Audubon QI Project: Improving the Care of NICU Graduates
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1. Study Purpose and Rationale:
Each year, about 10% of infants born in the United States are born premature[1]. A high number of these infants are admitted to NICUs throughout the nation, and later discharged with complex medical needs that require highly specialized follow-up care. The AAP recommends that these high-risk infants receive primary medical care from a physician with expertise in the area, and also advises that a medical home is in place to coordinate all the subspecialists that may be involved[2]. Many high-risk NICU graduates are followed in our resident clinics, and residents often feel unprepared to take care of this complex patient population. To better prepare residents and allow for a more standardized way of providing NICU graduate outpatient care, the Audubon Clinic plans to focus this year's Quality Improvement initiative on this population. Studies have shown that more comprehensive care for high-risk infants can decrease life-threatening illnesses, re-admission to the ICU, and also decrease number of ICU days[3].

In order to better achieve this Quality Improvement initiative, we are hoping to gather baseline data to see what the gaps of care currently are in NICU graduates that are followed at the ACN Clinics (specifically at the Audubon ACN site). Based on discussions with our NICU staff and residents at CUMC, we plan to focus on 6 objectives; providing higher-calorie formula to qualifying infants, appropriately scheduling audiology evaluations following discharge, appropriately screening for retinopathy of prematurity (ROP) after discharge, ensuring high-risk clinic follow-up with the NICU staff, improving administration of palivizumab (Synagis) to at-risk infants and referring preterm infants to Early Intervention in the outpatient setting. We do not currently know what our adherence rates are for these 6 objectives, but plan to gain this baseline data so that we can better characterize the gap in care. Our plan afterwards will be to design appropriate interventions to implement in the next year to improve the outpatient care of this complex patient population.

2. Study Design and Statistical Procedures: This study will be a retrospective chart review. No statistical analysis will be performed.

3. Study Procedure: None.

4. Study Drugs or Devices: N/A

5. Study Instruments: N/A

6. Study Subjects: This will be a chart review of all subjects who were discharged from the NICU at MSCHONY and the Allen Pavilion and then followed at the Audubon Clinic in the last 3 years (from September 1st, 2012 – September 1st, 2015).

- Inclusion Criteria: Children less than 3 years old, born at 36 weeks in the NICU at MSCHONY or in the NICU at the Allen Hospital.

- Exclusion Criteria: Any infant born at a gestational age of >36 weeks will be excluded.

7. Recruitment:
Subjects will not be recruited for this study. Rather, all patients who meet the above inclusion criteria will be included in this retrospective review.

8. Informed Consent Process: We are requesting a waiver of the usual informed consent process and HIPAA authorization as obtaining such consent and authorization would impose a greater inconvenience and violation of privacy upon subjects and families than involvement in this minimal risk study involving only analysis of existing clinical data.

9. Confidentiality of Study Data:
The medical records of patients will be collected and all information will be kept on a password protected, encrypted computer and stored at the Audubon ACN site. Only the study staff will have access to the link between the infants' medical record number.

10. Privacy Protections:
Individual patient demographic and clinical information will be kept confidential and stored on password-encrypted computers in locked offices. This information will not be shared with anyone or any organization outside the study team except as mandated by the institutional review board. Collection of sensitive information about subjects will be limited to the amount necessary to achieve the aims of the research, so that no extraneous information is collected at any point. Any information collected during this study that can identify a subject by name will be kept as confidential as possible. Research findings will not be part of a medical record. Once the chart review is completed, the data used will all be de-identified – any information that includes patient identifiers will not be stored after the chart review is completed and baseline data is collected.

11. Potential Risks: There is a potential risk of loss of confidentiality, which will be minimized by restricting access of any personal information to the study team and keeping any personal information in a secure location.

12. Data and Safety Monitoring
All data will be available upon request by the Authorities from Columbia University and New York Presbyterian Hospital, including the Institutional Review Board (IRB), and/or the Office of Human Research Protections (OHRP).

13. Benefits: There are no direct benefits to research subjects from participating in this observational study.

14. Alternatives: There are no proposed alternatives.

15. Research at External Sites: N/A

DATA COLLECTION SHEET

SUBJECT NUMBER: ____
DOB: _____
Sex: ___
Gestational Age at Birth: _____

1. *Nutrition*:
High-calorie formula continued until 1 year of age or adequate weight gain for adjusted age (10^{th} percentile for adjusted age): YES or NO
*High-calorie formula considered 22kcal or more kcal/oz

2. *Audiology*:
High-risk infant seen by audiology following discharge and prior to 1 year of age: YES or NO
*High-risk infant: VLBW (<1500g), ECMO patient, on mechanical ventilation, received ototoxic medications, had certain infections (ex: CMV), or <32weeks GA

3. *Vision*:
Repeat ophthalmology evaluation for all infants born at <32 weeks (before 1 year of age): YES or NO

4. *High-Risk Clinic*:
Seen in high-risk clinic prior to 1 year of age: YES or NO

5. *RSV Prophylaxis*:
Appropriate doses of palivizumab given in first few years of life: YES or NO

6. *Early Intervention:*
Infant referred to Early Intervention in first 6 months of life: YES or NO

References:

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2. American Academy of Pediatrics (AAP). "Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection." *Pediatrics*. 2014:134:415-420.
3. Broyles, R. S., et al. (2000). Comprehensive follow-up care and life-threatening illnesses among high-risk infants: a randomized controlled trial. *JAMA*, *284*(16), 2070-2076.
4. Andrews B, Pellerite M, Myers P, JR Hageman. "NICU Follow-up: Medical and Developmental Management, Age 0 to 3 years" *NeoReviews* 15(4):2014, 123-132.
5. Conrad, AL, et al. (2010). Biological and environmental predictors of behavioral sequelae in children born preterm. *Pediatrics*, *125*(1), e83-e89.
6. Lahood A, CA Bryant. "Outpatient Care of the Premature Infant." *American Family Physician* 2007. 76(8):1159-1164.
7. Young L, Morgan J, McCormick FM, McGuire W. "Nutrient-enriched formula versus standard term formula for preterm infants following hospital discharge" *Cochrane Database Systematic Reviews* March 2012
8. Fortnum, H. M et al.(2001). Prevalence of permanent childhood hearing impairment in the United Kingdom and implications for universal neonatal hearing screening: questionnaire based ascertainment study *Bmj*, *323*(7312), 536.
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10. American Speech-Language-Hearing Association. (2007). Year 2007 position statement: principles and guidelines for early hearing detection and intervention programs.