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IRB Proposal: CRC rotation
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1. Background: Study Purpose and Rationale:

While advances in neonatal intensive care have been associated with increased survival rate for high-risk infants, the total number of survivors at risk for neurodevelopmental morbidities has increased (Vohr, Wright, Hack, Aylward, & Hirtz, 2004). Research has shown that children born preterm (<37 weeks gestational age) and/or low birth weight (<1500 grams) are at an increased risk for neurodevelopmental complications, including Cerebral Palsy, intellectual disability, learning and behavioral difficulties, and hearing loss. While only 2.4% of children in the general population are identified as having special needs, close to half of preterm infants are identified as special needs at some point in childhood. The lower the gestational age and/or birth weight, the higher the incidence of significant variations (D'Agostino & Clifford, 1998; Nelson, 2006). Additionally, certain perinatal medical interventions may negatively impact long-term growth and developmental outcomes (Vohr, et al., 2004). Given the high risk of neurodevelopmental difficulties among graduates of the neonatal intensive care unit (NICU), it is imperative that follow up programs for high risk infants are equipped to educate, empower, and support caregivers to access early intervention services for their children following discharge from the NICU. Past research has shown that only a limited number of families of NICU graduates utilize the full range of early intervention services available in their communities (Tien, Peterson, and Shelly, 2002). This project aims to further examine this issue.

The proposed study is to examine caregiver perspective of early intervention services for graduates of the NICU. Four questions will be addressed: (1) To what degree do caregivers perceive and prioritize a need for developmental support and intervention for their child following discharge from the NICU? (2) What is the nature of early intervention services received by families following their child's discharge from the NICU? How much and what type of services are received? (3) What is the nature of caregiver experiences accessing services for their child? What problems or concerns do caregivers have navigating this process? (4) How satisfied are caregivers overall with their child's early intervention services? These questions will be addressed by conducting survey-based interviews with caregivers at two points in time: first when the child is beginning clinical follow-up care (around 6 months) and second when the child is aging out of follow-up and early intervention services (2-3 years).

The IRB for this project has already been approved and data on a total of 9 families has been collected and preliminarily analyzed. This preliminary data shows a significant difference in the demographics of families who qualify for follow-up (seen at 6 months), and those who participate in the program until their child ages out (seen at 2-3 years). Overall, caregivers of children in the 2-3 year age group were older at the time of the child's birth, had a higher level of education, and had a higher annual household income compared to those in the 6 month age group.

Going forward in data collection, in order to make the data more statistically accurate, it will be important to identify which families in the 6 month group are likely to complete participation in the NICU follow-up program (e.g. go to visits through age 2-3). We will attempt to do this by documenting which families in the 6 month group go to their second follow-up appointment. Those who go to the second follow-up appointment will be considered likely to complete participation in the NICU follow up program and will be analyzed in a separate group

from those who do not go to the second follow up appointment, and will be considered unlikely to complete participation in the NICU follow up program.

We hypothesize that, compared to families deemed unlikely to be complete follow-up (6 month group not returning for 2nd visit), the families deemed likely to be to complete follow-up (6 month group returning for 2nd visit AND 2-3 year group) will: 1. Be older at time of delivery, 2. Have higher level of education, 3. Have higher income, 4. Be more likely to have a perception of their child's needs that is similar to their actual needs, 5. Have children with higher number of co-morbidities experienced during NICU stay, and 6. Have children with higher number of ongoing morbidities

2. Study Design

This is a cross sectional study of a convenience sample of graduates of the NICU and caregivers who are enrolled in the CUMC Neonatal Follow Up Program. Participants will include infants ~6 months of age and caregivers who are beginning the program as well as toddlers two to three years of age and caregivers who are aging out of the program. Participants will complete a one-time questionnaire conducted over the phone gathering both demographic information and information answering the study's main research questions. In addition, a retrospective chart review will be performed to gather information about participants' medical condition and NICU course.

We will report descriptive statistics of subject characteristics, outcome variables and other independent variables. Categorical outcomes will be summarized as percentages, and continuous variables will be summarized as mean +/- standard deviation.

Our goal is to recruit 50 families for the 6 month group and 50 families for the 2-3 month group. Of the 6 month group, we predict that half (25 families) will come to their second appointment and be considered likely to complete the follow up program and half (25 families) will not come to their second follow up appointment and be considered unlikely to complete the follow up program.

We will perform a logistic regression with multiple factors (age, education level, annual household income, perceived developmental needs, actual developmental needs, primary language spoken at home, type of insurance, number of co-morbidities experienced during NICU stay, and number of ongoing morbidities) to determine differences between the two 6 month groups as well as between the 2-3 year group and both of the 6 month groups. This will help us understand if any of these factors influences a family's likelihood of completing the follow-up program. A power analysis using t-test for level of education showed that with 25 subjects in each a group, a difference in 0.81 between the groups will be significant. Thus, we believe that our study will be sufficiently powered.

3. Study Procedure

a. Questionnaire: An interview method will be employed to examine caregiver perspectives of early intervention services. Questionnaire content has been derived from literature review as well as from interviews with key stakeholders, including NICU staff, Neonatal Follow Up Program staff, and Early Intervention personnel. The questionnaire is based on the methods used by Kohler (1999) and Spann, Kohler, and Soenksen (2003) to examine parent perceptions of special education services. This questionnaire will be administered once per participant and will be used to examine caregiver perspectives on their child's learning and development and their experience with early intervention services. In addition, the questionnaire will also be used to collect data on

family demographics (e.g. race/ ethnicity, household income, number of children in household, etc.). The questionnaire will be administered to subjects over the phone by the investigator in a verbal, interview format. The investigator will manually input verbal responses into excel for data-analysis purposes only.

b. Retrospective Chart Review: A retrospective chart review will be used to collect the following information: child's birthdate, child's birth weight, child's gestational age, child's diagnoses, interventions child received while in the NICU, ongoing morbidities associated with NICU course, child's birth hospital, and child's discharging institution. Records reviewed are those to which the investigators normally have access for non-research purposes as members of the Neonatal Follow Up Program team. A retrospective review of the Electronic Medical Record (EMR) is part of the typical intake for patients enrolling in the follow up program, under non-research related circumstances.

4. Study drugs or devices: not applicable

5. Study Questionnaire: The questionnaire will ask demographic questions (e.g. race/ethnicity, household income, number of children in household, etc.). The questionnaire will then ask for caregiver perspectives on their child's learning and development and the special services available to support their child's learning and development. The questionnaire will address the nature of the services the child has received to-date, including how these services are paid for and how often the child receives them, as well as caregiver experiences navigating these services, including any difficulties caregivers have faced. The questionnaire will be administered in interview format over the phone and the investigator will manually input the subjects' verbal responses into excel for data analysis purposes only.

6. Study Subjects:
-Inclusion criteria: Study subjects will include children and caregivers enrolled and receiving clinical care in the Neonatal Follow Up Program at CUMC. Participants will be either caregivers and new patients under 12 months of age beginning clinical care in the program or caregivers and patients between 2 and 3 years of age who are aging out of the program and early intervention services, according to federal guidelines. English speaking and Non-English speaking families will be included in this study.
-Exclusion criteria: Children and caregivers involved with the Administration of Children's Services (ACS) will be excluded from the study, as will foster children and wards of the state. These children represent a population with a unique early intervention system and process that is beyond the scope of this study.

7. Recruitment:
Study participants will be recruited over the phone following the child's discharge from the neonatal intensive care unit and prior to the initial (~6 months) or final (2-3 years of age) appointment in the Neonatal Follow Up Program. Families will be informed that children enrolled in the Neonatal Follow Up Program may receive routine clinical care and follow up without participation in this study. For all potential participants, permission to be approached by the investigators will be requested by a member of the Neonatal Follow Up Team who is responsible for coordinating clinical follow up after NICU discharge under non-research related

circumstances. This request will take place during a routine phone call used for the purposes of scheduling and confirming appointments. Verbal consent will be obtained for all participants prior to the completion of research activities.

8. Confidentiality of Study Data:
All attempts will be made to ensure that data is secure. Any information collected during the study will be coded to maintain confidentiality. An arbitrary case number will be assigned to the child's study records and separate data files will be maintained with the child's name and other identifying information. These data files will be maintained on a password-protected, encrypted computer or flash drive with access only by study personnel.

9. Potential Risks:
There is minimal risk associated with participation in this study. There is minimal probability that involvement in this study will result in any harm or discomfort greater than that encountered in daily life or during the performance of routine physical or psychological examinations or tests. The research does, however, carry some risk of loss of confidentiality. All attempts will be made to ensure that data is secure.

10. Potential Benefits:
Participants will not directly benefit from participating in this study. However, information collected from this research may help others in the future. The future population of caregivers and infants graduating from the neonatal intensive care unit may benefit from this study, as it will contribute to an improved understanding of caregiver experiences with early intervention services and allow staff to better educate, empower, and support caregivers with regard to navigating these services.

11. Alternatives:
The alternative to participating in this study is to choose not to enroll. Infants enrolled in the Neonatal Follow Up Program may receive routine clinical care and follow up without participation in this study.

References:

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