

## **NICHD Neonatal Research Network Background and Overview of the Follow-up Program**

The Follow-up Program of the NICHD Neonatal Research Network is a comprehensive study which incorporates the necessary assessment tools to address five areas of concern in the growth and development of extremely low birthweight infants (401-1000 grams):

- outcome assessments that are performed early enough (at 18 + 4 months corrected age based on best obstetrical estimate) to directly reflect the perinatal-neonatal intensive care experienced by extremely low birthweight infants (ELBW), but at an age when accurate assessment of major neurodevelopmental outcome is assured;
- correlation of specific neonatal and perinatal morbidities (e.g., intraventricular hemorrhage) with developmental outcomes;
- relationship of family resources and environment to neurodevelopmental outcome including an evaluation of the quality of the family's interaction with the infant, both with and without other special services (e.g. early infant stimulation programs);
- correlation of the perceptions of the child's caretakers with objective measures of child behavior and development as assessed by developmental experts; and
- measures of the impact of an extremely low birthweight infant on the integrity and resources of the family (e.g. incidence of bankruptcy, divorce rate, child abuse, etc.).

### **STUDY OBJECTIVES**

The objectives of the Network Follow-up program are to:

1. track and successfully follow at 18 + 4 months (corrected age) more than 80% of the extremely low birthweight (ELBW) babies born after January 1, 1993, and enrolled into the NICHD Neonatal Research Network's Generic Data Base;
2. characterize the development of the study population by standardized methods in the areas of motor skills, cognitive skills, language and behavior;
3. determine the 18 + 4 month (corrected age) mortality and the prevalence of specific medical morbidities in ELBW infants;
4. characterize growth outcome and its relationship to neurodevelopmental outcome in this population at 18 + 4 months;
5. identify the socioeconomic status of families in this population and its relationship to developmental outcome;
6. identify significant family stress in this population and its relationship to family integrity as well as compliance with medical and developmental care; and
7. assess the utilization of special support services and early intervention programs by this population.

## **STUDY HYPOTHESES**

The following hypotheses shall be addressed by the follow-up protocol:

1. Improved survival of ELBW infants is associated with no increase in neurodevelopmental morbidity.
2. Improved neurodevelopmental outcome is associated with increasing birthweight/gestational age.
3. Improved neurodevelopmental outcome is associated with increasing SES.
4. Post hospital discharge mortality increases with decreasing SES and increased neonatal morbidity.
5. Incidence and severity of growth failure increases with decreasing birthweight/gestational age.
6. Poor developmental outcome is associated with family instability.
7. Utilization of special services is directly related to neurodevelopmental impairment.

## **STUDY POPULATION AND FUNDING**

All infants weighing between 401-1000 grams at birth admitted to the NICUs of the 14 Network centers after January 1, 1993 are followed up at 18 + 4 months corrected age. All these infants are currently included in the Network Generic Database (GDB) for prenatal and perinatal/neonatal outcome. All infants in this birthweight range are eligible for follow-up and there are no exclusion criteria. Additionally, those infants with gestational age less than 34 weeks from the Phenobarbital Trial, and those infants entered into the Nitric Oxide Trial are also being followed. The Centers receive capitation funding of \$300 per patient for follow-up enrollment, plus supplemental support from NIDCD for special audiologic testing for patients from the Nitric Oxide Trial.

The initial projection for the patient population was based on a GDB enrollment at 12 Network centers from June 1, 1992 to May 31, 1993; during this period, there were 1233 infants 401-1000 grams entered into the GDB. With survival to discharge of 63.1%, 784 infants were estimated to be eligible for follow-up. At an 80% follow-up rate for all centers, it was projected that there would be approximately 627 infants annually.

## **ASSESSMENT BATTERY**

The Neonatal Network follow-up assessment battery at 18+4 months corrected age includes:

1. demographic and medical history,
2. physical/neurological examination,
3. neurodevelopmental and behavioral assessment using the Bayley Scale of Infant Development-II,
4. parental assessment of the child's functioning and health status using the Functional Status II (R), and

5. measurement of the social and economic stress on the family using the Impact on the Family Scale / G Version and the Family Resource Scale.

The data collection has been designed to eliminate subjective answers as much as possible and to provide objective and quantitative information. A special effort has been made to develop an assessment battery that will minimize intercenter variability, assure uniformity in testing, and consistency in data collection.

## **FUTURE DIRECTION**

The development of a uniform approach to collect follow-up information in the very low birthweight (VLBW) infant is an essential component of the NIH Neonatal Research Network mission. Only by establishing a long-term outcome database can there be an evaluation of the risk and cost benefit of new technologies introduced in neonatal intensive care units. This study addresses outcome at a key developmental milestone and is considered the first phase in the development of long-term follow-up into childhood. The data will provide information that can be analyzed and used by health care providers, policy makers and health care planners. The data allows an analysis of cost of neonatal care in relation to intact versus handicapped survival. This study will also provide the opportunity to develop a uniform assessment battery that can be employed to assess new interventions and treatments in NICUs across the US. It also will permit analysis of center variability of outcome and relate it to perinatal and neonatal mortality and morbidity. Finally, the study established the infrastructure for 18-month follow-up and prepares for future programs to follow ELBW infants to school age.