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Impact of Parental Voice Recording Use in the NICU on Development at 12 and 18 months

A. Study Purpose and Rationale

In spite of significant advances in the survival of preterm infants over the last two decades, rates of neurodevelopmental impairment remain relatively constant. Disparities in speech and language are noted between preterm infants and their term counterparts starting in infancy and extending into adolescence^{1,2}. Preterm birth drastically alters the physical and social environment of infants and parents. Infant's auditory stimuli shift from the protected environment in utero to the Neonatal Intensive Care Unit (NICU). Rather than the low frequency, rhythmic noises of maternal language and heartbeat, the acoustic environment of the NICU is filled with high frequency, unpredictable, artificial noise, as well as long periods of silence³. Studies exploring the auditory environment of preterm infants found that the majority of auditory stimulation comes in the form of noise generated by monitors, alarms, and respiratory equipment^{4,5}. Whereas, adult language makes up a small percentage of the sounds to which preterm infants are exposed⁴.

This change in auditory and early language exposure occurs at a critical time of neuroplasticity, during which a language-rich environment drives neuronal processing and provides a foundation for auditory learning³. More adult language exposure has been associated with an increase in the number of infant vocalizations, as early as 32 weeks gestational age⁶. Additionally, more adult language exposure at 32- and 36-weeks gestational age was associated with higher infant cognitive and language scores at 7 and 18 months⁷. The scarcity of language stimulation in the NICU is a likely contributor to the long-term differences in receptive and expressive language processing, cognitive scores, and academic skills demonstrated in preterm children into adolescence, as compared to those born at term^{8,9}.

Given the implications on developmental trajectories, increasing positive auditory stimulation in the NICU through parental language is crucial. Several studies have shown parents' presence at bedside was associated with increased adult language exposure^{6,10}. However, barriers to parental visitation, including complicated postnatal care, work, childcare, and other life obligations, make it an elusive intervention point. An alternative means of increasing parental language input in the absence of parents is through parental voice recordings. Studies investigating the use of parental recordings have found positive short-term effects on neurobehavior, such as pain tolerance, improved feeding, and weight gain^{11,12}. However, few studies have investigated effects on cognitive and language development. Further studies about long-term effects on cognition will be valuable in understanding a potential intervention point to prevent the development of these cognitive and language development disparities seen among pre-term infants.

The primary outcomes of this study will be Bayley Scores of language development sub-scales at 12 and 18-24 months. Secondary outcome will be Bayley Scores of cognitive development sub-scales at 12 and 18-24 months. We hypothesize that infants exposed to parental voice recordings will have higher cognitive and language scores at 12 and 18 months, as compared to pre-term infants who have not been exposed to recordings.

B. Study Design and Statistical Procedures

This is an observational cohort study looking at the relationship between exposure to parental voice recordings, as part of the ongoing LionTales program, and cognitive and language development at 12 and 18 months. This study does not include any deviation from standard of care practice provided in the NICU and NICU Neurodevelopmental Follow Up clinic.

Participation in the LionTales program is routinely offered to any families in the Columbia NICU whose infant meets two of the following five criteria: <1000 grams or younger than 26 weeks at birth, have a complex diagnosis, are likely to have a long term stay in the NICU, parents have difficulty being at bedside, or parents have other children at home. Participation in the LionTales program means that families are able to record their voices on iPods provided through the program, and the iPods are played near the infant's bedside when the parents/family cannot be present. Families who participate receive several children's books and an iPod with information about applications to use to record readings. Families return the iPods to the bedside nurse who plays familial voice recordings once the infant is clinically stable in an open crib.

The NICU Neurodevelopmental Follow Up clinic currently follows all infants discharged from the NICU who were born at <28 weeks, <32 weeks and Birthweight <1250 grams, with significant neurological injury, or with congenital diaphragmatic hernia, single ventricle physiology, or who received Extracorporeal Membrane Oxygenation support. This clinic is tasked with tracking developmental progression of these children, supporting their unique developmental needs, and ensuring that children with delayed development are supported with appropriate services. Administration of developmental assessments called the Bayley Scales of Infant and Toddler Development is a routine part of care in the Neurodevelopmental Follow Up clinic; and its use is standard of care practice at many NICU Neurodevelopmental Follow Up Clinics nationally and internationally.

Current mean language scores on the Bayley exam for our neonatal population are 85. Using 80% power to calculate a difference of 5 points in language score in infants exposed to voice recordings, we calculated a sample size of 62. We have targeted an enrollment of 80 to account for possible dropout, incomplete data, or failure to follow up at each standard developmental assessment.

The control group will be selected from a population of infants who have received developmental testing with Bayley score in NICU neurodevelopmental clinic, but were not enrolled in the LionTales program. They will be matched to the study population by the

following covariates of interest: gestational age, neurologic injury, hearing screen results, parent time at bedside, parental primary language, and parental insurance. Multiple regression including the listed covariates will be performed to analyze differences in Bayley sub-scale scores among the LionTales study population and matched controls at the two time points.

C. Study Procedure

Eligible families whose infants are not yet 18 months corrected age will be followed prospectively. These families will be approached by one of the study personnel shortly before discharge from the NICU. just prior to their visit to the NICU Neurodevelopmental Follow Up clinic, or shortly after the time of their visit to the NICU Neurodevelopmental Follow Up clinic. If families consent to participation in the study, data from their time in the NICU will be retrospectively collected and data from their routine neurodevelopmental testing using the Bayley Developmental Assessment Tool will be retrospectively and prospectively collected. Data from the NICU stay will include clinically relevant information such as birth weight, gestational age, Apgar scores, diagnoses, length of hospitalization, parent presence at the bedside. Information will be collected and stored on a CUMC server MC domain Pediatrics in encrypted password protected folder. Password access will be restricted to study personnel. Data will be coded, and investigators of the study will have access to non-coded data.

Eligible families whose infants are 18-24 months corrected age or older and who have, therefore, completed their developmental follow up will be followed retrospectively. These families will be approached by one of the study personnel shortly after the time of their visit to the NICU Neurodevelopmental Follow Up clinic. If families consent to participation in the study, data from their time in the NICU and data from their routine neurodevelopmental testing using the Bayley Developmental Assessment Tool will be retrospectively collected. Data from the NICU stay will include clinically relevant information such as birth weight, gestational age, Apgar scores, diagnoses, length of hospitalization, parent presence at the bedside. Information will be collected and stored on a CUMC server MC domain Pediatrics in encrypted password protected folder. Password access will be restricted to study personnel. Data will be coded, and investigators of the study will have access to non-coded data.

D. Study Drugs or Devices

There are no study drugs or devices.

E. Study Questionnaires

The Bayley Scales of Infant and Toddler Development is an individually administered test designed to assess developmental functioning of infants and toddlers and identify those infants and toddlers with developmental delays. The Bayley assesses development in five areas: cognitive, language, motor, social-emotional, and adaptive behavior.

F. Study Subjects

Infants eligible for inclusion in this study are (a) those who are or were enrolled in the LionTales program and are referred for follow up in the NICU Neurodevelopmental Follow Up

clinic and (b) matched controls receiving developmental assessment in the NICU Neurodevelopmental Follow Up clinic beginning in December 2017 and ending in December 2020.

G. Recruitment

Demographic data will be screened surrounding discharge from the NICU or Neurodevelopmental Follow Up Clinic visit to determine eligibility of control subjects. Study subjects will be selected from existing databases and EMR based on participation in the LionTales program and gestational age. After receiving permission from the attending neonatologist, a member of the study team will approach the parent to present the study and obtain consent if the parent is willing to participate. In all cases, the study will be explained in the parents' native language or in a language that they fully understand.

H. Confidentiality of Study Data

Data will be stored on CUMC server MC domain Pediatrics in encrypted password protected folder. Password access will be restricted to study personnel. Data will be coded, and investigators of the study will have access to the non-coded data. Each subject will be assigned a unique study identification number to be used in all subsequent handling of the data on encrypted devices. The link between the study number and the patient will be destroyed at the conclusion of the study after data analysis has been completed. Throughout the study, only the study investigators will have access to the identifiable data.

I. Potential Risks

No associated risks except for potential loss of confidentiality. No new information will be obtained solely for research purposes.

J. Potential Benefits

There will be no direct benefit to the participants. There is the potential to benefit future families with preterm infants who may be able to influence their infants' cognitive and language development through the use of voice recordings.

References

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