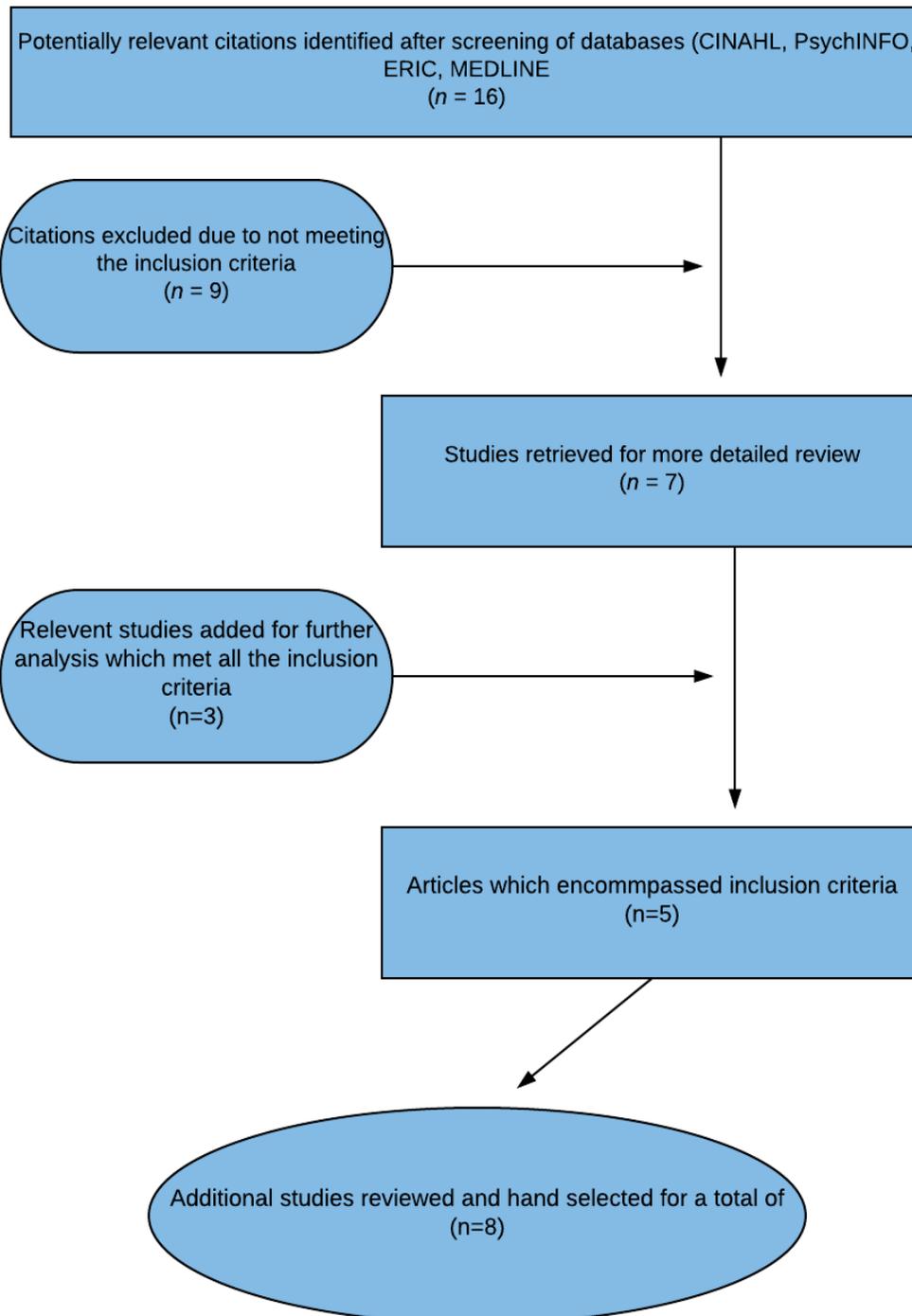
Research has demonstrated that noise pollution in the NICU can impact cardiovascular, respiratory, auditory and nervous systems of the neonate. This can have both an immediate effect that causes distress to the infant and lasting effects on overall development. Since nurses are a key participant in monitoring and maintaining the stability of the infants, it is important that they have evidenced based practice guidelines that will allow them ways to safeguard the neonate from environmental stressors such as noise.

Overall there is a need for improved noise reduction interventions within the neonatal intensive care unit. Nurses are responsible for maintaining the environment and the stability of the infants. These articles are inconclusive on both immediate and long term effects on the

growth and development of the infant. The studies reviewed in this systematic review of the literature suggest there is a need for better designed research with long term outcome measurement on neonatal noise exposure.

Appendix A: Figures

Figure 1: Consort Diagram



Appendix B: Table

Table 3: Table of Evidence

| Article | Design and Purpose | Sample Size | Intervention Measures | Key Findings | Implications |
|---|---|--|--|---|--|
| Abdeyazdan, Z., Ghasemi, S., Marofi, M., & Berjis, N. (2014). Motor responses and weight gaining in neonates through use of two methods of earmuff and receiving silence in NICU. <i>TheScientificWorldJournal</i> , 2014, 864780-864780. | Randomized clinical trial To compare the use of silence with the use of earmuffs on premature neonate's motor responses and weight gain. | 96 Preterm neonates were selected using convenient sampling. | Group 1 contained 32 infants which utilized earmuffs for 4 hours during the busiest times of the day for 2 consecutive days, and throughout the night for 10 nights. Group 2 had no intervention. Group 3 contained neonates who were kept in a silent environment during the same time period that group 1 wore earmuffs. | The study showed that both silence and the use of earmuffs resulted in fewer motor responses and weight gain. These trends were more pronounced in the earmuff group compared to the silence group. | This study indicated that the use of earmuffs compared with silence resulted in fewer motor responses and weight gain. |
| Abdeyazdan, Z., Ghassemi, S., & Marofi, M. (2014). The effects of | Clinical trial The purpose of this study was to | 64 Preterm neonates 32 neonates in | In the study group, minimuffs were placed on the neonate's external | This study found the use of earmuffs reduced the neonate's heart rate and respiratory rate while they | The study recommends the use of earmuffs routinely to protect preterm neonates from excessive noise as the results |

| Article | Design and Purpose | Sample Size | Intervention Measures | Key Findings | Implications |
|--|--|---|--|--|---|
| <p>earmuff on physiologic and motor responses in premature infants admitted in neonatal intensive care unit. <i>Iranian Journal Of Nursing And Midwifery Research</i>, 19(2), 107-112.</p> | <p>determine the effects of wearing earmuffs on physiological and motor responses in preterm neonates in the NICU.</p> | <p>the study group 32 neonates in the control group</p> | <p>ear between the hours of 9:00am-11:00am and 4:00pm-6:00pm. Heart rate and arterial oxygen saturations were continuously monitored. Respiratory rate was taken every 1 minute. Motor and physiological responses were measured every 15 minutes.</p> <p>In the control group no interventions were used, but vital signs and motor responses were recorded at the same intervals as the study group.</p> | <p>were being used, but the heart and respiratory rate returned to previous levels once the earmuffs were removed. A reduction in motor response was seen during the intervention and 1 hour after the intervention.</p> | <p>showed improvements in both physiological and motor responses.</p> |

| Article | Design and Purpose | Sample Size | Intervention Measures | Key Findings | Implications |
|--|--|--|---|---|---|
| <p>Abou Turk, C., Williams, A. L., & Lasky, R. E. (2009). A randomized clinical trial evaluating silicone earplugs for very low birth weight newborns in intensive care. <i>Journal of Perinatology</i>, 29(5), 358-363. doi:10.1038/jp.2008.236</p> | <p>Randomized clinical trial</p> <p>The purpose of this study was to evaluate the use and feasibility of earplugs in high-risk neonates to improve growth and development.</p> | <p>34 total neonates</p> <p>18 neonates in the study group</p> <p>16 neonates in the control group</p> | <p>Earplugs were worn continuously until the neonate was 35 weeks post menstrual age (PMA) or discharged, whichever came first. The earplugs were removed for only for social interactions and parental visits.</p> <p>The control group received no interventions. Standard care was provided</p> <p>.</p> | <p>Primary outcomes showed no significant differences were seen in weight between the study and the control group.</p> <p>Secondary outcomes showed that the study group outperformed the control during an evaluation performed at 18-22 months with better performance on the Bayley Mental Development Index (BMDI).</p> <p>The study also observed for any adverse reactions, such as irritation, throughout the study. No adverse reactions were observed.</p> | <p>The study indicated a need for further research with larger sample sizes to replicate the results of this study and to evaluate long term effects of the use of earplugs.</p> |
| <p>Abujarir, R., Salama, H., Greer, W., Al Thani, M., & Visda, F. (2012). The impact of earmuffs on vital signs in the neonatal intensive</p> | <p>Controlled prospective non-randomized study</p> <p>The purpose of this study was to evaluate the</p> | <p>182 neonates met the criteria and were included in the trial, although, only 100 neonates</p> | <p>The neonates in the study group wore earmuffs throughout their first 72 hours in the NICU and vital signs were recorded every hour.</p> | <p>This study showed that the use of earmuffs had a clear beneficial effect on the neonate's heart rate, respiratory rate, oxygen saturation, and days of oxygen requirements.</p> | <p>The study recommended that earmuffs be used on all neonates in the NICU since they showed a drastic improvement in vital signs. Although, the study also indicated that there is still a need for additional trials in</p> |

| Article | Design and Purpose | Sample Size | Intervention Measures | Key Findings | Implications |
|---|--|--|---|---|---|
| <p>care unit. <i>Journal of neonatal-perinatal medicine</i>, 5(3), 249-259.</p> | <p>effectiveness of the use of external ear barriers on neonate stability.</p> | <p>completed 72 hours inside the NICU. 50 Neonates in the study group 50 Neonates in the control group</p> | <p>The control group received no interventions.</p> | <p>No significant differences were seen in blood pressure, pain score, or temperature.</p> | <p>order to assess long term outcomes on neurodevelopment.</p> |
| <p>Aita, M., Goulet, C., Oberlander, T. F., Snider, L., & Johnston, C. (2015). Original article: A randomized controlled trial of eye shields and earmuffs to reduce pain response of preterm infants. <i>Journal of Neonatal Nursing</i>, 21, 93-103. doi:10.1016/j.jnn.20</p> | <p>Randomized controlled trial The purpose of this study was to evaluate neonate's pain response to a heel lance following a 4 hour period of wearing earmuffs and eye shields.</p> | <p>44 neonates 23 neonate in the study group 21 neonates in the control group</p> | <p>In the study group the neonates wore earmuffs and eye shields for 4 hours (6:00am-12:00pm) before and during a painful procedure (heel lance). The pain response of the neonates was measured using heart rate and heart rate variability.</p> | <p>Preterm neonates wore earmuffs and eye shields 4 hours before and during a heel lance.</p> | <p>This study concluded that the use of earmuffs and eye shields prior to and during a painful procedure did not decrease the pain response of preterm neonates. Although several limitations were found such as handling time prior to the procedure and the amount of time the procedure took as these were variable between the study and the control group. Due to these limitations the study recommended that</p> |

| Article | Design and Purpose | Sample Size | Intervention Measures | Key Findings | Implications |
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| 14.11.004 | | | The control group received standard care. | | further research should be done of interventions such as light and noise control on neonate's response to post procedural pain. |
| <p>Duran, R., Çiftdemir, N. A., Özbek, Ü. V., Berberoğlu, U., Durankuş, F., Süt, N., & Acunaş, B. (2012). The effects of noise reduction by earmuffs on the physiologic and behavioral responses in very low birth weight preterm infants. <i>International Journal of Pediatric Otorhinolaryngology</i> , 76(10), 1490-1493. doi:10.1016/j.ijporl.2012.07.001</p> | <p>Comparative prospective design</p> <p>The purpose of this study was to evaluate the effectiveness of the use of earmuff on neonates.</p> | <p>20 preterm neonates</p> <p>The study group acted as their own control.</p> | <p>The infants were divided into 2 groups. Half of the neonates wore earmuffs during the first 2 days of the trial and the other half wore earmuffs during the last 2 days.</p> | <p>The study found no significant differences in physiologic parameters including heart rate respiratory rate, temperature, blood pressure, and oxygen levels with use of earmuff or not. To measure behavior the study utilized the Anderson Behavioral State Scoring System (ABSS) and found that when using the earmuffs the neonates were observed more frequently in the quiet sleep state. When not using the earmuffs the neonates were more frequently in the awake and fussy/crying state.</p> | <p>The study concluded that earmuffs provide preterm neonates increases time of quiet sleep and improves sleep quality. Although the study also states there is a need for further studies to determine the long term effects of the use of earmuffs.</p> |

| Article | Design and Purpose | Sample Size | Intervention Measures | Key Findings | Implications |
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| Khalesi, N., Khosravi, N., Ranjbar, A., Godarzi, Z., & Karimi, A. (2017). The effectiveness of earmuffs on the physiologic and behavioral stability in preterm infants. <i>International Journal of Pediatric Otorhinolaryngology</i> , 98, 43-47. doi:10.1016/j.ijporl.2017.04.028 | A crossed over controlled trial study design was used to determine the effects of earmuffs on behavioral and physiological responses in preterm neonates. | 36 preterm neonates total acted as their own control | The neonates in group one wore earmuffs from 8 a.m. to 4 p.m. the first day while the second group went without intervention. On day two the second group wore earmuffs from 8 a.m. to 4 p.m. while group one had no interventions. | The study found significantly higher arterial oxygen saturation in preterm neonates when earmuffs were used. Also the neonates were more often observed in the quiet sleep state using the ABSS when wearing the earmuffs. | This study concluded that the use of earmuffs in preterm neonates improved physiological and behavioral responses. However, the study also noted that further studies are needed to confirm these results. |
| Zahr, L. K., & de Traversay, J. (1995). Premature infant responses to noise reduction by earmuffs: effects on behavioral and physiologic measures. <i>Journal</i> | The purpose of this study was to determine the effects of earmuffs on physiological and behavioral responses in preterm | Data was obtained from two separate settings with two different experimental designs. The first study | The neonates in the first study were randomly assigned to either the study group or the control group. The study group wore earmuffs during their stay in the NICU and the | The control and study neonates in study one showed no significant differences in physiological or behavioral responses. The neonates in study two showed significant differences in both physiological and | This study concluded that noise in the NICU has a negative impact on neonates. While the study found that noise reduction can significantly improve both physiological and behavioral responses in neonates, it could not conclude if earmuffs should be worn to reduce exposure to |

| Article | Design and Purpose | Sample Size | Intervention Measures | Key Findings | Implications |
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| <p><i>Of Perinatology: Official Journal Of The California Perinatal Association, 15(6), 448-455.</i></p> | <p>neonates.</p> | <p>contained 17 neonates that were randomly assigned to the control or the study group. 9 neonates were used in the experimental group and 8 were used in the control.</p> <p>In the second study 13 neonates acted as their own controls where they were observed with earmuff on one day and without earmuffs another day.</p> | <p>control group received no interventions. Data was collect for 2 hours in the morning and 2 hours in the evening for two consecutive days. During data collection observations and physiological responses were recorded every 5 minutes. The Anderson Behavioral State Scale (ABSS) was used to measure behavioral responses.</p> <p>The neonates in the second study acted as their own controls. This group was divided into 2 groups. One the first day one</p> | <p>behavioral responses. On the days when the neonates wore the earmuffs they showed significantly high oxygen saturation levels with fewer fluctuations. Based on the ABSS when the neonates were wearing earmuff they spent significantly more time in the regular quit sleep state then in the irregular quit sleep state.</p> | <p>noise. The study recommended further research in order to determine the effects of earing earmuff for long periods of time as well as to test the long term effects of earmuffs.</p> |

| Article | Design and Purpose | Sample Size | Intervention Measures | Key Findings | Implications |
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| | | | <p>group wore earmuffs and the others did not. The next day the groups were switched.</p> <p>Physiological and behavioral responses were measured and recorded the same as the neonates in the first study.</p> | | |

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