NICHD Neonatal Research Network
SURVEY OF MORBIDITY AND MORTALITY AMONG HIGH RISK PRETERM INFANTS
(GDB)

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ABSTRACT

The National Institute of Child Health and Human Development (NICHD) Neonatal Research Network (NRN), Survey of Morbidity and Mortality among High Risk Preterm Infants (GDB) provides a registry of baseline and outcome data for very low birth weight (VLBW) and early gestational age infants. These data are collected in a uniform manner from medical records of participating infants admitted to neonatal intensive care units (NICU's). Protocol development, data management, and analysis are the responsibility of the Data Coordinating Center.

INTRODUCTION

The NICHD initiated the NRN in 1986, to conduct multi-center clinical trials and observational studies in efforts to reduce infant morbidity and mortality and to improve the health of low birth weight and premature infants. The Network was created in large part because many of the treatment and management strategies in 1986 had become "standard of care" without being properly evaluated. Uniform registry to collect information in the very low birth weight infant (less than 1500 grams) has been an important component of the NICHD NRN mission. Registry data can be used to review changing patterns of diseases/morbidities and treatments and can help in evaluation of the risk and cost benefit of new technologies introduced into neonatal intensive care units.

PURPOSE OF STUDY

The purpose of the GDB is to provide data on risk factors for neonatal morbidities, consequences of neonatal disease, and to generate hypotheses for future studies. The registry allows us to monitor changes in demographic and other baseline characteristics of VLBW infants at study centers. In addition the registry provides timely information on the frequency and distribution of selected morbidities which can facilitate the design, sample size calculations and implementation of Network randomized controlled trials.

SPECIFIC AIMS

The aim of the GDB is to maintain a registry of baseline and outcome data for very low birth weight and early gestational age infants, based on data collected in a uniform manner from maternal and neonatal hospital records of infants hospitalized in neonatal intensive care units (NICUs) at institutions participating in the NICHD Neonatal Research Network.

SECONDARY OBJECTIVES:

1. To describe demographic characteristics of infants admitted to Network Centers,
2. To examine the relationship between baseline characteristics and outcome,
3. To monitor trends in incidence of various disease entities,
4. To monitor changes in VLBW and early gestational age survival,
5. To provide data for hypothesis formulation and sample size calculation for Network multi-center studies.

Study Design

The NRN Generic Data Base (GDB) is a repository of perinatal/neonatal outcome data collected on all infants born at one of the participating Centers.

Entry Criteria:

1. Inborn Cohort:
   Inborn infants who meet specified birth weight and/or gestational age criteria:
   a. Birthweight: 401-1000g inclusive and/or
   b. Gestational Age: 20 0/7 to 28 6/7 weeks gestational age, inclusive (<29 weeks)
2. Network Trials
   Infants enrolled in a Network RCT or prospective observational study (inborn and transferred infants may be included in the GDB dataset if requested by the study subcommittee and approved by the NRN Steering Committee. These may be otherwise premature and/or low birth weight infants outside the GDB gestational and birth weight criteria.

Selection of Participants and Recruitment Study Population

All infants meeting the above criteria who are admitted to the NRN NICU Centers are eligible for this study. In addition, all inborn, liveborn infants who meet the above criteria who die in the delivery room prior to NICU admission are enrolled posthumously. Participating centers in the NRN are located across the United States.

Study Procedures

Baseline and outcome data are obtained by trained research associates after review of the mother's and baby's charts. The data forms for the survey have been named "generic data forms" in recognition of the fact that the information collected is of universal interest and not specific to a particular disease or treatment. These data provide a descriptive summary of the babies' background, perinatal and neonatal experience. Baseline data are obtained soon after admission to the NICU and the outcome data are collected to the time of death or discharge from the hospital.

Assessment Battery

The data collection process has been designed to reduce subjective answers as much as possible and to provide objective and quantitative information. A special effort has been made to develop an assessment battery to minimize inter-center variability, assure uniformity in testing, and consistency in data collection. The GDB manual of operations provides detail of study procedures.

Data Storage and Management

Each study subject has a data file including contact information and study forms. All materials are stored in a secure locked area at the participating NRN Center. Data entry is completed at the NRN Center and electronically transmitted to the NRN Data Coordinating Center (DCC). The DCC is responsible for statistical design and analysis as well as data management of the study. In concert with the NRN Steering Committee, the DCC is responsible for the protocol, manual, and forms development. The DCC, in collaboration with the subcommittee, conducts all

statistical analyses and collaborates with the Steering Committee members in the preparation of reports based on the study results.

Sample Size

Approximately 4000 infants (from all participating centers) are enrolled in this protocol annually.

Risks and Benefits

There are no known direct health risks related to the assessments that are completed for this observational research study. There is minimal potential risk of loss of confidentiality.

There are no direct benefits for participating in this study. However, participation is likely to help high risk premature infants in the future by providing better understanding of the care and health of high risk premature infants. The benefits of the generic database include its utility in informing caregivers and families about the outcomes of high risk preterm infants in tertiary centers in the U.S. and the best strategies for optimizing the care of this population. There is a chance that during the baby's stay in the intensive care unit, something learned by researchers studying the Generic Data Base will lead to improvement in the care and outcome of the infants.

Based on the stated potential for benefit and the potential risks, we deem this study to meet the following designation: **Minimal risk without the potential for direct benefit to the subjects.**

Privacy and Confidentiality

The direct identifiers (e.g. name, hospital medical record number, etc.) of study participants are maintained by the study centers in a locked secure area but are not part of the study data base that is entered into the centralized DCC computer. Individuals are identified in the data base by a uniquely assigned study number that has nothing to do with the direct patient identifiers. The link between the study assigned numbers and patient identifiers resides only at the hospital which enrolls the patient and is under the control of the study PI and the study coordinator at the center. All communications between the DCC and the study centers regarding study subjects are

done with the study number. The data base at the DCC is password protected and accessible only by staff that have “a need to know”. Individual patient data are not presented publicly. Study wide data from the GDB are tabulated each year and distributed to the PIs of the study centers. Only one copy of this annual report is distributed to each center and there is agreement that no additional copies of the tabulations will be made at the centers and that the information will not be shared with individuals outside the study centers.

Payment for Studies

Study subjects and their families receive no payment for participation in his study.

IRB and Informed Consents

This protocol is reviewed by the IRB at each participating center. Waiver of consent is requested.

Withdrawals

For institutions seeking consent, any participant is permitted to withdraw from the study at any time without penalty. After consent, a written request will be required to withdraw from the study and eliminate any collected data from the proposed analyses. This request should come to the center PI.

DSMC

A Data and Safety Monitoring Committee is not necessary for this study since the protocol involves only data collection and involves minimal risk to participants.

Funding

The funding agency for this protocol is the NICHD.

REFERENCES

1991

Hack M, Horbar JD, Malloy MH, Tyson JE, Wright EC, Wright LL: Very low birth weight outcomes of the National Institute of Child Health and Human Development Neonatal Network. Pediatrics 1991;87:587-597.

1995

Hack M, Wright LL, Shankaran S, Tyson JE, Horbar JD, Bauer CR, Younes N. Very low birth weight outcomes of the National Institute of Child Health and Human Development Neonatal Network, November 1989 – October 1990. Am J Obstet Gynecol 1995;172:457-464.

Fanaroff AA, Wright LL, Stevenson DK, Shankaran S, Donovan EF, Ehrenkranz RA, Younes N, Korones SB, Stoll BJ, Tyson JE, Bauer CR, Oh W, Lemons JA, Papile LA. Very low birthweight outcomes of the NICHD Neonatal Research Network, May 1991-December 1992. Am J Obstet Gynecol 1995;173:1423-1431.

1998

Stevenson DK, Wright LL, Lemons JA, Oh W, Korones SB, Papile LA, Bauer CR, Stoll BJ, Tyson JE, Shankaran S, Fanaroff AA, Donovan EF, Ehrenkranz RA, Verter J. Very-low-birth-weight outcomes of the NICHD Neonatal Research Network, January 1993 through December 1994. Amer J Obstet Gynecol 1998;179:1632-1639.

2001

Lemons JA, Bauer CR, Oh W, Korones SB, Papile L, Stoll BJ, VerterJ, Temprosa M, Wright LL, Ehrenkranz RA, Fanaroff AA, Stark AR, Carlo WA, Tyson JE, Donovan EF, Shankaran S, Stevenson DK. Very-low-birthweight outcomes of the NICHD Neonatal Research Network, January 1995 through December 1996. Pediatrics 2001; 107: e1.

2007

Fanaroff AA, Stoll BJ. Wright LL, Carlo WA, Ehrenkranz RA, Stark A, Bauer CR, Donovan EF, Korones SB, Laptook A, Lemons JA, Oh W, Papile L, Shankaran S, Stevenson DK, Tyson JE, Poole WK. Trends in neonatal morbidity and mortality for very low birthweight infants. Am J OB GYN 2007 Feb;196(2):147.e1-8.