



African American Children's Transition to School

Grantee

University of North Carolina

Investigator

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Project Number MCI-370649

Project Period 10/01/1994-09/30/1999

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	106,020	47,179	153,199
Year 2	119,187	53,038	172,225
Year 3	142,384	63,361	205,745
Year 4	147,757	65,752	213,509
Year 5	150,980	67,186	218,166

Year 2000 Objectives

8.3, 17.15, 20.9

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

School Age Children, Parents

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

During the first few years of elementary school, children, families, and schools should be mutually adapting to enhance the academic success of the child and encourage the family's involvement in the child's schooling. This is especially important for African-American children from families in poverty, because they are at risk for school failure. More knowledge is needed concerning the child, family, and community factors in early childhood that help children succeed and protect them from experiencing school failure. The interrelationships of these factors and their effects on children's developmental trajectories will be examined in this study within an ecological framework.

This project builds on an earlier project (MCI-370599, Carolina Otitis Media Program, Oct. 1, 1990-Sept. 30, 1995) supported by the Maternal and Child Health Bureau. This earlier project studied African-American children whose otitis media history, psychoeducational development, family environment, and child care experiences have been prospectively documented between infancy and 4 years of age.

Research Questions or Hypotheses

The aims of the current study are to (1) identify the multiple determinants of language, cognitive, social, and academic skills of African-American children in early elementary school years within an ecological model of child development; (2) identify how

risk and protective factors lead to children's success or failure in school; and (3) describe the developmental trajectories of language, cognitive, and social development and academic achievement in African-American children from infancy through the early elementary school years.

Study Design and Methods

Measures of the child, family, and community will be examined in 75 African-American children from pre-entry into kindergarten through the end of the third year of elementary school. Child measures will examine academic achievement, language, intelligence, attention, health, and social skills. Family measures will examine daily routines, responsiveness and stimulation of the home environment, resources, and parental beliefs about parenting and ethnic socialization. In addition, general characteristics of the family such as maternal mental health, education, employment, and household composition will be collected. Community measures will include assessments of the school climate, quality of classroom environment, school demographics, parental attitudes and perceptions of their school and neighborhood, community services, and neighborhood demographics.

Population Description and Sampling Plan

This study will involve 75 African-American families and their children who were recruited during early infancy. The children included in the study have relatively normal prenatal and perinatal histories, are generally healthy, and were enrolled in one of nine local child care centers by the age of 1 year. The sample consists of 38 boys and 37 girls; 69 percent of the children were living below the Federal poverty level at time of enrollment in infancy, and 67 percent

had single mothers with a high school education (m=12.5 years). The children and their families have been engaged in intensive data collection from infancy to age 4.

Analysis Plan

Prior to statistical analysis, a small number of summary scores will be computed to represent each major dimension of the study at each assessment point for each informant, and to describe each of the dependent and independent variables. Two types of longitudinal analysis methods will be used to address all major research questions. First, longitudinal patterns of change in the child's school competence and the way these patterns relate to the types and changes in social risk factors and protective factors will be examined using hierarchical linear models (HLM). Individual and group growth curves will be estimated simultaneously to describe patterns of change in the outcome variables and to identify factors related to these patterns of change.

Second, various developmental pathways or prototypic patterns of development will be identified to determine which child, family, and community characteristics distinguish children displaying differing patterns of growth. Separate cluster analyses of the longitudinal measures of language, cognitive, academic, and social development will be performed and the clusters compared on child, family, and community characteristics to identify correlates of these different developmental trajectories. HLM analyses will also be used.



Pediatric Health Supervision to Promote Literacy

Grantee

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Project Number MCI-390631

Project Period 10/01/1993–09/30/1998

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	108,409	53,147	161,314
Year 2	105,903	54,011	159,914
Year 3	114,808	58,552	173,360
Year 4	123,707	65,565	189,272
Year 5	44,778	23,732	68,510

Year 2000 Objectives

8.3

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Infants, Toddlers, Preschool Children

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

Reading failure in elementary school is increasingly recognized as a major threat to children's future success, both in and out of school. In the national effort to improve school readiness and literacy, pediatricians remain an underutilized but potentially important resource. In 1985, the National Commission on Reading stated that reading aloud by parents is "the single most important activity for building the knowledge required for eventual success in reading." Recent experimental data suggest that reading books can be a powerful intervention for improving language among economically at-risk children.

This project could provide pediatricians with an effective and easily adopted means of addressing the problem of language delay and early reading failure. It could also be important in securing public and private support for pediatric clinic-based interventions to promote language and literacy development.

The subjects for the current study are predominantly African-American families of low-income status; thus, the sample population limits the project's ability to explore racial/ethnic differences in this study. The study can examine gender differences, however, as well as the contribution of parents' life experiences and education to their parenting beliefs and activities. Future research could examine the role of culture and ethnicity in the development of literacy and in the ways the health care system influences that development.

Research Questions and Hypotheses

We developed a program in which pediatricians provide free picture books and anticipatory guidance about language and literacy development at every health supervision visit beginning at 6 months of age. This study aims to assess the effectiveness of this pediatric health supervision intervention. We hypothesized that children given books and guidance at regular pediatric visits throughout early childhood will show more advanced verbal language skills at 2 years and more emergent literacy abilities (such as the ability to identify sentences) at 3-1/2 years than will a comparison group given nonverbal toys. We further hypothesized that these differences will be mediated through parental reporting of looking at books together with their children and that the relationship between the intervention and outcomes will be dependent upon preexisting characteristics of the families involved.

Study Design and Methods

This study is a prospective, randomized, controlled trial with 3-year followup. Children receiving primary care at the Pediatric Primary Care Center at Rainbow Babies and Children's Hospital in Cleveland were randomly assigned to receive either books and guidance at every visit beginning at 6 months, or a placebo intervention consisting of toys. Every 3 months, parents are interviewed by telephone or in person concerning their children's activities, including book use. More extensive evaluations will occur through home visits when the children are 25 months of age and through laboratory assessments when the children are 43 months of age.

Population Description and Sampling Plan

Subjects were recruited during their 4-month health supervision visit at the pediatric primary care clinic at Rainbow Babies and Children's Hospital. This center was chosen because of the high level of interest expressed by the medical and nursing directors, the appropriateness of the patient population, and the principal investigator's presence on the supervisory staff of the clinic. Children in the clinic are seen by pediatric residents (with attending supervision), attending physicians, or nurse practitioners. The clinic serves a primarily low-income population drawn from Cleveland proper. Approximately 90 percent of the children receive medicaid assistance and most (90 percent) are African American.

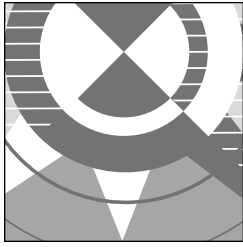
Over the first year of the study, 325 children were recruited in this manner. Following collection of baseline data, including a home evaluation, parent interview, and parent testing, subjects were randomized to receive either the experimental intervention (books) or the control intervention (toys) at each subsequent health supervision visit.

Analysis Plan

Principal outcomes include (1) periodic parental self-report of home book use, collected at 13 time points over the study period, and (2) measures of verbal language, measures of emergent literacy skills, and videotaped observations of parents and children playing and looking at books together, collected when the children are 25 months and 43 months of age. Analysis of the baseline data will include description of parents' beliefs about literacy and reading aloud as well as correlates of those beliefs (e.g., family composition, parental education, and reading ability). We will estimate the effect of the treatment by compar-

ing the experimental and control groups, using simple univariate statistics. Subgroup analyses will be performed to better define the characteristics of families for whom the intervention is most effective. We hope to receive additional support to follow this cohort

of children into elementary school, anticipating that differential assignment of children to “remedial reading” groups will provide direct evidence of the effects of the intervention.



Cost-Effective Emergency Department Screening for UTI Febrile Children

Grantee

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Investigator

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Project Number MCJ-420648

Project Period 10/1/94–9/30/97

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	106,955	58,719	165,674
Year 2	108,557	79,770	188,327
Year 3	115,315	65,974	181,289
Year 4			
Year 5			

Year 2000 Objectives

Study Design

Observational

Time Design

Cross-sectional

Care Emphasis

Noninterventional

Population Focus

Neonates, Infants, Toddlers, Preschool Children,
School Age Children

Race/Ethnic Focus

None

Summary

Statement of the Problem

Emergency department physicians should have a low threshold for screening for urinary tract infection (UTI), since it is often present even in children who have an equivocal alternative source of fever, such as viral illness or upper respiratory illness, and its sequelae are severe. There is little consistent information about the prevalence of UTI among febrile pediatric emergency department patients and much debate about the most appropriate clinical and laboratory criteria for diagnosis. Screening is uncomfortable for patients, and its costs are significant.

Research Questions or Hypotheses

This project will undertake a prospective study of febrile infants under age 1 and febrile girls ages 1–4, excluding those with a documented source of fever, in a high-volume urban pediatric emergency department. This study seeks to (1) determine the prevalence of UTI, (2) determine the utility of rapid screening tests for UTI, and (3) identify clinical predictors and develop clinical prediction models to stratify children at high risk for UTI. Using the information from this study, published reports, and a modified Delphi survey of pediatric emergency department physicians, nephrologists, infectious disease experts, and urologists, we will create a decision analysis model to determine cost-effective strategies for screening for UTI in the evaluation of febrile young children in an emergency department setting.

Study Design and Methods

The study design will consist of two parts. The first is a prospective cross-sectional concordance study. The primary outcome measure will be a positive urine culture. Clinical predictors will be obtained by the nurse or examining physician using a pretested standardized data collection form. Interobserver reliability will be measured, the sample population characterized, and prevalence rates determined. Sensitivity, specificity, and predictive value will be calculated for urine dipstick results performed on nonsterile urine obtained by urine bag and for enhanced and conventional urinalysis and dipstick on sterile urine. The second part of the study is a cost-effective decision analysis that will incorporate findings from the prospective study, medical literature, and expert opinions.

Population Description and Sampling Plan

The study will consecutively enroll all febrile infants under age 1 and girls ages 1–4, excluding those with an unequivocal source of fever, over a 2-year study period. The study will be conducted in the emergency department of the Children's Hospital of Philadelphia, which serves an indigent population.

Analysis Plan

The clinical prediction models, derived from multiple logistic regression, will be evaluated as a diagnostic test with receiver operator curves.



Behavior Problems in School-age Children of Teen Mothers

Grantee

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Investigator

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Project Number MCI-530589

Project Period 02/01/1993-01/31/1999

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	143,433	69,118	212,551
Year 2	229,426	53,404	282,830
Year 3	249,821	50,571	300,392
Year 4	211,238	48,645	259,883
Year 5			

Year 2000 Objectives

6.3, 6.13, 6.14

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

School Age Children, Adolescent Parents,
Parents

Race/Ethnic Focus

None

Summary

Statement of the Problem

Children with conduct problems constitute 4-10 percent of the population, represent a significant proportion of children with mental health problems, and make up the majority of referrals to mental health clinics. However, epidemiological studies indicate that, because of the high prevalence of conduct problems and the relative lack of long-term treatment success, these children are underserved. Intervention efforts are needed at the early stages of this progressive disorder, before the conduct problems become pervasive and severe. Moreover, understanding the developmental processes underlying conduct problems is essential for effective preventive intervention. While these processes are beginning to be delineated for boys, little is known about developmental pathways to conduct problems in girls. Children of adolescent mothers are at greater risk for developing conduct problems than are children of adult mothers, even when factors related to social status are controlled. However, there has been relatively little research assessing the outcomes of these children during the elementary school years or examining the risk and protective factors that affect outcome.

Research Questions or Hypotheses

This study will continue to follow a longitudinal sample of children of young women who became mothers as adolescents. The overarching long-term objectives are to (1) identify pathways for the devel-

opment of conduct problems in these young school-age children, and (2) identify risk and protective factors in the home, school, and peer environments that may contribute to or may inhibit the development of conduct problems. Of particular interest is a model in which parenting is assumed to have a major direct influence on the development and maintenance of child conduct problems. Furthermore, the impact of mother and child risk and protective factors is hypothesized to be primarily (though not exclusively) mediated through the quality of parenting experienced by the child. More distal risk and protective factors such as socioeconomic status or neighborhood quality are hypothesized to exert weak direct influences on child and maternal risk and protective factors and parenting. The applicability of this model to both boys and girls will be examined.

Study Design and Methods

This project, which is a continuation of a longitudinal study of children of adolescent mothers, has been funded by the Maternal and Child Health Bureau in two previous phases, beginning with MCH-530535, *Mothering in Adolescence: Factors Related to Infant Security* (1986–89), followed by MCH-530589, *Adolescent Mothering and Preschool Behavior Problems* (1989–93). This research will continue to follow the 114 mother-child pairs (who have participated since the children were infants) through the children's first 3 years of elementary school (grades 1–3).

The study assesses parenting (discipline, monitoring, positive parenting, parenting self-esteem, family-school relationships), child risk and protective factors (gender, attachment security, preschool behavior problems, social cognition, peer relationships, academic ability/performance), maternal risk and protective factors (depression, life stress, substance use, social support), and distal risk and protective fac-

tors (neighborhood quality, socioeconomic status, family size, family stability). Data are collected from multiple informants (mothers, children, teachers, independent observers), in multiple settings (home, laboratory, school), and on multiple outcomes (internalizing behavior problems, externalizing behavior problems, conduct problems, noncompliance).

Annual assessments will be conducted in school and in the laboratory in the spring and summer of grades 1–3. School assessments consist of teacher reports, classroom and playground observations, and school archival records. The laboratory assessment includes parent report, child report, assessment of the child's academic achievement, and observation of parent-child interaction (including attachment security at grade 1).

Population Description and Sampling Plan

This study sample will be drawn from children followed in the earlier phases of this study. The original sample from the 1986–89 study consisted of 244 adolescent mother-infant pairs; at the time of the first preschool assessment 3 years later, 152 of those pairs could be contacted. Data were actually collected on 114 of those pairs at the preschool assessment 1 year later (time 2). These 114 mother-child pairs are the sample followed in this study. The sample is primarily white (78 percent), with small proportions of African-American (9.6 percent), Native American (5.3 percent), and other (7.0 percent) groups; 53.5 percent of the children in the sample are female.

Mothers were originally recruited from the clinics, schools, and adolescent parent programs in the Seattle and the greater Puget Sound area. The mothers were included in the sample if the study child was born before the mother's 20th birthday and if the mother chose to parent her child. As noted above, the study

purposely seeks to address potential gender differences in the development of conduct problems and in the risk and protective factors. Because of the small numbers of non-white families participating in the study, it is unlikely that racial or ethnic health issues could be explored in secondary data analyses.

Analysis Plan

The study will employ both variable-oriented (correlational/regression analyses) and within-subject (growth-curve analyses) approaches to data analysis. Potential gender effects will be explored in all analyses. To examine developmental pathways, each subject will be categorized on the basis of changes in conduct problem status over time. Formal hypothesis-testing techniques (profile analyses) will be used to identify factors predicting conduct problem status over time. Separate analyses will examine the roles of parenting and maternal, child, and distal risk and protective factors. Additional growth curve analyses

will be conducted for those outcome measures administered repeatedly at each time point to characterize the rate of development of conduct problems in that subset of children who meet formal diagnostic criteria for one or more of the disruptive behavior disorders (attention deficit hyperactivity disorder, oppositional defiant disorder, conduct disorder). In conducting the analyses required by this approach, a developmental function can be fitted either for each subject (within-subject analysis) or for data aggregated at various levels.

The method of partial least squares will be used to identify the roles of risk and protective factors in parenting and child outcomes at each time point. A longitudinal model will test the roles of maternal, child, and distal risk and protective factors from the preschool assessment in predicting child behavior problems at school age. Additional analyses will examine the role of concurrent maternal and child risk and protective factors at each point.



Early Child Care Study of Children with Special Needs

Grantee

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Investigator

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Project Number MCI-530640

Project Period 04/04/1994–03/31/1999

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	142,524	69,612	212,136
Year 2	235,490	98,694	334,184
Year 3	214,105	103,841	317,946
Year 4	153,427	74,411	227,838
Year 5	110,450	53,568	164,018

Year 2000 Objectives

8.3

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

Infants, Toddlers, Preschool Children, Parents

Race/Ethnic Focus

None

Summary

Statement of the Problem

Very little is known about patterns of child care usage or effects of early child care in special populations. As P.L. 99-457 is implemented, case managers, family members, and service providers are being asked to make decisions about child care essentially in an information vacuum regarding children with disabilities.

Research Questions or Hypotheses

This study is examining the influence of variations in early child care histories on the development of children with special needs (those with disabilities or at high risk for disabilities).

Study Design and Methods

A longitudinal design is being used to evaluate child outcomes as a function of the complex interactions among child characteristics, family characteristics, and the quality and type of home, early intervention, and child care environments in which the children develop. Children and their families participating in the study are being assessed when the children are 12, 15, 30, and 45 months of age.

Family characteristics being measured include demographic variables, maternal stress and social support, maternal psychological adjustment, marital relationship, and maternal attitudes about employment, child-rearing, and child care. Characteristics of the

early intervention environment include the type and extent of services, age of onset, extent of maternal involvement, and extent of communication with the child care environment. Characteristics of the child care environment include quality, type of care, extent of care, and stability of caregivers.

Data for the 12-month assessment are being obtained in the child's home; data for assessments at 15 and 30 months are obtained in the home, in the child care setting, by telephone, and in the laboratory (month 30 visit only). The 45-month assessment will be conducted by telephone and in the laboratory.

Population Description and Sampling Plan

The sample will consist of 160 children, half of whom have a postnatal medical course that places them at high risk for mental retardation or developmental disabilities (e.g., neonates weighing < 1,500 grams or having severe respiratory distress syndrome, intracranial hemorrhage and neonatal seizures, central nervous system infection, or abnormal neurological signs). The remaining half of the study sample is identified as having mental retardation or one of a variety of developmental disabilities (Down syndrome, cerebral palsy, other physical and/or cognitive disability, other genetic disorder, or chronic illness resulting in diagnosed developmental delays).

Children are being recruited from a variety of early intervention programs and high-risk infant followup clinics. In the study sample, 63 percent of participating children are male and 78 percent are white.

Analysis Plan

First, in order to describe the natural history of child care usage, the data will be examined and summarized in various ways (by age, severity of risk/

disability, type of disability, etc.). The interviews and questionnaires will provide rich sources of data for these summaries. Second, analyses related to the prediction of child outcomes using an ecological model will be guided by a set of primary hypotheses. These primary hypotheses concern the effects of child care on child outcomes, as well as characteristics of the child, the family, and the home and early intervention environments as they moderate child care effects.

The following discussion illustrates data analytic methods for testing a specific hypothesis regarding cognitive development at 45 months. Similar procedures will be used for testing all major hypotheses. For illustrative purposes, we will consider the endpoint to be cognitive development measured at 45 months. The first step in this specific analytic domain would be a principal components analysis of the cognitive measures obtained at this age. The purpose of the components analysis is to determine the minimal set of cognitive measures required to understand the effect of child care on cognitive development. If considerable redundancy is found among the variables, summative measures or a selected subset of measures would be used in the subsequent analyses. On the other hand, if clusters of variables are found, separate analyses by cluster might be advisable.

The next step most likely would consist of a backward-elimination multiple regression seeking an optimal set of predictors of 45-month cognitive development from the cumulative child care record. The next step in the small analysis domain would be to repeat the backward-elimination regression, but with interaction variables included in the set.

In addition to such a global analysis, numerous subanalyses would be performed, including analyses that would seek to determine, for example, whether a relationship exists between cognitive outcomes and amount of child care when the mean quality of child care is partialled out—a followup question that might

result from the backward-elimination analysis. Other subsequent analyses might take the form of traditional analysis of variance (ANOVA), one way of examining the same question from a different, but related, analytic perspective. Regression analyses would also be performed—including child characteristics, family background, and home environment—to determine the contribution of child care to cognitive development beyond these background factors.

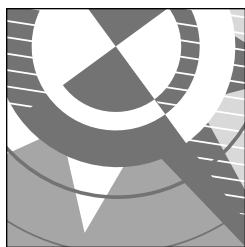
Some of the research hypotheses deal with the moderating effects of child, family, and home environment characteristics on globally observed relationships between child care and child outcomes. A number of analytic approaches are planned to deal with this construct; the two most direct approaches are (1) subset analyses and (2) covariant analyses.

When the moderating hypothesis is of the form “the relationship between X and Y differs for differing levels of Z,” subset analyses will be used. When,

for example, the relation between cognitive outcomes and quality of child care differs according to differences in the level of quality in the home environment, a direct comparison (such as testing the homogeneity of regression) of relations in the various subsets implied by the hypothesis will provide the direct test required.

In other cases, particularly those in which the Z variable is continuous, partial and bipartial correlation methods will be used to examine the moderation hypotheses—that is, the relationship between X and Y will be examined with Z partialled out of one or both of the X, Y variates.

Specific hypotheses concerning types of disabilities have not been proposed, although severity of disability will be included as a child characteristic. However, exploratory analyses are planned for testing the model on diagnostic groups of adequate sample size.



Maternal Birthweight and Reproductive Outcomes

Grantee

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Investigator

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Project Number MCI-530807

Project Period 09/01/1995–08/30/1998

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	108,290	52,521	160,811
Year 2	108,822	49,962	158,784
Year 3	93,865	47,871	141,736
Year 4			
Year 5			

Year 2000 Objectives

14.1, 14.2, 14.5, 14.7, 14.14, 17.10

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

Neonates, Infants, Pregnant Women

Race/Ethnic Focus

African Americans, Alaskan Natives,
Hispanics—Mexican Americans, Hispanics—
Puerto Ricans, Hispanics—All Others, Native
Americans

Summary

Statement of the Problem

Repetitive studies of maternal sociodemographic characteristics, prenatal care patterns, and nutrition during pregnancy have not resulted in an adequate understanding of determinants of pregnancy complications and adverse perinatal outcomes, particularly with respect to differences between African-American and white populations. For instance, in comparing infants of white couples and African-American couples whose level of education includes, at minimum, a college degree, the African-American infants have twice the risk of low birthweight and infant mortality and three times the risk of very low birthweight as the white infants.

The availability and widespread utilization of tertiary care in Boston did not erase the excess infant mortality among African Americans, regardless of socioeconomic status. Children and grandchildren of African-American physicians and dentists had higher rates of low birthweight and infant mortality than the general population. Furthermore, the gap between African Americans and whites with respect to low birthweight and infant mortality has been increasing. Appeals have been made for new and more comprehensive research approaches to these problems. There is substantial evidence that low maternal birthweight is related to several problems of pregnancy outcome, and these relationships persist after the usual statistical adjustments. However, none of the studies of maternal birthweight has integrated information about pregnancy complications and perinatal

morbidity and mortality. This study, therefore, has the promise of determining how the maternal birthweight effect is mediated.

Research Questions or Hypotheses

This project will further investigate the intergenerational relationships between the maternal birthweight and other maternal factors and several complications of pregnancy and birth outcomes: Pregnancy-induced hypertension, gestational diabetes, very low birthweight, moderately low birthweight, extreme preterm delivery and moderate preterm delivery, intrauterine growth retardation, and respiratory distress syndrome. If there are sufficient numbers of other outcomes, they will also be studied.

Study Design and Methods

This is a retrospective cohort study, using information from vital records and preexisting data bases. While virtually all studies of intergenerational factors have been in white populations, there will be sufficient numbers in this study to examine some relationships in African-American, Native American, and Hispanic populations. This study will focus on the major birth outcomes that occur in excess among low-income populations, particularly among African-American populations of low-income status. The causal factors for birth outcomes in these populations are poorly understood.

Population Description and Sampling Plan

The data for this study will derive from a linkage of several existing statewide data bases in Washington State, which include virtually all delivery and newborn hospital discharge summaries and data from live

birth, fetal death, and infant death certificates during the period 1987–93. Linked to this will be birthweight and other data from the birth certificates of mothers born in Washington State since 1949 (at which time birthweight began to be recorded on the birth certificates).

Because the overwhelming majority of births in Washington State are to white women, a 10-percent random sample—by year of baby’s birth—will be taken. The total population of births to African-American, Hispanic, and Native American women will be studied.

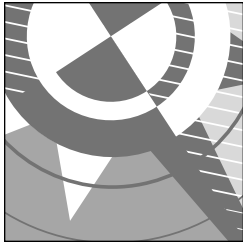
Analysis Plan

Initially, the relationship of low maternal birthweight to the various complications of pregnancy and to abnormal pregnancy outcomes will be determined in univariate analysis. Separate analysis will be performed for the four major racial/ethnic groups: White, African American, Hispanic, and Native American. Relationships between pregnancy complications, abnormal outcomes, and the usual sociodemographic variables will be determined in an effort to define confounders and effect modifiers. Multivariate analysis will then be built from the variables identified.

Since most of the pregnancy complications and outcome variables are binary, the primary analysis will be logistic regression, assessing the association between low maternal birthweight and the outcomes of interest. Adjusting for significant confounders will produce unbiased estimates of relative risk of low maternal birthweight. There will be sufficient numbers of mothers who were born preterm to study the effects of both maternal birthweight and gestational duration. Since infant birthweight and gestational duration are continuous variables, some linear regression analysis will also be done.

It is expected that the results of this study will lead to better understanding of causal factors, which in turn will suggest new approaches to intervention. The results will probably offer additional support for con-

sidering maternal birthweight as an important factor in determining the risk status of women, both before and during pregnancy.



Clinician Help for Mothers of Infants with Lung Disease

Grantee

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Investigator

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Project Number MCI-550806

Project Period 10/01/1995–09/30/1998

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	171,533	73,759	245,292
Year 2	175,856	74,438	250,294
Year 3	182,892	78,644	261,536
Year 4			
Year 5			

Year 2000 Objectives

2.4, 14.14

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates, Infants, Parents

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

The growing population of extremely-low-birth-weight (ELBW) infants with chronic lung disease (CLD) requires the skills of many clinicians, especially those providing primary/community-based and tertiary care, developmental/educational resources, and social services. Helping mothers to develop competencies in using clinician resources for infant dietary intake, growth, health, and development related to infant feeding could promote the infant's nutrition, growth, and development, and could prevent or reduce the impact of acute respiratory and gastrointestinal illnesses.

Research Questions or Hypotheses

This study aims to aid mothers of ELBW infants with CLD in developing competencies for using clinician resources in an appropriate, effective, and timely way. The three primary objectives of the study are to:

1. Test the effectiveness, through the infant's first postterm year, of an intervention to support the development of the mother's competencies in using clinician resources;
2. Examine differences longitudinally at 1, 4, 8, and 12 months postterm age (PTA) in dietary intake, physical health, and growth between infants in the intervention (treatment) group and those in the standard care group, and examine differences in development at 4 and 12 months; and
3. Examine the difference between infants in the inter-

vention group and the standard care group in their pattern of growth through the first postterm year. The hypotheses are as follows:

1. Mothers who receive the intervention will be reported by the infant's neonatal intensive care unit (NICU) and community clinicians as being more competent, both at NICU discharge and at 4 and 12 months PTA.
2. Infants in the treatment group will have (a) more adequate energy and protein intake; (b) fewer days of acute respiratory and gastrointestinal illness; (c) greater rate of weight gain and less deviation from the population median values in weight, length, and head circumference; and (d) fewer scores below 1 standard deviation from the population mean in mental and psychomotor development.
3. Growth in weight and length for infants in the treatment group will approach the population median (for infants of the same adjusted age) more quickly than for those in the standard care group.

The benefits of the intervention for the treatment group in regard to growth, health, and development, and the costs of acute illness care for infants in both the treatment and standard care groups, will be examined.

Study Design and Methods

This study is a longitudinal randomized clinical trial. Fifty families with infants who weigh < 1,000 grams at birth and who are at risk for CLD will be randomly assigned to the treatment group, and 50 will be randomly assigned to the standard care group, approximately 2 weeks after the infant's birth. A nurse will structure the intervention—guided participation—with the mother, starting when enteral feeding begins in the NICU. The intervention continues through the infant's discharge to home and during the first 12 months PTA.

Five areas of maternal competencies in using clinician resources will be addressed: (1) Task accomplishment, (2) role performance, (3) ability to organize and communicate information, (4) sharing of feelings, and (5) ability to manage the use of clinician resources. The mothers' beliefs and desires concerning how they work with clinicians in each of the five competency areas will be assessed with the Family-Provider Relationship questionnaire. Clinicians (NICU primary nurse and community primary care physician) will rate the mothers' competencies in using clinical resources on 11 items.

On a calendar, each mother will record her contact with clinicians regarding her infant's acute illness. Infant dietary intake will be assessed at home with a 3-day log kept prior to in-home data collection (at 1, 4, 8, and 12 months PTA). At these ages, the infant's weight, length, head circumference, and mid-arm muscle circumference will be measured. The calendar kept by the mother throughout the first postterm year will be used to obtain information on the extent of the infant's acute respiratory and gastrointestinal illness and the type of clinician aid sought by the mother. The Bayley Scales of Infant Development—II will be used to assess infant mental and motor development.

Population Description and Sampling Plan

The study population will consist largely of central-city African-American mothers at least 16 years of age and their infants weighing < 1,000 grams at birth. The two NICU sites from which families will be recruited are St. Joseph's Hospital and Sinai Samaritan Hospital. Both provide neonatal care to central-city families, primarily African Americans; St. Joseph's Hospital treats a suburban and rural population as well. Racial issues could be explored in secondary analysis of the data collected by the project.

Analysis Plan

Bivariate relationships will be examined with various measures of association contingent upon the description of the data distributions. Tests for linearity, independence, and distributional normality will also be conducted. To evaluate the equality of the treatment and standard care groups before intervention, *t* tests will be done on all pretreatment data. The overall differences between the treatment and standard care groups on repeated measures of maternal competencies (assessed at NICU discharge and at 1, 4, 8, and 12 months PTA) and of development (assessed at 4 and 12 months) will be analyzed with a multivariate analysis of variance (MANOVA) procedure. The infants' growth in weight and length over time will be explored with growth modeling proce-

dures. The trajectory of the mean infant growth in weight and in length will be examined, and variability in individual growth trajectories will be explored as a function of treatment or standard care. To assess the process effects of the intervention and the extent to which condition variables (infant birthweight, mother's receptive language ability, feeding competency, and social network and relationships) mediate the intervention effect, structural equations will be built for each group.

The cost of the intervention per family will be examined with descriptive statistics (mean, standard deviation). The distribution of the "dose" of the intervention across treatment group families will be examined, as well as the extent to which condition variables are associated with the level of intervention.