



Active Projects

FY 1998
AND
FY 1999

Maternal and Child Health **RESEARCH PROGRAM**



Maternal and Child Health **RESEARCH PROGRAM**

Active Projects FY 1998 and FY 1999



Supported by

Maternal and Child Health Bureau
Health Resources and Services Administration
U.S. Department of Health and Human Services

Published by

National Center for Education in Maternal and Child Health
Arlington, VA

Cite as

National Center for Education in Maternal and Child Health. 2000. *Maternal and Child Health RESEARCH PROGRAM: Active Projects FY 1998 and FY 1999*. Arlington, VA: National Center for Education in Maternal and Child Health.

Maternal and Child Health RESEARCH PROGRAM: Active Projects FY 1998 and FY 1999 is not copyrighted. Readers are free to duplicate and use all or part of the information (excluding photographs) contained in this publication. In accordance with accepted publishing standards, the National Center for Education in Maternal and Child Health (NCEMCH) requests acknowledgment, in print, of any information reproduced in another publication.

The mission of the National Center for Education in Maternal and Child Health is to provide national leadership to the maternal and child health community in three key areas--program development, policy analysis and education, and state-of-the-art knowledge--to improve the health and well-being of the nation's children and families. The Center's multidisciplinary staff work with a broad range of public and private agencies and organizations to develop and improve programs in response to current needs in maternal and child health, address critical and emergent public policy issues in maternal and child health, and produce and provide access to a rich variety of policy and programmatic information.

Established in 1982 at Georgetown University, NCEMCH is part of the Georgetown Public Policy Institute. NCEMCH is funded primarily by the U.S. Department of Health and Human Services through the Health Resources and Services Administration's Maternal and Child Health Bureau.

Library of Congress Catalog Card Number 98-99999
ISBN 1-99999-999-X

Published by:

National Center for Education in Maternal and Child Health
Georgetown University
2000 15th Street, North, Suite 701
Arlington, VA 22201-2617
Phone: (703) 524-7802
Fax: (703) 524-9335
E-mail: info@ncemch.org
Web site: <http://www.ncemch.org>

Single copies of this publication are available at no cost from:

National Maternal and Child Health Clearinghouse
2070 Chain Bridge Road, Suite 450
Vienna, VA 22182
Phone: (888) 434-4MCH (4624), (703) 356-1964
Fax: (703) 821-2098
E-mail: nmhc@circol.com
Web site: <http://www.nmhc.org>

This publication has been produced by the National Center for Education in Maternal and Child Health under its cooperative agreement (MCU-119301) with the Maternal and Child Health Bureau, Health Resources and Services Administration, U.S. Department of Health and Human Services.



Table of Contents

<i>Preface</i>	v
<i>Maternal and Child Health Bureau Research Grants Review Committee Roster of Members, FY 1998 and FY 1999</i>	vi
<i>Project Classification Guide</i>	vii
<i>Active Projects Abstracts</i>	
Adolescent Attitudes About Pregnancy <i>Catherine Stevens-Simon, M.D.</i> University of Colorado Health Sciences Center.....	3
Adolescent Health Care: A Comparison of Five Risk Adjustment Systems <i>Elizabeth A. Shenkman, Ph.D.</i> University of Florida.....	9
African-American Children's Transition to School <i>Joanne E. Roberts, Ph.D.</i> University of North Carolina.....	15
Alternatives for Developmental Screening in Primary Care <i>Harris Huberman, M.D.</i> Medican and Health Research Association of New York City, Inc.....	17
American Indian Fatherhood in Two Oklahoma Communities <i>Lisa J. Lefler, M.D.</i> University of Oklahoma.....	19
An Intervention for the Transition to Fatherhood <i>William J. Doherty, Ph.D.</i> University of Minnesota.....	24
Assessment of Enhanced Prenatal Care by Ethnically Diverse Women <i>Carol C. Korenbrot, Ph.D.</i> The Regents of the University of California.....	28
Biomarkers of Infection and Risk of Preterm Delivery <i>Michelle A. Williams, Sc.D.</i> Swedish Medical Center.....	32
Choices of Life for Adolescence Success <i>Larry E. Davis, Ph.D.</i> Washington University.....	36
Comprehensive Elementary School AIDS Education <i>David J. Shonfeld, M.D.</i> Yale University.....	39

Crossing Cultural Boundaries: An Ethnographic Study <i>Cheryl Mattingly, Ph.D.</i> University of Southern California.....	44
Does Education Limit Lead Burden? <i>Amos S. Deinard, M.D., M.P.H.</i> University of Minnesota School of Medicine.....	48
Does Lead Burden Alter Neuropsychological Development? <i>Elsa G. Shapiro, Ph.D.</i> University of Minnesota School of Medicine.....	52
Early Child Care Study of Children with Special Health Needs <i>Cathryn L. Booth, Ph.D.</i> University of Washington.....	56
Effect on Breastfeeding of Pacifiers and Bottle Feeding <i>Cynthia R. Howard, Ph.D.</i> University of Rochester.....	60
EICS Phase IV: Adolescence <i>Penny Hauser-Cram, Ed.D.</i> Boston College.....	64
Evaluation of Hawaii's Healthy Start Program - Phase Two <i>Anne K. Duggan, Sc.D.</i> Johns Hopkins University.....	67
Evaluation of Hawaii's Healthy Start Program <i>Anne K. Duggan, Sc.D.</i> Johns Hopkins University.....	73
Factors Associated with Nutritional Intake in Adolescents <i>Dianne Neumark-Sztainer, Ph.D.</i> University of Minnesota.....	78
Health Care Utilization: Pediatric Organ Transplantation <i>Margaret Stuber, M.D.</i> University of California, Los Angeles.....	81
Home Nursing to Avoid Pediatric Hospitalization <i>Kenneth McConnochie, M.D.</i> University of Rochester.....	86
Home Versus Group Visits After Early Postpartum Discharge <i>Tracy Lieu, M.D., M.P.H.</i> Kaiser Permanente.....	89
Improved Prenatal Detection of the Fragile X Mutation <i>Edmund C. Jenkins, Ph.D.</i> Research Foundation for Mental Hygiene, Inc.....	92

Improving Health/Development of Low Income Pregnant Women <i>Lee Anne Roman, Ph.D., R.N.</i> Spectrum Health.....	94
Increasing Safety Seat Use Among Preschoolers <i>Victor F. Garcia, M.D.</i> Children's Hospital Medical Center Research Foundation.....	97
Infant ETS Exposure: Clinic-Based Maternal Counseling <i>Melbourne F. Hovell, Ph.D.</i> San Diego State University Foundation.....	103
Infant Temperament: Neonatal–5 years in Rural Appalachia <i>Margaret Fish, M.D., Ph.D.</i> Marshall University.....	107
Interparental Conflict and Adolescent Violence <i>Jean Marie Tschann, Ph.D.</i> University of California-San Francisco.....	111
Life Around Newborn Discharge (LAND) <i>Henry H. Bernstein, D.O.</i> American Academy of Pediatrics.....	114
Maternal Health and Pregnancy Outcomes Among Hispanics <i>Edith C. Keiffer, Ph.D.</i> Regents of the University of Michigan.....	118
Maternal PKU Resource Mothers Program: A Clinical Trial <i>Susan E. Waisbren, Ph.D.</i> Childrens Hospital.....	124
National Practice-Based Network to Improve Children's Health Care <i>Richard C. Wasserman, M.D., M.P.H.</i> American Academy of Pediatrics.....	130
Neighborhood and Family Effects on Adolescent Health Behaviors <i>Cheryl Alexander, M.P.H., Ph.D.</i> Johns Hopkins University School of Hygiene and Public Health.....	132
Office Systems to Improve Preventive Care for Children <i>Peter Margolis, M.D., Ph.D.</i> University of North Carolina.....	136
Post-Traumatic Stress Disorder After Pediatric Traffic-Related Injury <i>Flaura Koplín Winston, M.D., Ph.D.</i> The Joseph Stokes, Jr. Research Institute.....	139
Poverty and the Ecology of African-American Children <i>Patricia J. O'Campo, Ph.D.</i> Johns Hopkins University.....	144

Predicting African American Children's School Compliance <i>Joanne E. Roberts, Ph.D.</i> University of North Carolina at Chapel Hill.....	147
Predicting the Need for Hospitalization in Childhood Asthma <i>Marc Gorelick, M.D.</i> University of Pennsylvania.....	150
Prenatal Antecedents of Infant Outcome <i>Janet A. DiPietro, M.D.</i> Johns Hopkins University.....	152
Preventing Mental Health Problems in Ill Children <i>Henry T. Ireys, M.D.</i> Johns Hopkins University.....	156
Prospective Investigation of Twin Gestation <i>Judith E. Brown, M.P.H., Ph.D.</i> University of Minnesota.....	158
Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two <i>Lynn Singer, Ph.D.</i> Case Western Reserve University.....	161
Puerto Rican Young Fathers' Involvement with Their Children <i>Sumru Erkut, Ph.D.</i> Wellesley College.....	165
Reducing Preterm Birth by Bacterial Vaginosis Screening <i>David Paige, M.D.</i> Johns Hopkins University.....	172
Responsiveness of CHIP to Children With Special Health Care Needs <i>Sara Rosenbaum, J.D.</i> George Washington University Medical Center.....	174
Role of Early Family Supports in Adult Self-Sufficiency <i>Frances A. Campbell, Ph.D.</i> University of North Carolina at Chapel Hill.....	179
Satisfaction with and Utilization of Prenatal Care <i>Arden Handler, Dr.P.H., M.P.H.</i> University of Illinois.....	182
Social Context of Puerto Rican Child Health and Growth <i>Odette Alarcon, M.D.</i> Wellesley College.....	185
Three-Generation Intervention Among Adolescent Mothers <i>Maureen Black, Ph.D.</i> University of Maryland School of Medicine.....	187
Welfare Reform and the Perinatal Health of Immigrants <i>Howard Minkoff, M.D.</i> SUNY Downstate Medical Center.....	192
Subject Index	201



Preface

This publication presents information for each of the 50 research projects active under the support of the Maternal and Child Bureau (MCHB) Research Program in FY 1998 and FY 1999. The variety of research topics and the diversity of research traditions represented by these projects mirror the broad mandate of the MCHB Research Program as well as the multidisciplinary approaches historically used by MCHB to carry out its mission. An underlying characteristic of the projects, as a group, is the applied nature of the research. This is consistent with the mandate authorized in an amendment to Title V of the Social Security Act, which established the MCHB Research Program in the early 1960s.

Projects are arranged alphabetically according to name. The projects are indexed by subject at the back of this publication.

This edition also features a classification system for quick identification of abstracts. Each study is classified according to the Healthy People 2000 objectives addressed, study design, time design, care emphasis, population focus, and racial/ethnic focus.

Except for the information in the pre-award evaluations (new projects only), the content of the abstracts is similar. The specific items in the summaries represent requests and suggestions from users of this information, both within and outside the Federal Government. Many of the intended users are concerned with the production of discipline-specific knowledge and with the overall technical aspects of conducting research and interpreting research findings; thus, the publication presents detailed descriptions of the research plan, particularly as it refers to the research study design, measurement approaches, sample size, and data analysis plan.

The information in the pre-award evaluation contains the written comments of the assigned reviewers as well as notes taken during the discussion that precedes the collective recommendation of the MCHB Research Grants Review Committee. This information is made available for several reasons. First, it attests to the significance of the research questions and the technical quality of the research plan, as judged by a panel of peers who are guided by a set of procedures designed to minimize bias and promote fairness and objectivity during the review process. Second, the pre-award evaluation indicates the strengths as well as the weaknesses of the proposal. This approach gives a more balanced view of the nature of funded research and emphasizes that, for the most part, it is less than perfect. Third, the pre-award information also attests to the contribution of the peer review process in improving the research that is ultimately funded. While the reviewers' recommendations for improvement are not binding on the investigators (unless issued as conditions of the awards), the recommendations are usually adopted before the research is begun. Fourth, the pre-award evaluation is instructive for those who practice or plan to practice the research crafts, particularly for graduate students and new doctoral-level professionals seeking to establish themselves in an extremely competitive field.

Gontran Lamberty, Dr.P.H.

Director, Maternal and Child Health Bureau Research Program

October 2000



Maternal and Child Health Bureau Research Grants Review Committee

Roster of Members, FY 1998 and FY 1999

Chair

Keith A. Crnic, Ph.D.
Department Head
Department of Psychology
Pennsylvania State University
612 Moore Building
University Park, PA 16802

Executive Secretary

Gontran Lamberty, Dr.P.H.
Director of Research
Maternal and Child Health Bureau
Room 18A-55
5600 Fishers Lane
Rockville, MD 20857

Members

Brenda A. Allen, Ph.D.
Associate Professor
Department of Psychology
Clark Science Center
Smith College
Northampton, MA 01063

Charlotte S. Catz, M.D.
(Ex Officio)
Chief, Pregnancy & Perinatology Branch/
Acting Deputy Director
CRMC, NICHD, NIH
6100 Executive Blvd. Suite 4B-03
Rockville, MD 20852

Gabriel J. Escobar, M.D.
Division of Research
Kaiser Permanente
3505 Broadway
Oakland, CA 94611-5714

Ellice S. Lieberman, M.D., Dr.PH.
Associate Professor
Department of Obstetrics & Gynecology
Brigham & Women's Hospital
Harvard Medical School
75 Francis Street
Boston, MA 02115

Frances J. Mather, Ph.D.
Professor
Department of Biostatistics & Epidemiology
Tulane University
1501 Canal Street
New Orleans, LA 70112

Cheryl Mattingly, Ph.D.
Associate Professor
University of Southern California
Department of Occupational Therapy
1540 Alcazar, CHP-133
Los Angeles, CA 90033

Carole M. Meyers, M.D.
c/o Dr. Pupkin
Mercy Medical Center
301 St. Paul Place
15th Floor
Baltimore, MD 21202

David M. Paige, M.D., M.P.H.
The Johns Hopkins University
School of Hygiene and Public Health
624 North Broadway, Room 245
Baltimore, MD 21205

Robert A. Terry, Ph.D.
Assistant Professor
Department of Psychology
739A Dale Hall Tower
University of Oklahoma
Norman, OK 73019

Francisco A. Villarruel, Ph.D.
Department of Family and
Child Ecology
Michigan State University
East Lansing, MI 48824-1030

Special Reviewers

Margaret Burchinal, Ph.D.
Associate Professor
Frank Porter Graham Center
University of North Carolina
521 South Greensboro Street
Carroboro, NC 27510

Tracy A. Lieu, M.D., M.P.H.
The Permanente Medical Group
Division of Research
3505 Broadway
Oakland, CA 94611

Susan S. Swadener, Ph.D., R.D.
Lecturer
California Polytechnic State University
2280 Sunset Drive
Suite B-3
Los Osos, CA 93402



Project Classification Guide

Each project in this book is classified according to the Healthy People 2000 objectives addressed, study design, time design, care emphasis, racial/ethnic focus (if applicable), and population focus. These categories are described below.

Healthy People 2000 Objectives

This category lists the Healthy People 2000 objective(s) addressed by the project. The number of the objective(s) is listed for each abstract and a complete listing of the objectives corresponding to these numbers is provided in the appendices of this book.

Study Design

The study designs are divided into three subcategories: (1) Experimental, which includes randomized clinical control trials; (2) quasi-experimental, which includes case/matched control, case/unmatched control, case/historical control, and interrupted time-series studies; and (3) observational, which includes studies that are purely descriptive or seek to elucidate cause and effect associations without the investigator actually seeking to control the situations under which these associations unfold or take place.

Time Design

This category includes three components: (1) Cross-sectional, (2) longitudinal, and (3) mixed. Cross-sectional studies describe or examine cause and effect relationships through measurements taken at one point in time. Longitudinal studies, however, seek to ascertain through serial measurements how cause and effect associations change or do not change over time. Mixed studies are those that include both longitudinal and cross-sectional components.

Care Emphasis

This category distinguishes between interventional and noninterventional studies. In interventional studies, the investigator, through a particular effort, treatment, or program, seeks to purposively influence the outcome(s) in an individual or a group. In noninterventional studies, the investigator merely observes, measures, and describes a situation without purposively manipulating or seeking to alter in any way the ensuing outcomes.

Population Focus

This category describes the investigation's primary population, including age, gender, family role, and pregnancy status dimensions or characteristics. The particular dimensions and subdivisions within these stated dimensions or characteristics (i.e., neonates, preschool children, pregnant women, etc.) are specific to maternal and child health program issues and concerns.

Race/Ethnic Focus

This classification sorts projects according to whether they are able to describe or elucidate issues related to race and/or ethnicity status, using either a within-group or a between-group study format. Studies that do not fall under this definition are classified as having no racial/ethnic focus.

**Active
PROJECTS ABSTRACTS**





Adolescent Attitudes About Pregnancy

Grantee

University of Colorado Health Sciences Center

Investigator

Catherine Stevens-Simon, M.D.
4200 East Ninth Avenue
Denver, CO 80262
(303) 861-6133

Project Number MCJ-080805

Project Period 10/1/1998-9/30/2001

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	85,501	43,606	129,107
Year 2	87,076	44,409	431,485
Year 3	62,665	31,959	200,150
Year 4			
Year 5			

Summary

Statement of the Problem

Primary health care providers are inadequately equipped to identify the factors that put their adolescent patients at risk for pregnancy. Efforts to predict which young women will conceive during adolescence have been largely unsuccessful because the similarities between socioeconomically disadvantaged adolescents who become parents and their peers who do not typically outweigh the differences. Thus, despite repeated attempts at intervention, the adolescent pregnancy rate in the United States remains one of the highest in the western world. Although the consensus is that a major reshaping of our approach to this problem is needed, empirical data provide little guidance about what additional programs and services might be required to prevent adolescent pregnancy. The goal of this research is to develop a screening tool that will enable clinicians with variable levels of training in adolescent medicine to formulate a differential diagnosis when they are confronted by the perplexing diagnostic dilemma posed by the noncontracepting, sexually active adolescent. Scientific knowledge about the consequences of adolescent pregnancy greatly exceeds knowledge of its antecedents. Indeed, the antecedents of adolescent childbearing attitudes have not been studied directly. We hypothesize that they arise from the simultaneous consideration of the effect that a baby would have on the various aspects or domains of life. This research tests this hypothesis by examining various sources of strongly positive, ambivalent, and strongly negative feelings about childbearing; the ways in which these feelings about the probable effect of childbearing on the various life domains influence intended pregnancy status and the capacity to use contraceptives; and the ways in which these intentions and capacities

Year 2000 Objectives

5.1, 5.1a, 5.1b, 5.2, 5.2a, 5.6, 5.7, 5.8, 5.10

Study Design

Observational

Time Design

Mixed

Care Emphasis

Noninterventional

Population Focus

Adolescents

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

influence the actual use of contraceptives and risk of conception among adolescents during the 4 months following a negative pregnancy test. The inclusion of ambivalence in the model is novel and, theoretically, extremely important because it implies that both the direction and the strength of the anticipated effects of childbearing on the various life domains contribute to the formation of attitudes and intentions about pregnancy and contraception.

We will use this information to accomplish the following: (1) Profile the characteristics, attitudes, and behaviors that antedate conception in a racially and ethnically diverse group of low-income, inner-city adolescents whose history of having just had a negative pregnancy test puts them at particularly high risk for conception; and (2) develop a preconception risk assessment questionnaire, "The Preconceptional Risk Assessment Battery," that will be appropriate for screening adolescent patients in primary health care settings. (In subsequent studies, we plan to use this questionnaire prospectively to guide the selection of interventions that are apt to be most helpful to individual adolescents in primary health care settings.)

Research Questions or Hypotheses

Pursuant to developing a brief screening questionnaire that will enable clinicians to determine which of their adolescent patients are at risk for pregnancy, we have formulated the following five research questions and a prediction or hypothesis about the probable answer to each:

Question 1. What is the relative prevalence of strongly positive, ambivalent, and strongly negative feelings about the probable effect of having a baby on the various life domains among adolescents following a negative pregnancy test?

Hypothesis 1. Following a negative pregnancy test, the majority of adolescents will express ambivalent feelings about the effect of having a baby soon; that is, most will not be certain that a baby will have a clearly positive (or negative) effect on their relations with parents, peers, and partners; feelings of self-worth; and future goals.

Question 2. How do the anticipated effects of having a baby on the various life domains shape intended pregnancy status among adolescents following a negative pregnancy test?

Hypothesis 2. Following a negative pregnancy test, the intent of adolescents to become pregnant is directly related to the number of aspects of their lives in which they anticipate a baby will be a positive influence. Adolescents who have positive feelings about babies, anticipate that a baby will improve their relationships with their family members, and anticipate that a baby will make it easier for them to socialize in their peer group will express a stronger desire to be pregnant than adolescents who anticipate that a baby will strain their relationships with their family members and/or make it difficult for them to socialize with their peers.

Question 3. How do the anticipated effects of having a baby on the various life domains affect the capacity of adolescents to use contraceptives following a negative pregnancy test?

Hypothesis 3. Following a negative pregnancy test, the capacity of adolescents to use contraceptives is inversely related to the number of aspects of their lives in which they anticipate a baby will be a positive influence. Adolescents who have positive feelings about babies, anticipate that a baby will improve their relationships with their family members, and anticipate that a baby will make it easier for them to socialize in their peer group will express more attitudes that make them incapable of using contraceptives than adolescents who anticipate that a baby will strain their relationships with their family members and/or make it difficult for them to be with their peers.

Question 4. How does intended pregnancy status affect the capacity of adolescents to use contraceptives following a negative pregnancy test?

Hypothesis 4. Following a negative pregnancy test, the capacity of adolescents to use contraceptives is directly related to the strength of their intention to remain nonpregnant; that is, adolescents who express a strong desire to remain nonpregnant will identify and encounter fewer obstacles to contraceptive use than adolescents who do not mind or who want to be pregnant.

Question 5. How do intended pregnancy status and the capacity to use contraceptives affect the consistency of adolescent contraceptive use and their exposure to the risk of conception following a negative pregnancy test?

Hypothesis 5a. Following a negative pregnancy test, the consistency with which adolescents use contraceptives is inversely related to their intended pregnancy status and directly related to their capacity to use contraceptives. Adolescents who desire pregnancy and have attitudes that make them incapable of using contraceptives will be less likely to use contraceptives consistently than adolescents who do not want to be pregnant and have attitudes that make them capable of using contraceptives.

Hypothesis 5b. Following a negative pregnancy test, exposure to the risk of conception is inversely related to the intended pregnancy status and directly related to the capacity to use contraceptives. Adolescents who desire pregnancy and have attitudes that make them incapable of using contraceptives will be more likely to expose themselves to the risk of conception

than adolescents who do not want to be pregnant and have attitudes that make them capable of using contraceptives when they are sexually active.

Study Design and Methods

This study uses a prospective, repeat-measures design to assess the relationship between the ways in which nulliparous adolescent girls anticipate that childbearing will affect the various domains of their lives at the time of a negative pregnancy test and the consistency with which they use contraceptives during the subsequent 4 months. Specifically, we plan to establish the validity of "The Preconceptional Risk Assessment Battery" as a predictor of both the adolescents' initial choice of contraceptives (e.g., at the close of the negative pregnancy test clinic visit) and the consistency with which they use the contraceptive methods they have chosen during the subsequent 4 months. We have chosen to study adolescents who have had negative pregnancy tests because they are easy to identify and are at extremely high risk for conception; we have chosen a 4-month observation period because studies of oral contraceptive users indicate that the discontinuation rate is maximal during the first 3–4 months of use, and because it will give those who choose to use oral contraceptives or DepoProvera time to demonstrate their willingness to obtain a second prescription or injection.

Population and Sampling Plan

This research is being conducted at three adolescent clinics in the Denver metropolitan area. All nulliparous females under 19 years of age who reside in the Denver metropolitan area and are not using a reliable form of contraception consistently are asked to participate in the study when they obtain a negative pregnancy test. Eligible, consenting adolescents are enrolled consecutively. The majority of adolescents who patronize these three adolescent clinics come from low-income families. Race and ethnicity varies among the clinics, but we anticipate that the study population will ultimately be composed of approximately 130 non-Hispanic, white adolescents; 130 Hispanic adolescents; 120 African American adolescents; and 20 adolescents of other races. We are targeting this racially and ethnically diverse population of low-income adolescents because the results of our preliminary studies indicate that 68 percent of the adolescents who have negative pregnancy tests at these clinics become pregnant within 18 months.

Analysis Plan

To obtain a basic understanding of the data, frequencies and correlations among key variables will be examined. Analysis of variance will be used to measure differences in the consistency of contraceptive use related to each of the intervening variables. Those variables that are statistically significant predictors of contraceptive use will be included in the multivariate analyses used to test the study hypotheses.

Next, the psychometric properties (e.g., the internal consistency and reliability) of "The Preconception Risk Assessment Battery" will be evaluated. To that end, exploratory and confirmatory factor analyses will be used to determine precisely which combination of the life domains will be included in the model.

The five study hypotheses will be tested individually, at first, and then the overarching model will be tested in its entirety by employing Bentler's EQS structural equation program. This is a mediational model in that both the direction and the strength of the anticipated effect of childbearing on the various life domains are hypothesized to affect the following: (1) Intended pregnancy status (Hypothesis 2), (2) the capacity to use contraceptives (Hypothesis 3), and (3) the correlation between these two mediators (Hypothesis 4). Ultimately, we anticipate that the interaction between these two mediators will predict the consistency of contraceptive use (Hypothesis 5a) and the risk of pregnancy (Hypothesis 5b). Initially, for each of the study hypotheses, the direct association between the independent variable and the outcome of interest will be determined with Spearman rank correlations (when the dependent variable is treated as a continuous variable) and Wilcoxon rank tests (when the dependent variable is treated as a categorical variable). The results of these initial correlational analyses will also be used to inform the path analysis models to be examined.

After establishing the predictive validity of "The Preconceptional Risk Assessment Battery" for the consistency of contraceptive use by adolescents following a negative pregnancy test, we will modify this lengthy battery of questionnaires into a briefer, less cumbersome, and easier-to-use screening questionnaire; this briefer questionnaire will enable primary health care providers with variable levels of training in adolescent medicine to not only systematically identify their adolescent patients who are at highest risk for conception following a negative pregnancy test, but also determine why each of them is at such high risk. To this end, factor analyses will be performed to determine if the number of variables can be

reduced to a smaller number of psychometrically sound predictors.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This study is based upon a conceptual model that extends our understanding of the possible groups of teens that do and do not become pregnant. This is a major strength in that the simple pregnant/not pregnant dichotomy usually used to study this problem has always seemed insufficient. The range of reasons underlying why a particular teen falls into one or the other group tends to get lumped into two big piles by the fact that they are either pregnant or not. Anticipating more variation in the phenomena of teen pregnancy and sexual behavior will allow for a more complex, yet clear look at the possible pathways towards a positive or negative pregnancy status.

Regional and National Significance

As stated in the introduction of the proposal, current policies have reduced the number of teens who have access to contraceptive information and methods, yet the teen pregnancy rate remains at an unacceptably high level. A better understanding of the factors related to avoidance of contraceptive behavior is greatly needed if we are to reduce the number of children born to young women who have not completed the requisite life preparation to insure a life beyond poverty.

Scientific and Technical Merit

The research questions and hypotheses stated are clearly linked to the literature and model presented. Moreover, the progression of preliminary studies conducted by the principle investigator seems to lead logically to the proposed project. The variables chosen for study are clearly delineated and span a range of issues which may converge to predict those most at risk for teen pregnancy. The scoring of the independent variable is a bit confusing. The effects of pregnancy on different life domains are measured by the individual's positive, ambivalent or negative endorsement of statements within each domain. The author states that a strongly positive attitude is the result of positive endorsement of all the statements, while a less strongly positive attitude is indicated by positive endorsement of statements about family, partner and peer relations but negative endorsement of future plans and sense of self. Aren't there some other possible combinations? A more elaborate explanation of how the scale is scored does not appear anywhere else in the proposal. The scale is described and the internal reliability is reported, but the scoring is not detailed. The description says that each sub-scale consists of four items. What if half are endorsed positively and the other two receive a negative and ambivalent response. How is this pattern scored? Percentage of a particular type of score is discussed, but the relationship between percentage and overall scores is unclear. The scoring of the remaining scales is clear.

While it seems reasonable that contraceptive use is the best dependent variable for the study, the possible effects of social desirability responses within a study such as this seems high. Asking such questions in a clinic setting where these young women have just received a second pregnancy test seems to be asking for socially desirable, or maybe more appropriately, denial responses. An alternative may be to complete the scale first and then have the pregnancy test, or to complete the questionnaire and the interview in a non-clinic setting and have the teen go from the interview to the clinic in order to take the test and receive the \$15 compensation. It seems that the pressure of the test results and the environment of the clinic may influence how the young women respond to the self-report measure.

The study has good ethnic representation but the socioeconomic status is biased towards working class. It seems that economic status variation would add greatly to the type of information yielded from such a study.

There are no human subjects concerns and the personnel appear well suited to conduct the proposed project.

Evaluator 2

Originality and Importance

The proposed research seeks to develop a brief screening questionnaire, which will profile characteristics, attitudes, and behaviors that antedate conception in a racially and ethnically diverse group of poor, inner city teenagers who are at particularly high risk of pregnancy. A clear theoretical framework is given linking domains childbearing could affect with intended pregnancy status, capacity to use contraceptives, consistency of contraceptive use/pregnancy risk and traditional risk factors for teen pregnancy.

The investigators make an excellent argument for not categorizing adolescents based on their pregnancy status, i.e. those who become pregnant and those who do not. Some pregnancies may have been contraceptive failures while some non-pregnant individuals may have just lucky. They give good evidence for questioning the assumptions that a) women can control their fertility, b) all teenagers who become pregnant fail to use contraceptives consistently, and c) all teenagers who do not become pregnant either use contraception consistently or abstain. Much previous work has failed to acknowledge that pregnancy may have significant benefit to the adolescent and many do not actually wish to avoid pregnancy. They argue convincingly for the need for a more appropriate screening tool as the ones now available do not specify etiologic relationships between risk factors and outcomes.

Regional and National Significance

This is an extremely well written, well-justified application which proposes to investigate reasons for adolescent pregnancy. Problems resulting from adolescent pregnancy and the long-term implications for mother and child are well known. Most research on adolescent pregnancy has focused on the individual and societal costs to the mother and child. The proposed research approaches the reasons for pregnancy in this population from a less commonly studied angle and questions some of the widely held assumptions.

Scientific and Technical Merit

A detailed, clear review of the literature is provided briefly reviewing societal costs of teen pregnancy, but focusing on how previous research has blurred the reasons for the failure to impact the teen pregnancy rate and the benefits of pregnancy for an adolescent.

Four prior studies by the principle investigator are reviewed which directly relate to the research. She has found that in the population to be studied, 68% of adolescents conceived within 2 years after a negative pregnancy test, despite contraceptive counseling and prescription. Many were concerned about their fertility (22%) and half either wanted to be or wouldn't mind being pregnant. Teens who were concerned about their fertility were less likely to use contraceptives, as were those who were ambivalent about becoming pregnant. Finally, adolescent's concerns about contraceptive side effects increased as their ambivalence towards pregnancy increased. In other words, many teens look for reasons to stop contraceptives and allow pregnancy to occur. The principle investigator's previous work in this field is clearly a strength of the application.

Concepts of domains childbearing could affect intendedness of pregnancy status, capacity to use contraception, motivation to use contraception, consistency of contraceptive use and risk of conception are clearly defined.

Five research questions are posed and stated in 6 hypotheses. In addition, a brief screening questionnaire will be developed for clinical use. The independent variable is the anticipated effect of childbearing on domains of life. Intervening, mediating and dependent variable are given along with how they will be measured and the units of measurement for each. A few need specification, such as "older boyfriend" and "involvement in socially deviant behaviors". No information is collected from the questionnaires included with the proposal that might give information on socially deviant behaviors. What qualifies and how will the information be obtained?

The measurements to be used have been piloted on 22 adolescents drawn randomly from the target population. There are several strengths to the questionnaires: the pilot information showing their validity in this population, original development based on established instruments, the proven ability to detect ambivalence in this population and the close attention the investigators have paid to reliability of the information obtained. The investigators acknowledge the problem of relying on self-report in collecting this information, particularly information of contraceptive use, which may be thought of by the

adolescent to be socially desirable. They justify this by stating, "Although actual pregnancy status would be easier to document objectively, it is not an appropriate outcome measure for this study because during adolescence many conceptions are determined by chance variations in fecundity and contraceptive efficacy."

The study design is detailed in the text and summarized in a figure. A strength of the study is that background sociodemographic information and type of contraceptive chosen will be obtained on all eligible individuals seen in clinic, allowing the investigators to establish if the study population is representative of the clinic population as a whole. All subjects enrolled will be followed for 4 months, a time frame chosen because discontinuance of contraceptives is highest in the first 4 months after initiation. Many will not have returned for a second Depo-Provera injection, or to obtain a refill for oral contraceptives. Subjects not returning for their follow up research appointment will be contacted by phone. From previous experience, 75% of the enrolled individuals are expected to return to complete the second interview.

Good descriptive information is available for the three clinics that will enroll subjects. Adequate sample size is calculated to be 280, so the expected enrollment of 300 should be fine, even if attrition is somewhat higher than anticipated. Data will be analyzed by correlation between the key variables and analysis of variance in consistency of contraceptive use for each of the intervening variables. Variables significant at the .10 level will be included in the Bentler's structural equation model. Each hypothesis will be tested individually before testing the model.

Time line is given and seems appropriate. No other source of funding is sought. IRB approval has been obtained. A history of sexual abuse or symptoms of depression may be identified through the questionnaires. Will the nurse administering the questionnaires address these issues?

The budget is appropriate, requesting 30% time for the principle investigator, 100% time for a research assistant, 50 hours of consultation per year with a psychology consultant and a statistical consultant. Patient incentives (maximum of \$25) are budgeted at \$8500. The only unnecessary expenses are \$900 for condoms and \$400 for educational materials, which should be available already in the clinics. Medical directors of the three adolescent clinics have committed to the project with no request for funds.

The principle investigator is extremely well qualified to carry out this work having published extensively on the topic of adolescent health. She has 15% current support and 65% pending.



Adolescent Health Care: A Comparison of Five Risk Adjustment Systems

Grantee

University of Florida

Investigator

Elizabeth A. Shenkman, Ph.D.
Office of Research and Graduate Education
P.O. Box 115500/219 Grinter Hall
Gainesville, FL 32611-5500
(352) 392-5904, ext. 222
(352) 392-8822 fax

Project Number MCJ-120827

Project Period 4/1/1998-3/31/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	137,840	23,295	161,135
Year 2	121,118	20,469	141,587
Year 3			
Year 4			
Year 5			

Year 2000 Objectives

3.9, 14, 18, 19

Study Design

Observational

Time Design

Mixed

Care Emphasis

Noninterventonal

Population Focus

Adolescents

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Most children are healthy and consume relatively few health care resources. When compared to younger children, however, adolescents (ages 12 through 18) are particularly at risk for increased morbidity and mortality from a variety of causes such as intentional and unintentional injuries, tobacco use, alcohol and other drug use, and sexually transmitted infections, including human immunodeficiency virus (HIV) infection. Because adolescents are a rapidly growing segment of our population, such an increased need for health care services may place insurers and health care providers at financial risk, particularly within capitated managed care arrangements.

Our study includes adolescent medicaid enrollees, adolescents enrolled in the Florida Healthy Kids program (a major component of Florida's State Children's Health Insurance Program, or SCHIP, initiative), adolescents seen at a tertiary care center, adolescents enrolled in children's medical services (CMS), and commercially-insured adolescents from three insurers. We will apply five diagnostic-based risk adjustment models to adolescents in these populations and to a subset of adolescents who have special health care needs as determined by the presence of selected *International Classification of Diseases, 9th Revision, Clinical Modification* (ICD-9-CM) codes. The five risk adjustment systems are the Ambulatory Care Groups (ACGs), the Disability Payment System (DPS), the Diagnostic Cost Groups (DCGs), the Global Risk Adjustment Model (GRAM), and the Classification of Congenital and Chronic Health Conditions (CCCHC).

There are no studies exploring various risk adjustment approaches in the adolescent population, and simple adjustments for age and gender are inadequate. Greater precision can be achieved in predicting health care use and charges by using diagnostic-based approaches to risk adjustment and altering capitation payments accordingly. Thus, health care plans and providers face strong financial disincentives when caring for those individuals with increased health care needs, such as adolescents. Several diagnostic-based systems are available and some are widely used. Each system uses a different conceptual framework to group diagnoses in predicting health care use and charges. The lack of information on the predictive accuracy of these systems in the adolescent population motivated this study.

Research Questions or Hypotheses

This study will examine six categories of health care use: Total health care, inpatient, outpatient, emergency room, inpatient intensive care, and physician specialists. We will address the following questions in the study (as of this date, the CCHC is not available as a commercial product):

1. How well do the ACGs, DPS, DCGs, and GRAM predict concurrent and future health care use and charges in the six categories above for the adolescent population when compared to demographic risk adjusters only?
2. How well do the ACGs, DPS, DCGs, and GRAM predict all types of concurrent and future health care use and charges for the adolescent population when compared to each other across the six categories?
3. For each adolescent, what are the actual versus the expected health care use and charges for each of the six categories of use (as predicted by the ACGs, DPS, DCGs, and GRAM)? When collapsed across all adolescents, is the average discrepancy between observed and predicted use smaller for one system than the other?
4. Is the predictive ability (for all categories of concurrent and future health care use and charges) of the ACGs, DPS, DCGs, and GRAM greater for adolescents with special health care needs versus those who do not have special needs? How effective are the systems among the population of adolescents with asthma in predicting emergency room, intensive care unit, and inpatient use?
5. How does the predictive ability of the ACGs, DPS, DCGs, and GRAM vary across the five groups of adolescents (medicaid, Florida Healthy Kids, a single tertiary care center, CMS, and commercial)?

Study Design and Methods

This is an observational study that primarily uses information commonly collected by public and private insurers on their enrollees. The goal is to compare and contrast the performance of different types of diagnostic-based risk adjustment systems on the Florida Healthy Kids, Florida medicaid, one tertiary care center, CMS, and commercial adolescent populations. Using different populations of adolescents who presumably have different underlying risks and socioeconomic backgrounds enhances the generalizability of the results.

Population and Sampling Plan

The study population is made up of approximately 35,000 adolescents between the ages of 12 and 18 who are enrolled in one of five types of programs for health care coverage within the State of Florida: The Florida Healthy Kids program, Florida medicaid, a single tertiary care center, Florida's Children's Medical Services, and commercial insurance. There are more than 9,000 adolescents between the ages of 12 and 18 in the Florida Healthy Kids program included in this study. The same number of adolescents (9,000) in the Florida medicaid population will be randomly drawn from the counties in which the Florida Healthy Kids program operates. There are approximately 1,500 adolescents for whom we have obtained health care use data from a tertiary care center and 9,000 adolescents enrolled in CMS. All adolescents (approximately 5,000) enrolled in three commercial health plans will be included in the study. Aside from the random sampling within the full medicaid population, a census of the available data in the other four populations will be used to compare risk adjustment methods. In addition to assessing all adolescents within these five populations, a census of all adolescents meeting the criteria for having a special health care need, those with asthma, and those who have diagnoses that may indicate risky behaviors will be used to assess risk adjustment methods separately. Based on analyses we have conducted among these populations, we expect approximately 12–15 percent of the adolescents in Healthy Kids and the commercial groups to have a special health care need. Of those with a special health care need, we expect approximately 25 percent to have asthma and 75 percent to have one of the other special needs diagnoses included in our list. For the medicaid population, we expect 20 percent to have a special health care need, with 27 percent having

asthma and 77 percent having one of the other special needs diagnoses. For the tertiary care center, 30 percent will have a special health care need, with approximately 45 percent having asthma. In the CMS population, all of the adolescents are considered to have a special health care need, but by our estimates, 62 percent meet the screen for a special needs diagnosis, with just more than 10 percent having asthma. We expect to identify in each population between 20 percent and 45 percent who meet the diagnostic-coding screen indicating adolescents who have risk-related behaviors.

Analysis Plan

The first step in the data analysis plan is to calculate the proportion of adolescents who were eligible to use the health care services but did not use them during the 2-year timeframe of the study. We will model the probability of use (1) as a function of the demographic variables available on all adolescents (age, gender, and payer status) and (2) as a function of age, gender, payer status, race, and ethnicity in the Healthy Kids, medicaid, and CMS populations. This will be done using standard logistic regression methodology.

For those adolescents who used the health care services at least once, we will create the outcome measures of use rate and charges in the six categories of types of use for each adolescent in the five populations and investigate the statistical properties of their distributions. It is expected that these distributions could be heavily skewed to the right, reflecting extreme cases, and that they will require some level of truncation (e.g., removal of outliers or "trimming"). Inclusion of such outliers could overly influence model fit, thus reducing its usefulness in making inferences for the majority of cases. Those cases not included in the model will be described separately with the intent of explaining why they were unusual and what the impact might be because they were not included in the risk adjustment models.

Because all study questions require the use of regression-type models to predict expected use at the adolescent-specific level, it will probably be necessary to either transform the response measures so that the underlying assumption of normally distributed errors is reasonable or use a generalization of usual regression analysis. The generalized linear model (GLM) theory can accommodate a more general class of underlying (and skewed) distributions, such as the log-normal, in the same sort of regression framework. For the sake of simplicity of discussion, we will simply presume that a log transformation on the response will be sufficient to meet the underlying assumptions of usual regression analysis—recognizing that the GLM approach may be used instead.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

The investigators are proposing a project that will analyze the effectiveness of five diagnostic-based risk adjustment methods in predicting the concurrent and prospective health care use and charges among adolescents, as well as the added predictive value of information on health status and risk behaviors. The project is designed to provide information that will be useful in determining the appropriate payments to providers in a capitated system since inadequate levels of reimbursement may be a disincentive to caring for high risk individuals. Little information is available on the utility of such systems in adolescents. The project proposed by the investigators is well thought out and the approach is original. The issue of risk adjustment is an identified priority for MCH.

Regional and National Significance

No statement of regional and national significance.

Scientific and Technical Merit

This well-written proposal has many strengths. The investigators present the background and reasons why they believe the research is needed. They carefully describe each of the diagnostic-based risk adjustment systems and the likely strengths and weaknesses of each. The hypotheses are clearly stated and the variables to be used clearly defined.

The researchers clearly have experience in using the kind of data to be used in the analyses. They have maintained an ongoing database with such information and have established working relationships with the different insurance groups

involved. Necessary letters of support are included. The plan for selecting the populations to be included in the analyses are also clearly presented. The researchers also seem experienced in conducting interviews. They have used information from previous studies to estimate response rates and adjusted the sample approached accordingly.

There are several issues that need to be addressed. It is not clear how useful prediction of health care utilization will be useful among adolescents without special health care needs. As the investigators note, the major morbidity and mortality in this group result from intentional and unintentional injuries, tobacco use, alcohol and other drug use, sexually transmitted infections including HIV, unhealthy dietary behaviors and physical inactivity, factors not predictable based on existing diagnoses. Aside from those with special health care needs, does the population to be studied include other groups where great variation in service utilization and cost would be expected (e.g., homeless children)? And if those adolescents are included, would the investigators be able to identify such children for separate analysis given the information they are provided?

Also, while the survey to obtain information on risk behaviors and health status will provide interesting preliminary information from a research perspective, it does not seem likely to provide a method to adjust risk assessments on an ongoing basis. Even if risk taking behavior is found to be predictive of health care costs in a study setting, the interview is lengthy and it is unlikely to be practical (or cost effective) to administer such an instrument routinely. While the investigators recognize this problem and will try to identify subscores that could be used to limit the information that would need to be collected, none is put forward as a likely candidate by the investigators and it is not at all certain that any will be identified. In addition, information collected by insurance companies may be much less reliable than data collected as part of a study as it will not be anonymous.

One more minor issue is that the only commercial insurance groups included in the study belong to HMOs. What impact will this have on generalizability?

The power calculations could be more completely presented. The data analysis section could better illustrate how data will be interpreted.

A time line is presented though the format is a bit difficult to use. The timing of events is better described in the text.

No other financing is being sought.

The investigators seem qualified to carry out the proposed research.

The budget is not presented in the clearest possible manner. First, the institutional base salary as presented seems to include the fringe. In addition, the split between salary and fringe is different for each individual. Fringe rates seem to vary from about 40% to 60%. In addition, for some individuals (Shenkman, Breiner), the investigators report a higher level of effort than is indicated by the funds requested (e.g., 25% effort with only half requested from MCHB).

Also, it is not clear why the investigators have chosen to finance the interviews on a time basis (\$1 per minute) at a cost of over \$43,000. A full time individual could be hired for less. Also in year 3, the travel budget does not need to include \$3900 for investigators to travel to meet with MCHB staff.

Facilities are adequate to carry out the proposed research.

Human subjects have generally been adequately dealt with. The investigator will not make primary contact with subscribers to commercial insurance or Medicaid. (Healthy Kids participants have already agreed to be contacted upon enrollment.) The investigators will obtain consent from both parents and the participating adolescents. They should assure that participants do not feel coerced to participate by specifically noting that refusal will not influence coverage and that specific questions may also be skipped.

Evaluator 2

Originality and Importance

This study addresses three important issues affecting adolescents: 1) the lack of validated risk-adjustment measures, 2) the need to empirically test existing measures on adolescents (as opposed to simply assuming that they work), and 3) the need to relate such measures to total health care costs (i.e., to include out of pocket expenses). This is a problem of national and, indeed, international significance and is clearly in synchrony with MCHB and Healthy People 2000 priorities.

Regional and National Significance

No statement of regional and national significance.

Scientific and Technical Merit

This study has many strengths. The first is that it zeroes in on two major problems affecting health insurance: the need for risk-adjustment methods that are empirically validated on specific sub-populations. The authors point out, correctly, that the most common measures currently in use for adolescents - demographic factors - only predict a minute fraction of total resource consumption. Further, the limited amount of validation work that has been performed has been of fairly coarse grain (pediatrics) and has ignored the important characteristics of adolescents.

A second major strength is that the authors are making a conscious effort not to assume the existence of a "gold standard." Instead, because of their familiarity with this area, they are making multiple comparisons between specific risk-adjustment methodologies and demographic predictors, and between the risk-adjustment methodologies themselves.

A third strength is that the authors are also attempting to measure out of pocket costs. Given the growing tendency to reduce health care coverage in the United States, measuring these costs is becoming increasingly important. Much of what goes under the label "cost-containment" is actually transferring costs to the patients themselves.

The study does suffer from significant weaknesses. The first of these is a lack of focus. Because the authors want to "settle" this issue, they are proposing a massive number of analyses - for starters, they have over 8 hypotheses considered "primary," plus a number of secondary ones as well. It is difficult to follow the various analytic paths proposed, and one is left with the feeling of analytic exuberance. The authors do not provide a convincing case that it is, in fact necessary to perform so many analyses to prove their points.

A second major weakness is the excessive focus on utilization and resource consumption to the virtual exclusion of other outcomes (e.g., ICU admission for asthma or a gunshot wound). Since lack of utilization can be related to the occurrence of adverse outcomes, some attention should be paid to how well some of these risk adjustors predict outcomes (e.g., death, severe illness, and hospitalization). Failure to consider this point could lead to misleading conclusions.

Finally, although the inclusion of non-utilization measures (COPE, CHIP-AE) and the measurement of out-of-pocket expenses are laudable and presented in an apparently straight forward fashion, close reading of the proposal suggests that this part of the study could actually become a massive endeavor in and of itself. The authors point out - correctly - that it is hard to justify data collection efforts that go beyond usual types of data (e.g., ICD-9CM or CPT-4 codes). On the other hand, they are proposing to conduct a series of analyses to determine what domains of COPE and CHIP-AE are worth collecting. This is a huge undertaking. It is particularly problematic given the high degree of attrition and refusal that can be expected.

The grant also attempts to avoid length limitations by using small fonts with tight spacing. Considerable shortening of the text could be achieved without sacrificing content.

The principle investigator is a relatively junior investigator with a modest publication record She appears to be beginning to publish in this area (risk-adjustment using large data sets). Dr. Pendergast has a strong background and publication record involving large data sets. Several of the consultants are individuals of national stature in the area of risk-adjustment. However, the consultants' role will be relatively minimal. Project management staff appear appropriately trained, although their experience with phone surveys is hard to assess.

Approximately 10% of the project budget is being contributed by the University of Florida. The project team is a bit top-heavy (60-70% FTE investigator time) and rather lean on programmer time (only 70%, low given the massive data sets to be created and analyzed). Some travel expenses are cryptic (e.g., year 3 travel "for two project team members to go to meet with the project officer and other interested staff at the MCHB offices during the early weeks of the third year of funding. These meetings will be essential for outlining the work that is still needing to be accomplished in the last six months of funding.").

Protection of human subjects is adequate.



African-American Children's Transition to School

Grantee

University of North Carolina

Investigator

Joanne E. Roberts, Ph.D.
 Frank Porter Graham Child Development Center
 105 Smith Level Road, CB#8180
 Chapel Hill, NC 27599-8180
 (919) 966-7159
 (919) 966-7532 fax
 joanne_roberts@unc.edu

Project Number MCJ-370649

Project Period 10/1/1994-9/30/1999

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
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

Noninterventional

Population Focus

School-Age Children,
 Parents/Families/Mothers/Fathers (Adolescent
 Parents)

Race/Ethnic Focus

African-American

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 of the child, family, and community factors during early childhood that help children succeed and protect them from 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 study builds on an earlier project supported by the Maternal and Child Health Bureau, the Carolina Otitis Media Program, a study of 88 African-American children whose otitis media history, psychoeducational development, family environment, and child care experiences have been documented between infancy and 4 years of age.

Research Questions or Hypotheses

The aims of the study are to: (1) Determine 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 African-American children's language, cognitive, and social development and academic achievement from infancy through the early elementary school years.

Study Design and Methods

Measures of the child, family, and community will be examined for 88 African-American children from prior to their entry into kindergarten through the end of the third year of elementary school. The child measures will examine academic achievement, language, intelligence, attention, health, and social skills. Family measures will examine daily routines, 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 the classroom environment, and school demographics, in addition to parental attitudes and perceptions of their school and neighborhood, community services, and neighborhood demographics.

Population and Sampling Plan

This study will involve 88 African-American children who were recruited during early infancy. To be included in the study, the children had to have relatively normal prenatal and perinatal histories, be generally healthy, and have enrolled in one of nine local child care centers by age 1. The sample consists of 41 boys and 47 girls who are generally living below the poverty level (69 percent) and have single mothers (67 percent) 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 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 how 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 identify factors related to these patterns of change. Second, various developmental pathways or prototypical patterns of development will be identified to determine which child, family, and community characteristics distinguish children displaying different patterns of growth. Separate cluster analyses of the longitudinal measures of language, cognitive, academic, and social development will be performed and the clusters compared by child, family, and community characteristics to identify correlates of these different developmental trajectories. HLM analyses will also be used.



Alternatives for Developmental Screening in Primary Care

Grantee

Medical and Health Research Association of New York City, Inc.

Investigator

Harris Huberman, M.D.
 99 Hudson Street, 10th Floor
 New York, NY 10013
 (212) 925-4217
 (212) 925-5317 fax

Project Number MCJ-360833

Project Period 10/1/1997-9/30/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	115,076	12,774	127,850
Year 2	114,933	12,930	127,863
Year 3	114,865	12,922	127,787
Year 4			
Year 5			

Year 2000 Objectives

6.3, 6.14, 8.14, 17.20

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Infants, Toddlers, Preschool-Age Children

Race/Ethnic Focus

African-American, Hispanic (Hispanic overall)

Summary

Statement of the Problem

Regular developmental screening of the 5 to 15 percent of the population of infants ages newborn to 3 years who are at risk for delay is widely promulgated but rarely achieved. This is increasingly true as primary care providers face cost-containment measures, including staffing reductions and higher patient volumes. Screening approaches that use parent-completed developmental questionnaires such as the Ages and Stages Questionnaire (ASQ) offer valid and reliable screening and opportunities for parent involvement, in addition to freeing staff to meet other professional duties. However, the use of these tools as reliable screening instruments needs to be assessed in low-income urban settings with high-risk families in unstable housing situations.

Research Questions or Hypotheses

The goal of this randomized, clinical controlled trial is to examine the feasibility of three different approaches to the periodic screening of at-risk children within the context of a public health agency/primary care clinic. Three approaches are to be compared: (1) The Denver Developmental Screening Test (Denver II), to be administered by a provider, plus an initial ASQ, which will be mailed to parents one time only; (2) the ASQ alone, which will be mailed to parents at certain stages of their

child's development; and (3) the ASQ mailed to parents (same frequency as in group 2), plus a monthly parenting newsletter and toy.

Six hypotheses are proposed:

1. The percentage of initial screening by ASQ will be equal to or better than the rate of initial assessment by providers;
2. Patient retention will be equal or higher in groups 2 and 3 than in group 1.
3. The percentage of ongoing screening in group 3 will be greater than in group 2;
4. In a child who has been screened with both the Denver II and a one-time ASQ, there will be concordance on suspected delay.
5. With ongoing screening, cross-group comparisons will show that the rate of "suspected delay" screening in the ASQ groups (groups 2 and 3) will be equal to or greater than in group 1.
6. Certain subgroups (defined by demographic and/or risk factors) may respond better than others to an ASQ approach.

Study Design and Methods

This randomized clinical controlled trial seeks to compare three approaches to developmental screening within the context of a public health agency/primary care clinic. Study subjects are referred to the Infant-Child Health Assessment Program (ICHAP), which randomizes the subjects to one of three group formats for screening.

For subjects enrolled in group 1, the Denver II screening will be administered by the primary care provider when the child is 6, 12, 20–24, and 30 months of age. In addition, the ASQ will be mailed one time to the parents. Parents of children in group 2 will receive only the ASQ when their child is 4, 6, 8, 12, 16, 18, 20, 24, 30, and 36 months of age. The parents of children in group 3 will receive the ASQ with the same frequency as those in group 2, but will also receive a monthly newsletter plus a toy. For the latter two groups, ICHAP handles all subsequent outreach to the family, conducts the mailing and scoring of ASQs, and submits feedback to the pediatrician. For those in group 1, the pediatrician periodically administers the Denver II.

Population and Sampling Plan

The project will be implemented at two sites selected because of their large at-risk populations: One site has a predominantly black population, the other a predominantly Hispanic population.

Families with at-risk children ages 3–18 months who attend a pediatric primary care center and are eligible for ICHAP (New York's P.L. 99–457, Part C, Child Find program) are offered enrollment by their pediatrician. Approximately 400 children will be enrolled, with an estimated 30 percent loss to followup.

Eligibility for the study is based on the following criteria: (1) The child has one or more risk factors, based on a list by ICHAP of New York; (2) the child has no known developmental delay; (3) the child is between 3 and 18 months of age; (4) the caregiver speaks English or Spanish; and (5) the caregiver can be contacted by telephone (either a personal phone or a friend's phone).

Analysis Plan

For each of the three groups, the project will examine the rates of initial and followup screenings obtained, the rate of positive screenings, and the percentage of at-risk children who remain engaged in care. Additionally, the degree to which income, maternal education, risk status, and other factors predict outcomes within the three groups will be analyzed. This project will also explore the feasibility of a public health/primary care/parent partnership that could lead to a cost-efficient model adaptable for wider use in Part C at-risk programs.

Preliminary data analysis will start 3 months after the beginning of enrollment and will continue through the followup period to monitor progress.



American Indian Fatherhood in Two Oklahoma Communities

Grantee

University of Oklahoma

Investigator

Lisa J. Lefler, Ph.D.
 Health Promotion Programs
 555 East Constitution Street, Building 4, Room 138
 Norman, OK 73072
 (405) 325-1790
 (405) 325-7126 fax
 llefler@ou.edu

Project Number MCJ-400807

Project Period 10/1/1998-9/30/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	112,033	52,656	164,689
Year 2	100,052	47,024	147,076
Year 3			
Year 4			
Year 5			

Summary

Statement of the Problem

Fatherhood is a relatively recent area of study for many social scientists, yet few would hesitate to acknowledge the importance of the role of fatherhood to the health, development, and well-being of children and families cross culturally. Because of changes in familial division of labor, structure, and composition in the United States, studies have focused on those aspects of these changes that affect parental responsibilities and, thus, the health of children. Unfortunately, there have been very few studies that have focused specifically on American Indian fatherhood. This population has been the interest of much health-related research in recent years, including research on alcohol abuse, cancer, fetal alcohol syndrome, and diabetes. Astonishingly, demographics have shown that "recent estimates place the excess death rate of American Indians under 45 at 43 percent, which is significantly higher than that of blacks at 39 percent." Yet relatively little has been done to gain insight into family issues and even less has been done to specifically target the roles and expectations of fathers within these families. Researchers do not know how American Indian men perceive their roles as fathers in their communities nor do researchers understand the cultural contexts and social issues in which these perceptions are developed.

Year 2000 Objectives

No Stated Healthy People Objectives

Study Design

Observational

Time Design

Cross Sectional

Care Emphasis

Noninterventional

Population Focus

Parents/Families/Mothers/Fathers (Adolescent Parents)

Race/Ethnic Focus

Native American

Research Questions or Hypotheses

Because this ethnographic study is using a methodology that will permit construction of categories to better reflect local understanding, we are not primarily oriented to hypothesis testing of relationships between predefined variables. Nevertheless, we will be collecting some fixed-category data and expect to examine how these are related to emergent constructs.

There are several questions concerning the roles and expectations of American Indian fathers that this study addresses:

1. Is the role of American Indian fathering perceived the same across different tribal communities that have different cultural histories and traditions (for example, traditionally matrilineal and traditionally patrilineal tribes)?
2. How do American Indian men (and women) come to define and interpret their own realities and the realities of others, particularly as they relate to parenting?
3. What is the relationship of fatherhood to community problems and solutions?
4. What factors do American Indian men feel are barriers to successful fathering?
5. How do fathers socialize their children with regard to issues of American Indian identity and biculturalism?
6. How have American Indian families and the role of fathering changed, if any, in the past three generations?

Study Design and Methods

Information will be gathered by using the qualitative research principles of grounded theory and comparative analysis described by Strauss and Corbin; this method has previously been applied to the study of the meaning of fathering among European-American fathers from intact families. Along with the collection of more objective demographic and personal data (i.e., employment status, occupation, tribal affiliation, number of children, etc.), interviews will include questions phrased at the most general level of abstraction that is feasible (i.e., "What does it mean to be a 'good' father?"). These questions will be followed by more specific, probing questions (i.e., "What is an example of a 'good' father?") that are intended to add specificity and texture to the responses received at the more general level.

A total of 200 subjects will be interviewed (80 men and 20 women from both the traditional matrilineal and the traditional patrilineal communities in Oklahoma) three different times over the course of a year and a half. Six tribal members trained in ethnographic interview methodology are conducting the interviews. Each interview instrument was constructed in conjunction with focus groups that provided tribal representation and insight. Two ethnographers have been placed to live there (one in each of the two communities) for at least one year. Each ethnographer will participate in community events; visit and engage in informal conversations in places where native men and/or families congregate; record indepth life histories or case histories from key consultants; offer the community assistance in health promotion and wellness projects; function as a liaison among community leaders, interviewers, and investigators; and conduct independent observations of activities related to fatherhood in the community.

Focus groups that consist of tribal liaisons, ethnographers, tribal interviewers, researchers, and other tribal members who are interested in the project meet at least monthly to discuss issues, get feedback, provide updates, and plan for fathering activities and strategies to meet the goals of the study.

Population and Sampling Plan

Oklahoma is home to the largest number of American Indian tribes in the United States. According to the 1990 census data, approximately 8.5 percent of Oklahoma's population is made up of American Indians. This study will focus on native populations within two communities of Oklahoma: The 13-county area of the Chickasaw Nation in south-central Oklahoma, and the 5-county area of the Kiowa, Comanche, and Ft. Sill Apache Nations in southwest Oklahoma. These latter three tribes are considered a "Plains Indian coalition" and are referred to locally as the "KCAs." The participants ($n=160$) are biological and/or social fathers who are members of American Indian tribes and may have one or more tribal affiliations. A smaller sample ($n=40$) of participants are American Indian women who are biological and/or social mothers of American Indian children and have one or more tribal affiliations. American Indian blood quantum and tribal affiliation(s) are self-reported.

The population for this study shows representatives of low, middle, and high socioeconomic status categories and ranges from 17 to 86 years of age. Participants are recruited by tribal agency referrals (i.e., family services, adult education, American Indian Head Start, senior citizen centers, etc.), by other tribal members, and by information booths at traditional and community events. The Chickasaw Nation has also included project information and solicits interested members to

participate on its official Chickasaw Nation Web page. Newspapers and media often used by tribal members are other sources that provide information about how to participate in the project.

Analysis Plan

Structured portions of the interviews will elicit objective data that refer to the subject's responses to quantitative, categorical, or forced-choice questions; the latter will be subsequently analyzed and coded to allow the possibility of treatment as independent or dependent variables for hypothesis testing. Each participant will be interviewed three times. The first instrument will provide basic demographic information, family size, organization, and history and will include a host of questions concerning fathering generationally. Many open-ended questions ask for individual responses that may reflect specific cultural ideals (i.e., discipline, contributions to care, gender roles and expectations, etc.) and other microsocial phenomena.

The second interview includes a standardized instrument that is contributed by Native American psychologist and educator Dr. Teresa LaFromboise and uses an orthogonal model to assess orientation to American Indian identity and bicultural competence. Forced-choice and structured questions concerning stress and posttraumatic stress disorders are also included. Each instrument is coded to note those men who are veterans. The third instrument will be developed from answers provided by instruments one and two (i.e., free lists) and from feedback elicited from focus groups that concern interests of the tribes.

Formal interviews are taped with permission of the interviewee. Tapes are being transcribed and placed into AFTER, a qualitative ethnographic software program, for coding and further analysis. An SPSS program is being used for standard statistical analysis of other demographic and quantitative data.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This proposal seeks to gain understanding of Indian male socialization as it relates to the construction of an idea of fatherhood.

Regional and National Significance

The proposed study is of national significance in that the literature on the nature of family and family roles has only recently considered the influence of proactive culture in the differential understandings of human relationships and responsibilities. As such, much of what we know about non-middle-class white United States families and role constructions is how they deviate from an implicit cultural norm. This is especially problematic when such information is used to guide policies and interventions because we only know what they do not do, not what they do. Such may be why so little progress has been made in the extent to which programs have impacted the life conditions of particular cultural minority groups. Thus, culturally specific knowledge about family roles in general and male roles in particular may be very useful in the quest towards useful interventions.

Scientific and Technical Merit

The major strengths of this project are its proposed populations and its design. The project will sample from two distinct Indian tribal groups and within each of these groups variation in socioeconomic class, health status, age and current circumstances (employment status, legal status, etc.) will be actively sought.

This sampling goal is a strength for several reasons. First, it helps to limit the tendency to generalize from one tribal experience to all Native peoples. The two groups chosen differ by their history with the U.S. government and by the maternal versus paternal focus of their tribes. These variations may surely impact how these individuals see themselves in relation to one another and in relation to the wider society. With regard to variations within group, the sampling method will make it possible to see, for example, the effects of acculturation within and across tribes. The inclusion of standard measures here will surely help to make this point. In addition, the data will reveal insights into several phenomena. Such phenomenon include whether people of different tribes and within tribes perceive the relationships among health, legal status

and the role of fathers similarly, and whether natal cultural views impact perception of the male roles in a similar fashion across individuals with different current concerns. Finally, interviewing both men and women about their views of a good versus a bad father is implicit acknowledgment that perceived roles and responsibilities can not only be seen from the target point of reference. If men and women are not consistent in their cultural expectations, then relationship problems will surely arise. In both of the proposed tribal groups, there are a significant percentage of female-headed households. It will be interesting to see how views of males as fathers, from both the men's and women's perspectives, relate to current family configurations. In all, the variation sought in the subject population should lend clear insights to the types of particulars very rarely sought in most research and especially research on populations outside of the dominant group.

The qualitative nature of the study design is also a major strength. The author took care to present several theoretical issues about fatherhood and how societal and cultural issues may mediate role perceptions and has taken the time to generate an initial interview protocol. However, consistent with good grounded theory work, she has also left enough open-endedness in her presentation to allow for the particulars to be generated by those who will be interviewed. The semi-structured nature of the interview instruments shows that a great deal of work has been done in anticipation of the general issues, but the principle investigator has left the particular constructs to be generated by the data collected. Moreover, the use of ethnographers to generate insight into fatherhood within the two communities as a supplement to the interviews, as well as a guide for revision to the interviews gives greater strength to the ethnographic technique. Using such data along with focus group feedback before the big part of the interviews are conducted should help to insure that the researchers are on the same page as the community people.

The researcher has also included a consultant with experience studying native populations. The consultant should be an added strength given that the entire principal research team is fairly new to the research arena. No budget or human subjects concerns are apparent.

Evaluator 2

Originality and Importance

The researchers propose to study a little known area, the self-perceptions of fathering among several native communities in Oklahoma. This comparatively small study addresses an important, little known topic with important health implications for Native American communities.

Regional and National Significance

This study looks at differences among different kinds of communities with different kinship patterns (e.g. matrilineal and patrilineal) which may, indeed, produce important differences in fathering patterns. These interviews may generate some valuable data upon which subsequent, more extensive research could be based.

Scientific and Technical Merit

The interview strategy of combining some open-ended questions with the closed structured interview is important in allowing researchers to identify emergent themes. Both participation and observation data collecting strategies are included.

This research team is well situated with the Native American communities they intend to study. The principle investigator and co-investigators have detailed and in-depth knowledge of these communities and extensive experience working with them. The full-time role of the principle investigator is a strength. The principle investigator is a medical anthropologist with experience in collaborative projects concerning Native American populations. She has carried out previous research in these communities in related areas. Her high level of involvement is clearly necessary to carry out and analyze 240 interviews in the space of two years, including open-ended data.

One of the trickiest aspects of this research is how to get truthful answers on the range of highly sensitive topics under investigation (e.g. alcoholism, economic status, living arrangements, paternity of children, etc.) through an interview. While this is something worth questioning, the principle investigator is fully aware of this problem and has built into the design

the collection of data from members of the Native American communities themselves.

Researchers note that they will be able to expand their ability to carry out other methods of data collection traditional to ethnographic research that will allow for triangulation of methods. In the design they will incorporate one year, full-time ethnographic field placements in both communities in a way that will allow the ethnography to both inform and be informed by the survey portion of the project. This is significant to the design and should do much to allow the research team to analyze their survey data with greater subtlety than would otherwise be possible.

To aid the analysis of this data, the team has added a prominent American Indian researcher. She will assist in both survey construction and analysis.

The author notes that "provision has been made for breaks between the first, second, and third interviews, during which time the native interviewers can themselves serve as focus group informants on insights they may have gleaned and avenues for inquiry in subsequent interviews." This is a fortunate design decision in which the interviewers can assist the principle investigator and co-investigators in considering the meaning of the data already collected and in shaping subsequent data collection.



An Intervention for the Transition to Fatherhood

Grantee

University of Minnesota

Investigator

William J. Doherty, Ph.D.
Department of Family Social Science
290 McNeal Hall
1985 Buford Avenue
St. Paul, MN 55108-6140
(612) 625-4752
(612) 625-4227 fax
bdoherty@che2.che.umn.edu

Project Number R40MC00141-01

Project Period 8/1/1999-7/31/2002

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	271,788	72,682	344,470
Year 2	263,005	114,490	377,495
Year 3	199,834	67,157	266,991
Year 4			
Year 5			

Summary***Statement of the Problem***

The issue of father involvement with children is receiving increasing attention in academic, applied, and policy settings. A clear consensus has emerged at many levels of society that children's well-being is enhanced by high levels of nurturing involvement by fathers combined with cooperative father-mother coparenting. Unfortunately, millions of children in single-mother families are being raised without meaningful involvement with their fathers, and even in two-parent families the degree of paternal involvement is less than optimal for today's two-earner families and the needs of children. This study addresses the transition to fatherhood, the time when father identity is formed and co-parenting practices are established. There appears to be no better time to forge strong father involvement with children, and mutually satisfactory co-parental relations, than at the birth of a first child. Although a number of studies have described the process of becoming a father, little research has been done on how to intervene in this process in order to promote active, responsible fathering and good mother-father cooperation.

Research Questions or Hypotheses**Year 2000 Objectives**

8, 14

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Pregnant Women,
Parents/Families/Mothers/Fathers (Adolescent
Parents)

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

The main research question is whether an educational intervention during the transition to parenthood can increase father involvement with children, enhance the quality of father-child relationships, promote co-parenting partnerships, and decrease parenting stress.

The second research question inquires about which factors are associated with successful outcomes of the intervention. Factors investigated here are prenatal attitudes towards fathering, prenatal relationship satisfaction, attitudes towards the pregnancy, family of origin experiences with fathering and co-parenting, and social support during pregnancy and after the birth.

Study Design and Methods

First time fathers and mothers in the second trimester of pregnancy are being recruited into the study. They must be married or cohabiting, and the child they are expecting must be the first one for both parents. Half of the couples are randomly assigned to an intervention group and half to a control group. The intervention group receives an eight-session educational intervention designed to promote father involvement, father skills, and co-parental cooperation, and to reduce parental stress. The first session is in home and the last seven are in group classes in an HMO clinic. A standard curriculum is being implemented by experienced parent educators, and sessions are being observed by graduate students who take detailed notes about the process for ethnographic analysis. Control group couples are followed without intervention. All couples in the study are assessed at the second trimester of pregnancy and again at six months and 12 months after the birth. A variety of father, mother, child, and parent-child assessment tools are used to determine which fathers will become more involved, the fathers' level of skill with the baby, the quality of the mother-father relationship, the couples' level of stress, and other factors.

Population and Sampling Plan

One-hundred seventy couples in the second trimester of their first pregnancy are being recruited from an HMO and through public media. They must be married or cohabiting, age 18 or over, and speak and read English. Couples are being recruited to reflect the demographic characteristics of the Minneapolis-St. Paul region. There are no primary plans to test specifically for racial or ethnic health issues, but these will be explored in secondary analyses of the data if feasible.

Analysis Plan

After preliminary analyses to establish the success of the randomization procedure to yield demographically equivalent groups, the primary test of the efficacy of the intervention will be conducted with 6 month and 12 month outcome data, using analysis of variance with repeated measures, with two factors: Group (experimental versus control) and Time (6 months and 12 months). Separate ANOVAs will be conducted for coparenting outcome scores, quality of father-child interaction outcome scores, and parenting stress outcome scores. For the three father involvement variables, a MANOVA will be conducted on father engagement scores, father accessibility scores, and father responsibility scores. Ethnographic field notes will be subjected to qualitative content analysis for emergent themes that characterize interactions in the classes.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This proposal addresses a number of issues that are central to MCHB priorities, primarily the focus on fathering and enhancing processes that might predict more positive parenting by fathers.

Regional and National Significance

No statement of regional and national significance.

Scientific and Technical Merit

This proposal is well written, and is impressive in many respects. The strengths include the conceptual model that drives the intervention plan and the proposed measurement scheme, the attention to the role of the mother and the nature of the co-parenting relationship, the study design that attends well to various important threats to validity, and the investigator's care in noting that intervention implementation will be carefully monitored and assessed to assure comparability. Randomization plans are appropriate, sample size and power issues are addressed, and the assessment plans are comprehensive. The design also mixes basic quantitative approaches with qualitative approaches to data collection and analysis, a combination of methodologies that may prove intriguing in the findings it generates and the explanatory power offered. Finally, the investigative team is excellent.

Concerns about the lack of child measurement, particularly the lack of expected effect of the intervention on the child remain. The principle investigator has included a Bayley Scale measurement, as well as a number of behavioral indices coded from the father-child interactions. The principle investigator is to be commended for selecting the observed child behaviors during interaction. These should provide excellent indices with which to understand the impact of the quality of fathers' involvement. The Bayley is a rather weak choice, in contrast. Such global cognitive measures are not very likely to be very sensitive to the interventions being planned; a fact that has been repeatedly documented in previous early intervention studies with like methodologies. Despite the inclusion of the measures, it is surprising to see that the investigator expects "no effects" of the intervention on children's behavior. Such expectations seem contrary to a vast parent-child interaction literature, as well as the rationale for this study overall. If one purports that early fathering interventions are needed to increase the quality and involvement of fathers in their children's lives, but then suggests that no differences between children in the intervention and control groups would be expected, then it raises the question of whether the interventions are really meaningful. The principle investigator makes the case that the effects are more likely long term than short term; yet most studies suggest that the most proximal relations are usually the strongest. Likewise, there is a huge literature on the nature of "reciprocal" effects in parent-child interactions; and the historical parent-effect model has proved to be not very useful in describing the actual nature of parent-child relationships. The likelihood of significant differences between groups of children on the behaviors of interest are great IF the intervention accomplishes what the principle investigator suggests it will.

One area in which the principle investigator has provided a strong rationale is that of whether there is sufficient descriptive data available to guide an intervention in the first place. The principle investigator notes that "the literature focusing on the transition to fatherhood is primarily small-scale, with non-representative samples, and is seldom guided by theory." Also, the principle investigator notes that "there is relatively little empirical research specifically dealing with the transition to fatherhood," and that "most studies of fathering deal with ongoing father-child relations with young children, not on the transition to fatherhood." Relatively little attention has been paid to how these bonds are forged during the transition to parenthood. The principle investigator attempts to make the case for the intervention focus in the introduction, noting that there have been three major longitudinal studies of the transition. Given the explicit conceptual model they present, they believe that more can be learned by trying to prevent and modify than by taking a descriptive approach "one more time." Yet, the "one more time" notion seems clearly at odds with the idea that there has been "little" work done in the area. There is some conceptual inconsistency here. The basic issue is whether there is sufficient data available to suggest that the specific transitional processes and parenting behaviors to be taught the fathers and mothers are the ones that are indeed (1) lacking, and (2) most related to child and family outcome. This is an issue open to interpretation within the literature.

One area in which the principle investigator has clearly given substantial attention is in the development and presentation of the intervention protocol. The principle investigator has gone to great lengths to include descriptive information about the intervention protocol and the underlying mechanisms of change involved with each aspect of the intervention.

The principle investigator wants to explore the combinatorial function of father and mother data after first testing the effects separately. Although there are those who suggest that two measurement sources for one construct will increase reliability and validity of measurements, this may not be the case when the data are basically subjective and the measurement sources may or may not share appropriate frames of reference. Is there any reason to assume that mothers and fathers reports of fathering behavior or attitudes are or should be correlated? Combining measurements that are unrelated may not offer more explanatory power; in fact, it may offer more confusion than enlightenment. This is, of course, an empirical question. Data analyses otherwise continue to appropriately address the questions raised.

This investigative team remains strong. The principle investigator has an excellent record of scholarly productivity. An expert on fathers of color will serve as a consultant. This team is very well qualified to conduct this research.

No concerns on human subjects are apparent.

Sub contracts are proposed with Georgia State University and with Health Partners, Inc. These seem appropriate to the scope of the work proposed.

The budget was judged to be rather high. Specifically, the consultant time is higher than the justification makes a case for. In addition, clarification of the subcontract would be appropriate.

Evaluator 2

Originality and Importance

The proposal requests four years of funding to implement and assess a randomized clinical trial of an intervention designed to increase fathers' involvement and improve fathers' relationships with their infants across the transition to fatherhood. The proposal is exceptional, building upon the extensive work of the principle investigator and his collaborators both within the State of Minnesota and at the University of Georgia. Moreover, the proposed project focuses on the MCHB priority of fathering, which as is noted in the literature review, is an area that has received far too little attention.

Regional and National Significance

There are a number of strengths to the proposed research. Conceptually, the principle investigator has presented a very strong conceptual rationale for conducting a clinical intervention as opposed to a descriptive, longitudinal study. Specifically, the principle investigator asserts that the latter would elaborate on the challenges that confront couples as they transition into the new roles of parenthood. Whereas, the clinical intervention allows the researchers to test the utility of a multidimensional conceptual framework by focusing on the transition to fatherhood and by attempting to influence how that transition occurs. Concurrently, this clinical intervention affords the researchers to focus on the co-parenting relationship, and to further understand this impact on child outcomes.

Scientific and Technical Merit

A major strength of this proposal is the scientific integrity of the design which addresses important threats to validity. The principle investigator and his colleagues should be commended for their scientific rigor.

There are, however, a few remaining questions that arise in relation to the proposal as well. The study will use a randomized clinical control trial design to recruit participants. Health Partners, a closed-panel HMO, and Regions Hospital will be the two main sources from which subjects will be identified. Health Partners is described to be comprised of primarily middle-class white-collar workers. Regions Hospital has been targeted to insure adequate ethnic and socioeconomic diversity in the sample. Herein, are some important issues the principle investigator has not adequately developed. What comprises an "adequate ethnic and socioeconomic" sample that is diverse? What are the parameters of ethnic diversity? And if multiple ethnic groups are recruited, what might be the contribution of ethnic ideologies to paternal involvement in the socialization of young infants? Granted that the principle investigator has clearly stated that all participants must speak English, does this mean functionally or as a second language? The principle investigator states, for example, that "Because the intervention and assessment will be conducted in English, they must be able to read and speak English. " How will this be evaluated? No measures of verbal communicative competence or literacy competency have been incorporated into this study. And given that a diverse sample population is targeted, should there not be some measure of cultural ideology and beliefs? If these are mute points, then why is a consultant who has expertise on cultural competence built into the project?



Assessment of Enhanced Prenatal Care by Ethnically Diverse Women

Grantee

The Regents of the University of California

Investigator

Carol C. Korenbrot, Ph.D.
Office of Research Affairs
3333 California Street, Suite 11
San Francisco, CA 94143-0962
(415) 476-3094
(415) 476-0705 fax
ckoren@itsa.ucsf.edu

Project Number R40MC00137-01

Project Period 3/1/1999-2/28/2002

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	181,720	86,317	268,037
Year 2	190,501	90,488	280,989
Year 3	83,389	39,610	122,999
Year 4			
Year 5			

Year 2000 Objectives

16.6

Study Design

Observational

Time Design

Cross Sectional

Care Emphasis

Noninterventional

Population Focus

Pregnant Women

Race/Ethnic Focus

African-American, Hispanic (Hispanic overall)

Summary*Statement of the Problem*

The general aims of the study are to determine whether enhanced prenatal services that include nutrition, psychosocial and health education services are associated with measurable benefits as perceived by women enrolled in Medicaid managed care plans, and whether those benefits differ for African-American, Hispanic and white (non-Hispanic women).

Research Questions or Hypotheses

The fundamental research questions are, 1) Whether quality prenatal psychosocial, health education and nutrition services delivered according to official guidelines are associated with better provider-patient interactions, patient satisfaction and behavioral adherence to advice according to the women; and 2) Whether these perceived benefits differ for African-American, Hispanic and white women.

Study Design and Methods

To answer these questions, a consumer survey instrument with measures for quality of prenatal care advice, quality of interpersonal care, patient satisfaction, and behavioral compliance with prenatal care advice has been developed. The reliability and validity of these measures for African-American, Hispanic and white low-income women will be determined. The survey will be useful for measuring enhanced prenatal care quality and outcomes by Medicaid managed care plans and others who want to evaluate the quality of the enhanced prenatal services.

Population and Sampling Plan

The populations of interest are African-American, Hispanic and (non-Hispanic) white pregnant women enrolled in public Medicaid managed care plans in the four San Francisco Bay Area counties in California. Women surveyed will be between the ages of 18 and 44, and their pregnancies will be between 24 and 32 weeks gestation. Each woman included must have made at least two visits with a prenatal care provider in the plan but have not yet given birth. We seek a final sample of 300 eligible subjects per ethnic group (900 respondents in all).

Analysis Plan

Once the surveys are completed, the data will be cleaned, coded and missing data will be considered for possible imputation. The variability of different measures will be examined and those with limited variability will be dropped. For multi-item scales, multivariate regression Structural Equation Modeling (SEM) techniques will be used for factor analysis of appropriate items to include in the scale for each latent variable. Reliability of the survey will be assessed, i.e. the extent to which scales are free of random error and are thus reproducible will be examined. Since no gold standard exists for the measure of process of care, the focus will be on construct validity.

SEM will be used to facilitate determination of the adequacy of hypothesized relationships between latent variables in this study. The hypothesized relationships between main variables are tested in two stages. First, analyses are conducted separately for each ethnic group to evaluate the fit of each model for each hypothesized relationship. A common model (including potentially confounding variables) with adequate fit across all three groups for each hypothesis must be identified prior to proceeding to the second step. Next, in a multiple group analysis, parameter estimates are constrained to be equal across groups. The two models (separate parameter estimates in all groups and constrained parameter estimates) are compared. If there is not a significant decrement in fit when the parameter estimates are constrained to be equal, the hypothesis that the relationship in the three ethnic groups is different can be rejected, and the strength of the hypothesized relationship can be tested across groups. If the models are significantly different, further investigation can be conducted to identify which specific parameters are different across groups for inspecting the modification indices. These indices suggest which parameters are most influential on the goodness-of-fit indices.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

It is not clear exactly how these findings will have relevance to the national scene due to the very local aspects of the managed care plan implementation, especially in the absence of collection of birth outcomes. Yet in the sense that California is a nation unto itself, it might be argued that enough population is affected to make this an important project.

Regional and National Significance

No statement of regional and national significance.

Scientific and Technical Merit

Several concerns remain to be resolved. First, the telephone-sampling plan has problems. The principle investigator expects to get a consent rate of about 50 percent, a rate they declare acceptable in hard to reach populations. Yet what matters is not the absolute percentage of the eligible population that one samples; rather it is how representative the sample is that allows one to draw strong inferences. The principle investigator attempts to address this issue of non-response by evaluating the

difference between the responders and non-responders on socio-demographic and health variables and adjusting accordingly. Yet this assumes that non-response is related to some set of these variables. One wonders if it would be feasible to go out in the neighborhoods and draw a random sample from those who could not be contacted by telephone to better evaluate this assumption.

The role of the advisory board is not clear. The principle investigator proposes to seek out advice from a whole range of members drawn from both managed care plans and local communities to "advise on how to implement our research study, while being accountable to the constituencies involved." This obviously entails the strong possibility that the research plan, as proposed here, will not be the one implemented if the constituencies involved do not concur with the plan.

It is also clear that the measurement development will depend heavily on the outcomes of the focus group work and every attempt will be made to construct instruments that are culturally sensitive. While this is commendable, it also directly contradicts the data analytic strategy for assessing measurement invariance and the steps that will be taken if measurement invariance is not found. If one understands correctly, the principle investigator intends to modify the measurement model by deleting items that do not demonstrate invariance across ethnic groups via the equality of factor loading, thereby eliminating items which, empirically, demonstrate differential cultural sensitivity. If only invariant items remain, then such items are by definition culturally insensitive. Therefore, one must generally choose between the two alternative strategies in that they maximize different aspects of validity. It is not clear which emphasis the principle investigator prioritizes.

The strategy to investigate both measurement and structural invariance across the three ethnic groups presupposes that a common model can be found which fits well in all groups, before between-group structural differences are examined. This position makes the assumptions that the best-fitting model within each group is simply a nested version in some fashion to the models that fit in other groups. It is the intention of the principle investigator to restrict model searches for best-fitting models only to those that are common, thereby eliminating the potential that very different, non-nested models might fit best in each of three different groups?

How the principle investigator attempts to incorporate covariates into the SEM analysis is not clear. There are a number of different strategies for doing so (either explicit inclusion into the model or by analyzing partial-covariance matrices) each with their respective pluses and minuses. This principle investigator must address this issue.

There was no power calculated for the SEM analyses. When one looks at the MacCallums' Tables for assessing fit, it appears that the model given had sufficient power to detect a non-fitting model. Yet because the manner in which the principle investigator intends to handle covariates is not made clear, one is not sure if the power one has calculated is correct.

Finally, the principle investigator still intends to address reliability as assessed by an internal-consistency measure by splitting the scale items and computing alpha. One wishes again to assure the principle investigator that it is not necessary to split the items into subsets to compute alpha, since alpha is proportional to the average of all possible split-half reliabilities.

Evaluator 2

Originality and Importance

Twenty percent of the nation's children living in poverty live in California, and one fourth of the Hispanic births in the country are to women in California. Therefore, the results are applicable to a large enough group of women and children to merit funding.

Regional and National Significance

The information learned should be useful in providing services to women in Medicaid managed care in other areas of the country, or at least in developing research in those populations.

Scientific and Technical Merit

An initial issue of concern was how representative was the sample to be studied, or more importantly, the characteristics of the unstudied women (i.e., whether they vary in demographic and health characteristics from the population that is actually studied). Results of other studies showing no differences in responders and non-responders is given. More importantly, a field interview company has been identified with experience in locating and interviewing hard to reach individuals. The company will use the study interviews in teams with an interviewer from the company trained in working in these frequently unsafe areas.

The advisory board's role is clear. They will be used only to help the investigators better understand the constituencies being studied in a way that will make the proposed study more acceptable to the potential subjects.

The proposal will attempt to devise instrument questions that are culturally sensitive. Configural invariance and factorial loading invariance are to be used to detect cultural sensitivity in the measurement models. Two additional levels of factorial invariance, strong factorial invariance and strict factorial invariance will also be tested. It is clarified that the best fitting model will be found for each group and differences in the models between the cultural groups will be reported.



Biomarkers of Infection and Risk of Preterm Delivery

Grantee

Swedish Medical Center

Investigator

Michelle A. Williams, Sc.D.
 Center for Perinatal Studies
 747 Broadway, 4-North
 Seattle, WA 98122-4307
 (206) 386-3107
 (206) 386-3173 fax

Project Number MCJ-530829

Project Period 10/1/1998-9/30/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	172,195	54,586	226,781
Year 2	175,271	55,561	230,832
Year 3			
Year 4			
Year 5			

Year 2000 Objectives

14.1, 14.2, 14.5, 14.7

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

Pregnant Women

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Preterm delivery (PTD), which is defined as delivery before the completion of 37 weeks gestation, continues to be a significant public health problem. Although progress in caring for preterm neonates has been made during the last three decades, the identification of women at high risk for delivering preterm and the development of appropriate preventive measures for PTD remain an unresolved problem in perinatal medicine. PTD prediction models that are currently available do not adequately distinguish pregnant women who are at high or low risk for delivering preterm. Results from two currently active areas of research suggest that biomarkers of abnormal immune activation (elevated maternal serum ferritin concentrations) and subclinical intraamniotic infection (elevated amniotic fluid interleukin-6 (IL-6) concentrations) are likely to be valuable predictors of PTD. Evidence that suggests a positive association between elevated maternal serum ferritin concentrations, which are measured during the second and third trimesters, and increased risk of PTD is emerging. It has been hypothesized that elevated maternal serum ferritin may be a marker for acute phase response. Studies have also shown that elevated amniotic fluid IL-6 in the second trimester is associated with an increased risk of PTD among women who have had a genetic amniocentesis. This latter finding is particularly suggestive of subclinical intrauterine inflammation or infection as an important determinant of spontaneous PTD. Although it has been suggested that amniotic fluid IL-6 and serum ferritin levels are correlated, no one has systematically evaluated these two potentially important markers of PTD in

the same population.

Research Questions or Hypotheses

The goals of this project are to test the following hypotheses:

1. Elevated maternal serum ferritin in the second trimester is associated with an increased risk of PTD;
2. Elevated amniotic fluid IL-6 in the second trimester is associated with an increased risk of PTD;
3. Second trimester amniotic fluid IL-6 and serum ferritin concentrations are correlated; and
4. Elevated second trimester amniotic fluid IL-6 and serum ferritin are independently (and possibly interactively) associated with an increased risk of PTD.

Study Design and Methods

This study employs a prospective case-cohort study design. The study cohort is comprised of pregnant women who received prenatal care and who delivered at Swedish Medical Center (SMC), Seattle, WA, from 1994 to 1996. We obtained frozen second trimester amniotic fluid and serum samples that remained from specimens collected by patients' health care providers and kept the samples in freezers at -70° C for long term storage. Second trimester amniotic fluid specimens are only available for those women who received an amniocentesis as part of their prenatal care. We have linked collected specimens to corresponding labor and delivery and medical record information for a base cohort of 3,753 women. Following a case-cohort sampling plan, we selected a subcohort comprised of a stratified random sample of women from the base cohort. This subcohort of women was stratified based on the distribution of type of sample available and the quarter of the year when samples were collected for the women who were cases. Cases consisted of women with preterm labor and those who delivered preterm. The comparison group included women who delivered at term from the subcohort. We used all cases, and we will perform laboratory assays on identified cases and comparison groups and abstract their medical records to obtain relevant information. Laboratory assays include two-site immunoradiometric assays (IRMA) and enzyme-linked immunosorbent assays (ELISA) to determine the concentration of serum ferritin and amniotic fluid IL-6, respectively. These assays will be carried out in the laboratories of the Fred Hutchinson Cancer Research Center, Seattle, WA. The remaining study activities, such as medical record abstraction, will be executed in the Center for Perinatal Studies, SMC.

Population and Sampling Plan

The base cohort population from which study subjects were sampled for this research (*n*=3,753) comprised all pregnant women (regardless of age, race, or health status) who received prenatal care within the SMC health care provider network and who provided a second trimester serum and/or amniotic fluid specimen between January 1, 1994, and December 31, 1995, and later delivered at SMC. As previously described, we followed a case-cohort sampling plan. For the 3,253 women for whom we have only a serum sample, 387 women were identified with preterm labor and/or PTD. From this group of 3,253 women, we selected 387 women to constitute the subcohort; among these women, there were 363 who delivered at term to serve as the comparison group (approximately a 1:1 control-to-case ratio). For the 500 women for whom we have both serum and amniotic fluid specimens, we identified 70 with preterm labor and/or PTD. From this group of 500 women, we selected 280 women to constitute the subcohort; among these women, there were 236 comparison women (approximately a 3:1 control-to-case ratio).

Analysis Plan

The analysis plan for each hypothesis is provided below.

1. Plan for data analysis for hypotheses 1 and 2: Tests or potential associations between serum ferritin or amniotic fluid IL-6 and PTD risk will be assessed by defining women in the highest serum ferritin or amniotic fluid IL-6 quintile (quintile cut points will be established by using the serum ferritin or amniotic fluid IL-6 distribution for the comparison group) as the exposed group. Multiple logistic regression analyses will be used.
2. Plan for data analysis for hypothesis 3: The correlation between serum ferritin and amniotic fluid IL-6 levels will be evaluated among the 306 subjects for whom both serum and amniotic fluid samples were collected. Spearman's rank correlation coefficients will be evaluated along with linear regression and r^2 values, differentiating between the cases and the comparison group to evaluate any differences in correlation.

3. Plan for data analysis for hypothesis 4: We will use a binary exposure variable for ferritin defined by dichotomizing at the upper quintile of the distribution and a similar binary exposure variable for IL-6. We will use logistic regression modeling procedures for this analysis, which includes indicator variables to specify whether subjects are unexposed to both factors (i.e., the referent group), exposed to either factor alone, or exposed to both factors.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

Premature delivery is an important problem in perinatology. The proposal seeks to investigate the relationship between two biomarkers, AF IL-6 and second trimester maternal serum ferritin and the incidence of very/preterm birth. These biomarkers may help identify women at risk for preterm delivery.

Regional and National Significance

Approximately 350,000 infants are delivered prematurely each year with NICU costs of over \$400 million per year and long term physical and neurological impairment of the children. Little progress has been made in prevention of preterm birth and this work promises to extend the current work associating infection with preterm delivery.

Scientific and Technical Merit

The investigators are well qualified to perform the work.

Hypotheses are clearly stated, measurement issues addressed, population resources described, sample size justified and appropriate data analyses proposed.

There is marginal information available on which to base the potential relationship of SF to PTD. There are 8 papers mentioned of which only 2 are related to PTD. The best paper to date was a prospective study with SF measured at 19,26 and 36 WG in 380 black women. Although the sample size is larger in the proposed study, it is a case control study with only a single measure of SF in a primarily white population.

The AF IL-6 studies are more common and the most recent is prospective (290 very PTD and 290 FTD). The proposed study will have only 111 cases of PTD, in a case control design with limited power. Will the results of the proposed study improve on those of the prospective study?

Recent work by Goldenberg and others suggest that bacterial vaginosis, the presence of fetal fibronectin and short cervix are important predictors of spontaneous preterm births. They note different predictors by race. There is little discussion of these factors in this proposal and how serum ferritin or IL-6 may contribute over and above these predictors. Absent from the proposal is a conceptual model giving an overview of the many factors associated with PTD. Parry and Strauss provide a review article on the mechanisms of disease in premature rupture of the fetal membranes. The schematic diagram of the various mechanisms that have been proposed to result in premature rupture or preterm premature rupture of the fetal membranes resembles a cobweb of interrelations among the biochemical process affecting the membrane. The authors suggest that research priorities include elucidation of the normal biologic processes of the fetal membranes and how exogenous risk factors including nutritional deficiencies, smoking, and infection, promote premature rupture of the membranes. These articles appeared in print after the proposal was submitted, but much of the work on fetal fibronectin was available in earlier papers.

A consultant perinatologist has agreed to provide quality control evaluation of medical record abstraction. A letter of agreement to participate is included.

Evaluator 2

Originality and Importance

No statement of originality and importance.

Regional and National Significance

No statement of originality and importance.

Scientific and Technical Merit

The review of the literature is clear and supports the research to be performed. However, the estimated incidence of pre-term delivery is given as 8%, but 10% is used throughout the sample size calculations. These are estimates from the literature and it would be helpful to know that the incidence of pre-term labor in the population to be studied.

One area that needs additional clarification is the determination of gestational age of delivery. Investigators state that when LMP and early ultrasound information disagree, gestational age will be estimated using the obstetrician's best estimate, based on ultrasound and clinical evaluation of the mother or newborn exam. Three clinicians will blindly reexamine relevant information to assure consistent criteria for the calculation of gestational age of delivery are applied. Do they have a specific protocol for which criteria will be used when there is a discrepancy? This is important for cases that are borderline in gestational age. When comparing serum ferritin to amniotic fluid into IL-6, will they limit their study to those who had the samples drawn on the same day? It seems that this would be preferable, if at all possible. Since 78% of the women have these samples available on the same day, will there be enough to maintain the power of the study if it's done this way?

The strength of the study is the demonstration by the investigators that they can link the labor and delivery records with available specimens. Although some links still remain to be done, there are currently 41,000 cases available. A sub-set of samples will still be sent out confirmatory for testing at an outside lab. It is not clear why this is necessary or how the samples will be chosen. However, the amount of money is only several hundred dollars. The study power does seem adequate, but may change if their incidence of pre-term delivery is lower than 10% or if they limit the study to only those with paired samples drawn on the same day.

A large amount of data is collected from cases and controls. It is unclear how all of this information will be used or how it relates to the study hypothesis. Much of the information seems to be known risk factors for preterm delivery, but there is no plan to analyze this data.

The time line seems appropriate, although data entry cleaning and analysis goes on up to one month before the end of the study.

There are no human subjects concerns.

The investigators seem qualified to carry out the study, although all personnel are budgeted for two complete years. Some of these should be decreased and limited to the time that they will actually spend on study work. For example, laboratory testing is estimated to take nine months and those involved with laboratory testing should only be budgeted for these nine months rather than a full two years.



Choices of Life for Adolescence Success

Grantee

Washington University

Investigator

Larry E. Davis, Ph.D.
One Brookings Drive
St. Louis, MO 63130
(314) 935-6632
(314) 935-8511 fax

Project Number MCJ-290644

Project Period 10/1/1996-3/1/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	79,720	94,643	124,366
Year 2	81,609	45,701	127,310
Year 3	13,102	7,337	20,439
Year 4			
Year 5			

Summary*Statement of the Problem*

Little attention has been paid to how African-American adolescents make important life decisions. Although the decision concerning whether or not to stay in school is one of the most important, little is known about the process by which youth make this decision. Understanding why most youth persevere and receive their high school diploma, while other youth do not, has important relevance for social policy.

Research Questions or Hypotheses

This project is a continuation of a previous study. The specific aims of the project are to: (1) Follow the original sample through completion of the senior year in high school, (2) examine the long-term prediction of school-completion decisions based on components of the Theory of Planned Behavior, (3) examine the long-term stability of model components, and (4) more clearly establish the role of social norms and racial self-esteem in the decision-making process. Research questions concerning stability of adolescent attitudes and perceptions will be examined, as well as differences in the profiles of adolescents who drop out of school early compared to those who drop out later.

*Study Design and Methods***Year 2000 Objectives**

8.2

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

Adolescents

Race/Ethnic Focus

African-American

Questionnaire packets will be administered to study subjects in groups of 20 at the beginning of the junior and senior years. Data will be collected on the number of unexcused absences, suspensions, and expulsions as well as academic rank. Other study measures include behavioral intention to complete school, attitudes toward completing school, views of important others concerning their school completion, perceived control over school continuation, perceived consequences of staying in school, self-esteem, and racial self-esteem. Youth who stop attending school will be tracked through telephone calls, neighborhood visits, registry of motor vehicles, the correctional system, and death certificates.

Population and Sampling Plan

Students volunteered for the study through homeroom classes in an inner-city high school in St. Louis. The sample is composed of 232 African-American students (approximately 77 percent of the class).

Analysis Plan

Data will be analyzed using hierarchical multiple regression and covariance structure analysis.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

Little attention has been paid to how African-American adolescents make important life decisions. Although the decision about whether to stay in school is one of the most important made by youth, the process by which the decision is made is little understood. The project focuses on this important decision and how it made by adolescents.

Regional and National Significance

This study addresses an area of critical national importance. It is based on the Theory of Planned Behavior, which posits that the immediate predictor of behavior (in this case, either staying in school or dropping out) is the intention to carry out the behavior. Attitudes toward the behavior, subjective norms, and perceived behavioral control determine the intention. The proposal takes a positive approach to the issue, noting that most low-income youth graduate from high school even when environmental circumstances and employment outcomes do not seem to support school continuation. Understanding why most youth persevere and receive their high school diplomas while others do not has national policy relevance.

Scientific and Technical Merit

This continuation request results from three major findings in the original study. First, the dropout rate at the end of the freshman year in the study sample was substantially lower than anticipated (5.2 percent), given that the overall dropout rate for the study population across the high school years was expected to be 40 percent and a dropout rate of 15 percent was expected after the freshman year. The low dropout rate compromised the ability of the original study to statistically test its key hypotheses, since the original study only followed the youth through the beginning of their sophomore year in high school. Continuing the study until the cohort of youth complete high school would allow the study to more adequately address the original research questions. Much of the information to be gained by conducting the research in the first place would be lost if the study is discontinued after the current academic year (the final year of the current grant period).

The second argument for the continuation request concerns the study's failure to find a significant role for social norms in the prediction of intentions and decisions to stay in school. It is likely that the low dropout rate and its resulting lack of statistical power were responsible for this finding. Data indicate that youth in the study sample entered high school with very high intentions to complete school and perceived few barriers to that outcome. Documenting the timing and nature of any changes in social norms is important and cannot be accomplished without a continuation of the project.

The third rationale for the continuation concerns an unanticipated and interesting relationship between personal self-esteem and racial self-esteem. Students with high personal self-esteem were found to be more likely to intend to complete school, while students with high racial self-esteem were found to be less likely to have intentions of completing high school. The researchers suggest that these findings may explain the attitude of some African-American youth that seeking academic success is "acting white." They cite some support in the literature for the lack of convergence between personal self-esteem

and racial self-esteem. Further investigation of this finding could yield interesting new information.

The study suffers from certain weaknesses. It is still extremely focused on individual perceptions and intentions. Ecological issues are given very little attention. Since the authors have not made any attempt to obtain comparison data (i.e., on the 23 percent of students not in the sample), it is difficult to determine what this low dropout rate might mean.

Another problem is that the investigators' description of the cohort enrolled so far is extremely vague. They note that "a larger number of students did not complete the survey because they were not currently attending the high school. Followup efforts are under way to determine their status." No information is provided about the cohort (e.g., with respect to class rank, absences, etc.). Data presented are very unclear and do not match the descriptions in the text.

The principal investigator has devoted his professional career to the study of psychological and social issues among African Americans. He is well-qualified to lead this study, as are other members of the research team.

The budget is reasonable, and the protection of the rights of human subjects is adequate. Internal review board approval for the continuation of the investigation is pending.

The investigators' presentation of the work completed to date is vague in some areas and unclear in others. The recommendation is for approval with the condition that the investigators satisfactorily address the following concerns:

1. What are the relevant characteristics (i.e., socioeconomic status, race, gender, etc.) of the freshman class as a whole?
2. What are the relevant characteristics of the 23 percent of the freshman class that did not participate in the study, and how do they compare with the freshman class as a whole and that of the study sample?
3. What were the specific reasons and circumstances for the 23 percent nonparticipation?
4. What are the relevant characteristics of the 5.2 percent dropout group, and what were their reasons for dropping out?
5. How efficient is the study tracking system? The principal investigator should detail how the tracking is currently being done.



Comprehensive Elementary School AIDS Education

Grantee

Yale University

Investigator

David J. Shonfeld, M.D.
 Department of Pediatrics, School of Medicine
 333 Cedar Street
 P.O. Box 208064
 New Haven, CT 06520-8064
 (203) 737-2182
 (203) 737-1366 fax
 david.Schonfeld@Yale.edu

Project Number MCJ-090833

Project Period 10/1/1998-9/30/2002

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	257,441	193,081	450,522
Year 2	263,312	197,484	460,796
Year 3	291,745	218,809	510,554
Year 4	238,312	178,734	417,046
Year 5			

Summary

Statement of the Problem

One of every four cases of sexually transmitted diseases and one of every four new infections with HIV occur in adolescents; every hour, approximately two adolescents in the United States become infected with HIV. Adolescents represent one of the fastest growing risk groups becoming infected with HIV.

In many urban centers within the United States, significant numbers of children are already sexually active by the time they complete elementary school. Early onset of sexual activity is associated with unprotected sex and is more common among low-income and African-American and Latino adolescents. Research has shown that it is more effective to delay the age of initiation of sexual intercourse and/or to promote the initial adoption of safer sexual practices than to attempt to intervene once adolescents have already established patterns of high-risk sexual activity. For AIDS prevention efforts to be of maximal benefit, they will need to begin before the age when children and adolescents initiate high-risk behaviors that place them in jeopardy of acquiring HIV. Yet few school-based AIDS education efforts have involved young children, and those that have did not assess behavior change, which provides little empirical data about the characteristics and instructional content of effective programs for elementary school students.

Year 2000 Objectives

18.10

Study Design

Experimental

Time Design

Mixed

Care Emphasis

Interventional

Population Focus

School-Age Children

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

This study will assess the efficacy of a 3-year elementary school AIDS education initiative involving AIDS prevention instruction in the fifth through seventh grades, embedded within a comprehensive social development program based on social cognitive and social influence theories. If successful, it will be the first demonstration of an effective AIDS prevention initiative at the elementary school level and will have practical implications for the prevention of the initiation of risky sexual behaviors in preadolescents and young adolescents.

Research Questions or Hypotheses

The major goal of the project is to evaluate the efficacy of a comprehensive elementary school AIDS education initiative to prevent the adoption of high-risk sexual behaviors as compared with a nonenhanced, standard social development curriculum with limited AIDS prevention content. The study will also investigate the impact of the intervention on key mediating variables (i.e., perceptions of vulnerability, fears about AIDS, peer sexual norms, and perceived self-efficacy for risk prevention measures).

The primary hypothesis is that students in the intervention group will have fewer self-reports of high-risk sexual behavior than students in the control group, as assessed at the end of the seventh grade upon the completion of the 3-year intervention. Specifically, significantly more students in the intervention group will remain abstinent through the seventh grade than those in the control group, and students in the intervention group who initiate sexual intercourse by the seventh grade will be more likely to use condoms than students in the control group. The intervention effect will persist after controlling for covariates (sociodemographic and academic variables and personal experience with AIDS).

Because the intervention effect may actually be more subtle and/or more widespread, we also propose hypotheses to test the impact of the intervention on key mediating variables. We hypothesize that students in the intervention group, as compared with students in the control group, will perceive themselves as less vulnerable to HIV disease and will have more realistic fears about AIDS, peer sexual norms that are more supportive of abstinence and condom usage, and greater perceived self-efficacy for risk-prevention measures.

Study Design and Methods

This project is designed to assess the efficacy of a 3-year elementary school AIDS education initiative involving AIDS prevention instruction embedded within a comprehensive social development program that is based on social cognitive and social influence theories. This integrated curriculum will be tested in a randomized, controlled trial involving all 1998–99 fifth graders (*n*=1,530) who will be followed through the seventh grade while attending regular education and bilingual classes within New Haven Public Schools, an urban school system within an AIDS epicenter. The intervention group, consisting of 13 schools, will receive an enhanced social development curriculum that includes the following: (1) Monthly teacher-in-service training, (2) ongoing facilitation and coinstruction by a social development facilitator, (3) additional AIDS prevention lessons, (4) a peer education program, and (5) involvement of community educators to assist with the training and support of peer educators. A cohort of 1998–99 seventh grade students (*n*=60–70) will serve as peer educators (over 3 years) to the fifth grade student cohort in the intervention group to accomplish the following: (1) Foster group norms that favor risk-reduction behavior, (2) model skills to resist peer pressure, and (3) provide a supportive network of older peers to assist with the transition to middle school. Students in the control group will receive a standard, limited curriculum on social development that includes only one lesson on AIDS education in the sixth grade. At the end of the sixth, seventh, and eighth grades, the rates of sexual abstinence and, for those who are sexually active, the proportions who adopt safer sexual practices (measured by reported use of condoms and the avoidance of drug or alcohol use and sex), will be measured in both groups using a confidential, self-administered survey (the Social and Health Assessment Survey (SAHA)) that is administered systemwide, independently of this project. The AIDS Survey for Kids (ASK), an individually administered, standardized, semistructured interview, will be given to a random sample of 280 students drawn from the intervention and control schools to measure factual knowledge, conceptual understanding, misconceptions, perceptions of personal vulnerability, and fears about AIDS.

Population and Sampling Plan

Because classroom instruction in social development (including AIDS education) is currently provided to all students within the school system who are participating in the project, and because the principal outcome measure (SAHA survey for determination of self-reports of sexual behavior) is administered districtwide, all students attending regular education fifth

grade classes, including bilingual classes, in 1998–99 will participate in the study except for those whose parents disapprove of their child's participation. There are 1,530 eligible students (57 percent black, 29 percent Hispanic, 12 percent white, 2 percent other, 52 percent female) in the 1998–99 fifth grade cohort. The SAHA survey will first be administered to this cohort in the spring of 2000; based on prior administrations, it is anticipated that less than 1 percent of parents will deny permission for participation in the survey.

A subsample (*n*=283) of randomly selected fifth graders who provided assent and written parental consent were interviewed during the first year of the study.

Analysis Plan

In order to test the primary hypothesis, both of the dichotomous outcome measures (i.e., "yes" or "no" to engaging in sexual intercourse and, if sexually active, "yes" or "no" to using a condom during the most recent incidence of intercourse) will be regressed against group assignment (i.e., intervention vs. control group). If a significant effect for the intervention is demonstrated, the following additional predictor variables will be entered into the logistic model to determine whether the effect remains: Covariates (sociodemographic and academic variables and personal experience with AIDS), elementary school attended, middle school attended, and an intervention dosage variable to control for the percentage of the curriculum received by the student. The mediating variables (social skills, AIDS factual knowledge and conceptual understanding for the subsample of children ($n=283$) who completed the ASK interview, perceptions of vulnerability, fears, sexual norms, and perceived self-efficacy) will also be added to the model to measure their contribution to the treatment effect. We will use the t test for comparing independent groups to determine the differences between the intervention and the control group on the following variables: Perceptions of vulnerability to HIV disease, fears about AIDS, peer sexual norms, and perceived self-efficacy for risk prevention measures.

We will have 80 percent power to detect an increase in the rate of abstinence at the end of the sixth grade from a baseline rate of 75–82 percent ($\alpha = 0.05$). There will be sufficient power to detect a smaller increase at the end of the seventh and eighth grades.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

The proposed project represents an excellent and quite timely idea. The proposed work indeed makes a strong case for the need for such work.

Regional and National Significance

The project addresses a variety of MCH research priorities. Providing an effective prevention intervention for high risk sexual behavior and AIDS is significant.

Scientific and Technical Merit

The strengths of this proposal: (1) the proposed work is intelligently developed, (2) the investigative team is strong, experienced, and already in place, (3) the investigators have worked already within the New Haven School system to establish relationships and develop the base for the AIDS education initiative, (4) preliminary work by the investigators has established some support for the model that underlies the intervention effort, and (5) the preventive model is developmental in its approach.

The investigators provide an in-depth discussion of the underlying social-cognitive framework for the study. The principle investigator goes to lengths to describe the basic underlying propositions within models of social-cognition and social influence and the mechanisms within each that would be likely to promote the intervention effect hypothesized to be found. This was a well-considered presentation that clearly articulated the concepts.

The principle investigator has made significant efforts to address detail. A description exists for the standard curriculum, the specific enhancements to the standard curriculum for the intervention group, how classroom teachers and the social development facilitator will be trained to implement aspects of the curriculum, the specific AIDS lessons that have been added to the standard curriculum (6 sessions for 4th graders and 7 sessions for 8th graders), and the peer education aspects of the intervention. From the greater detail, it is apparent that the variability in the curriculum is not problematic, and there is support for the appropriateness of the level of intervention to produce the desired effect.

The principle investigator discusses strategies to document the integrity of treatment administration, treatment integrity across teacher training and observational evaluation, as well as peer training and observational evaluation, and effect of the use of peer education processes within each classroom. This represents thoughtfulness to process issues in the intervention protocol.

The principle investigator proposes to assess a spectrum of related factors that would logically be affected by the intervention as well as abstinence and condom use. Covariates such as academics and personal experience with AIDS will be included in the analysis scheme, as will mediating variables such as social skills, AIDS factual knowledge, conceptual understanding of AIDS, perceptions of vulnerability, fears, perceived self-efficacy, and sexual norms. Further, the analysis of treatment process factors will add to the understanding of these more broadly based factors as well.

Evaluator 2

Originality and Importance

This proposal seeks four-years of funding to assess the efficacy of a three-year AIDS education initiative for elementary aged children. The proposed curriculum will be piloted with 1,400 4th through 6th grade youth enrolled in bilingual and regular education classes within the New Haven school district. The proposal has an array of strengths: It is being implemented in a community where nearly twenty five percent of all children are sexually active, includes youth with limited-English proficiency, involves multiple sectors of the New Haven community, and addresses an important public health problem (AIDS and sexual activity).

Regional and National Significance

The proposed project addresses a host of AIDS education issues in a developmentally appropriate manner, while addressing a targeted population where there has been a noted increase in AIDS.

Scientific and Technical Merit

The principle investigator has assembled a collaborative team that presents an array of unique talents that are complementary. He has apparently identified several significant consultants who will contribute to the overall project in a meaningful and facilitative manner. Taken together, the array of investigators and consultants provides a well-rounded, multidisciplinary team of experts who contribute to the fulfillment of the investigative goals and objectives. Moreover, the extensive work that several of the co-investigators have been involved in underscore the unique contributions of this collaborative effort.

One of the proposal strengths is the literature review. Although the literature is focused primarily upon adolescent issues, the investigator effectively uses this focus to illustrate the dearth of programmatic and research that has been conducted with elementary-aged children. Significant ties to literature related to the delay of sexual intercourse and the adoption of safer sex practices underscore the theoretical and developmental approach that the investigator seeks to examine in this investigation. This approach is particularly important given the earlier onset of sexual activity among urban minority youth as cited.

The evidence related to optimistic bias provides additional support related to the targeted population of this investigation. Specifically, the authors note that "...perceived vulnerability to health problems increases between the ages of 8 and 13, and then decreases during adolescence. The sixth grader therefore sits, unprepared, on the threshold of adolescence, a time when the health and safety consequences of unrealistic optimism intensify as autonomy increases and risky behavior accelerates." There are, nonetheless, a series of shortcomings and questions that require elaboration.

With respect to the intervention, the utilization of multiple facilitators (peers, investigators, teachers, and members of the community) provides an array of role models for young children. Such an array may facilitate the development of interpersonal relationships for young children. This in turn may contribute to the desired outcomes. Yet, it is curious that this is not part of the model. It should be noted that throughout the document the importance of role models and interpersonal relationships is stressed.

For example, the literature related to peer-educators and the reduction in risk behaviors is not fully developed. A discussion of the effectiveness of this approach within and across ethnic groups is nowhere found. Similarly, the potential differences that might occur across SES categories and ethnicity have not been addressed.

The process evaluation that has been described is adequate, but perhaps not the strongest type of evaluation that might be utilized. While this focus on documenting the implementation of the intervention is noteworthy, it does not allow for an examination of the extent to which the program's highest priority goals are and are not being achieved. Some of these goals may be cognitive (gains in knowledge or skills) or affective (e.g., ability to cope with peer pressure). Through the introduction of an outcome-based evaluation model, the investigators would be able to discern the impact that this intervention program has on the intended population. While it is acknowledged that this is the intent of part of the evaluation, there are an array of outcomes that could be focused upon to enhance the lessons learned during this investigation.

The plan for data analysis for the first hypothesis appears to be adequate. However, it is not clear why the children enrolled in bilingual classes will be excluded from the analysis. It is also stated in the plan for analysis that "initial analyses will be restricted to those students who remain within the same treatment condition throughout the three years of the study." Based on this statement, it can be interpreted that youth who transition out of the bilingual education classroom settings will be treated as either missing data or as having terminated their participation. Why? Toward that end authors state that "a sample size of 270 assigned to each treatment condition is sufficient to detect a 10% difference between the control and intervention groups." Does this imply that the bilingual population is sufficiently large?

The timeline that has been provided is clear, and reflects the feasibility of completing the study in the allocated time.

The budget for the proposed project, while reflective of the multiple stakeholders that will be involved, appears to be rather extensive. The second research associate, for example (TBH) will receive a salary that exceeds the current research associate. No institutional matches are offered for any of the investigators on the project. Moreover, the fees offered to the Institute for Community Research, Inc. seem to be somewhat inflated.



Crossing Cultural Boundaries: An Ethnographic Study

Grantee

University of Southern California

Investigator

Cheryl Mattingly, Ph.D.
 Department of Occupational Therapy
 1540 Alcazar
 CHP-133
 Los Angeles, CA 90033
 (213) 342-2820
 (213) 342-1540 fax

Project Number MCJ-060799

Project Period 1/1/1997-12/31/1999

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	133,730	61,940	195,670
Year 2	141,764	69,482	211,246
Year 3	143,774	70,515	214,287
Year 4			
Year 5			

Year 2000 Objectives

17.14, 17.20, 22.4

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

Infants, Toddlers, Preschool-Age Children,
 School-Age Children

Race/Ethnic Focus

African-American

Summary

Statement of the Problem

The research questions which drive this study concern the problem of misunderstanding and miscommunication between the family and the various interdisciplinary team members of the child's health care services network. In essence, the problem involves crossing cultural boundaries created by the multiple cultural worlds that intersect in clinical interactions. Both family members and practitioners live and operate in a multiplicity of cultural domains shaped by their profession, economic class, ethnicity and community affiliation. When practitioners and family members interact, their values, assumptions and perceptions about the interaction are shaped by their membership in these cultures.

Understanding family perspectives and developing effective partnerships with families are especially salient concerns in the contemporary health care climate. Practitioners and policy makers have recently embraced principles of family-centered care as the organizing framework for services for infants and young children with special health care needs.

Despite the recognition of the need to involve families in the therapeutic process and to incorporate family perspectives in decisions over the direction of treatment, evidence of success in enacting these principles within daily practices has been limited. It is difficult for professionals to implement the shifts in practice required to make families central. Practices steeped in medical traditions frequently adopt professional/client relationships based on hierarchical models or expert drive

models. The challenges are magnified when practitioners attempt to implement culturally relevant and responsive services for families who live in cultural worlds that differ significantly from those of the practitioner. Misunderstanding about the nature of the disability and treatment focus intensify when the child comes from a cultural background which differs significantly from clinic culture.

Research Questions or Hypotheses

The purpose of this three-year ethnographic study is to examine how the problems of children with special health care needs are variously understood or framed by family members and health care practitioners, the influence on different frames or misunderstandings on the intervention process, the process undertaken by family members and practitioners to negotiate or impose alternative views, and the impact of these multiple perspectives on the effectiveness of interventions.

The research questions which drive this study concern the problem of misunderstanding and communication between the family and the various interdisciplinary team members of the child's health care services network. In essence, the problem involves crossing cultural boundaries created by the multiple cultural worlds that intersect in clinical interactions. Both family members and practitioners live and operate in a multiplicity of cultural domains shaped by their profession, economic class, ethnicity, and community affiliation. When practitioners and family members interact, their values, assumptions and perceptions about the interaction are shaped by their membership in these cultures.

Study Design and Methods

Narrative interviews, focused interviews, participant observations, videotaping, and document review will be conducted. Intervention events that are perceived by both providers and parents as successful and events that illuminate as dilemmas in family-centered care will be closely examined. Coding schemes will be developed for emergent themes. Interpretations of the data will be reviewed by a family advisory group and a roster of consultants.

The projected outcomes of this study are the generation and dissemination of new knowledge in the following areas: (1) understanding of family perspectives on their experiences in caring and nurturing young children with special health care needs; (2) family, practitioner, and researcher perspectives on factors that contributed to successful collaboration; and (3) interpretation of the misunderstandings and confusions that permeate services for a chronically underserved population—African-American families from inner-city neighborhoods.

Population and Sampling Plan

The research team will follow 30 African-American children ages 0-8 with special health care needs, their families, and the health care providers that serve them over an approximately three-year period.

Analysis Plan

An essential feature of this ethnographic study is the iterative process through which data are collected and analyzed. Six separate periods of data analysis are spread throughout the three year period.

Analysis will involve developing codes that thematize data from all sources: observation, videotapes, interviews and documents. Themes will be derived from both etic and emic perspectives. An emic perspective refers to the culture specific framework for making sense of experience. Etic categories (or the outside researcher's categories) will be derived from the theoretical literature in medical ethnography, psychological anthropology and ethnography of organizations. Emic categories and meaning will be derived from open-ended and narrative interviews which allow respondents to describe and reflect on their experience in their own words. Overall research direction for the analysis will be guided by the four team members of the team primarily responsible for data collection (the PI the co-PI and the two research associates) who will meet weekly.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This strikingly innovative and exciting study shows promise of going beneath the surface of two different systems and

noting their points of intersection in order to improve interactions, communications, and mutual cooperation in African-American families and in the medical culture. Few studies to date have approached this issue at an ethnographic level, so the study holds great promise of yielding new data.

Regional and National Significance

The regional and national significance of the study seems enormous. In centers from coast to coast that primarily serve minority clients, most of the medical staffs have not received sufficient training in how to work most effectively and sensitively with diverse populations.

Scientific and Technical Merit

The major purpose of this study is to examine how the problems of inner-city African-American children with special health care needs are understood or culturally "framed" by their family members and by health care practitioners. Specifically, the research questions explore the problems associated with misunderstandings and miscommunications between the family and the child's health care providers. The investigators propose to follow a cohort of 30 African-American children, their families, and their health care providers over a 3-year period. The methodological approach will consist of ethnographic-narrative interviews, focused interviews, participant observations, videotaping, and document reviews, and these will constitute the primary modes of data collection. The study will closely examine interventions that are perceived as successful both by parents and by providers, and will also examine dilemmas in family-centered care.

When this proposal was originally reviewed in March 1995, the committee requested clarification of a number of methodological issues, including validity and reliability of the data and sample size. Budgetary questions were also posed. The investigators responded with a comprehensive statement submitted in August 1995, and the committee reviewed the information in November 1995. The proposal was then approved for funding and was scheduled to be implemented through the University of Illinois at Chicago. However, before the study began, both the principal investigator and the co-principal investigator took positions with the University of Southern California (USC).

The investigators now plan to carry out the proposed study at Children's Hospital of Los Angeles (CHLA) and through California Children's Services (CCS), since many of the low-income families and children first treated at CHLA are subsequently referred to CCS. This resubmission presents evidence of the investigators' ability to carry out this project in Los Angeles.

In this submission, the investigators provide a detailed summary of how a site change might affect the validity of the originally planned study, addressing each point separately. This study requires investigators to be able to collect observational and interview data from a number of different study participants ranging from family members to a variety of health care professionals. The study also involves following each family through subsequent transition sites where their child receives health care services. Clearly, lack of comparability concerning subjects and access to clinical sites could potentially undermine the study.

The investigators point out the similarities between the initially proposed locale (Chicago) and the new locale (Los Angeles), with respect to both target site and patient population. Many inner-city, low-income African-American families living in Los Angeles face the same kinds of problems as those living in Chicago; these problems include joblessness, homelessness, and violence. Furthermore, the primary family structural features in African-American families in Chicago, such as extended kinship networks and high levels of foster parenting for children with special health care needs, are also characteristic of African-American families living in Los Angeles.

CHLA, which is significantly larger than the University of Illinois Hospital in Chicago (UIH), provides more extensive services, is entirely devoted to pediatrics, has a larger pediatric occupational therapy department, and provides a much larger potential population from which to recruit the study sample. CHLA is located in an inner-city, high-density, low-income, culturally diverse neighborhood in the heart of Los Angeles. Although the percentage of African-American children treated at CHLA is proportionally lower than at UIH, the larger number of patients overall ensures a highly adequate sampling pool. In preparation for the study's implementation, the principal investigators during recent months have (1) gained entry to the primary clinical site (CHLA); (2) identified and gained entry to a transition site (CCS); (3) established initial working relationships with key clinicians at both sites; (4) identified key local personnel for project staff positions and for the advisory panel; (5) secured Institutional Review approval at USC, with Institutional Review submission at CHLA still under review; and (5) started to collect pilot data at CHLA.

The following three factors have enabled the investigators to rapidly gain entry to the clinical sites: First, the study itself has generated a great deal of interest; second, both CHLA and CCS have a history of collaboration with the occupational therapy department at USC; third, professionals at these sites are very familiar with the investigators' previous work. Both

CHLA and CCS have expressed strong interest in participating in this study, and investigators have had personal meetings with a variety of physicians, occupational therapists, physical therapists, and nurses at both institutions. The investigators have also had the opportunity to discuss how key staff interact with families from a variety of racial and ethnic backgrounds. These meetings have focused on the details of this study, including questions of feasibility and relevance to the concerns and commitments of the institutions.

The study design, including the number of clinical videotapes and family interviews, remains unchanged from the approach proposed in the previous application, with one exception: The study will now include children ages newborn through 8 (compared with the initial proposal, which included children through age 3 only).

The investigators plan to adhere to the timeline and budget as initially proposed, except for a later start date; completion dates would be adjusted accordingly. With increased in-kind contributions from USC, investigators will be able to fully implement the project with the previously approved total amount for direct costs. As a result of this agreement, the investigators have been able to expand their effort from 40 to 50 percent without requesting an increase in salaries.

Questions regarding the researchers' ability to carry out the proposed study at the new site have been fully addressed by the principal investigators. The recommendation is for approval.



Does Education Limit Lead Burden?

Grantee

University of Minnesota School of Medicine

Investigator

Amos S. Deinard, M.D., M.P.H.
Box 85 UMHC
420 Delaware Street, SE
Minneapolis, MN 55455
(612) 627-6888, ext. 212
(612) 627-4205 fax
deina001@maroon.tc.umn.edu

Project Number MCJ-270801

Project Period 1/1/1995-12/31/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	181,294	0	181,294
Year 2	190,646	0	190,646
Year 3	164,559	0	164,559
Year 4	123,475	0	123,475
Year 5	178,599	0	178,599

Summary*Statement of the Problem*

Lead abatement is a costly and disruptive secondary prevention procedure, whose effects benefit only those who live in the abated home. Primary prevention interventions—which may be less expensive and reach more people—are necessary. Establishing the efficacy and cost-effectiveness of such primary prevention strategies will affect policy decisions related to prevention and intervention strategies for lead burden.

Research Questions or Hypotheses

The purpose of this study is to assess the efficacy of a community-based, intensive, culturally specific educational intervention for the primary prevention of lead burden. The goal is to maintain lead levels below 10 µg/dl in offspring of mothers who receive the education. It is hypothesized that the lead levels of the children whose mothers receive the intensive education will remain lower than those of children whose mothers receive the basic education. It is hypothesized that mothers receiving the education intervention will perform better on knowledge-based tests than will mothers who do not receive the intervention.

Year 2000 Objectives

8.11, 11.4

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates, Infants, Toddlers, Preschool-Age Children, Parents/Families/Mothers/Fathers (Adolescent Parents)

Race/Ethnic Focus

African-American, Asian (Asian overall), Hispanic (Hispanic overall), Native American

Study Design and Methods

Two groups—one basic and one intensive—have received educational materials in this randomized trial. The basic educational materials consist of face-to-face advice given routinely to patients by health care providers as well as pamphlets (typically in English but occasionally translated into the participant's native language) commonly found in doctors' offices or distributed by the local health department. All participants have had access to this information throughout the study, regardless of their group assignment. In addition to the basic material, each mother in the intensive education group is receiving 20 intervention sessions, primarily during the first year of the child's life. The intervention is being conducted primarily in the mother's home and in her own language by a peer teacher from her own community and racial or ethnic group who has assisted in developing the form and content of the educational materials. Quarterly booster sessions that are tailored to the developmental stage of the child are conducted (following the first two sessions) for the remainder of the study.

The intensive educational phase and booster sessions have been tailored to the racial or ethnic background of the participant. Through participation in focus groups conducted by the research team, members of different racial or ethnic groups have expressed an interest in receiving more information through different media. Intensive interventions and booster sessions have focused on sanitation, hygiene, and nutritional guidelines for the prevention of lead burden.

Prenatal exposure to lead has been measured by maternal and cord blood levels. Lead levels of the children are being assessed three times per year by analyzing 5 mL of venous blood with atomic absorption spectroscopy. At enrollment and whenever relocation, remodeling, or rehabilitation of the home has occurred, samples of paint, dust, water, and soil have been taken from each participant's home. Dust samples have been collected once or twice per year throughout the study because changes in household sanitation resulting from participation in the intensive education intervention would be likely to affect only this source of lead contamination.

Population and Sampling Plan

Over 600 mothers from the Phillips neighborhood of Minneapolis and parts of adjacent neighborhoods have been recruited during the prenatal period or during their offspring's early infancy. They have been randomly assigned within racial or ethnic groups (African American, Native American, white, Southeast Asian, Hispanic) to an intensive or basic education group.

Analysis Plan

Lead levels of the offspring of mothers in the basic and intensive education groups will be compared to determine whether the levels for those in the intensive education group have remained significantly lower than for those in the basic education group. Data analyses will focus on two primary outcomes consisting of blood lead levels (prenatal and prospectively collected samples every 3 months) and knowledge base (including risks of lead burden, effects of lead burden, and preventive strategies).

Analyses of continuous variables for knowledge and blood lead will be done by general linear models for correlated data (SAS procedure MIXED). This approach will allow for repeated measures when there may be partial data. Dichotomous outcomes (i.e., blood lead levels $>10 \mu\text{g/dl}$) will be analyzed by applying the general linear model to distributions (SAS macro GLIMMIX). In addition, actuarial methods, including Kaplan-Meier nonparametric stratified survival analysis and Cox proportional hazards, will be used to assess time to an outcome.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This proposal makes an effective and convincing argument that home-by-home lead abatement will never adequately address the public health problem of lead exposure in millions of U.S. children. A simple but credible alternative is proposed: Use intensive, culturally appropriate educational interventions to alter household practices with known influences on the degree of exposure to lead in contaminated environments. The study is original because it offers a plausible alternative to current public health practices, and it is important because of the magnitude and potential consequences of lead burdens in the

Nation's children.

Regional and National Significance

The principal issue addressed in this application—the possible short-term and long-term developmental consequences of lead exposure in early life—is an important scientific and public health issue. Recent surveys suggest that environmental lead exposures affect 3 to 4 million U.S. children; of these, 1 in 6 children is younger than 6 years of age. While the neurologic and encephalopathic consequences of acute high-level lead exposures are recognized and well known, little is known about the more subtle behavioral and developmental effects of chronic low-level exposure. If widespread chronic lead exposure can result in deficits in attention and memory, these cognitive and behavioral obstacles to learning would constitute a far greater threat to public health than the occasional acute lead intoxication seen in urban medical centers. Thus, the national significance of the proposed research lies in the possibility that subtle but highly prevalent neurotoxic effects on learning may be present in millions of U.S. children.

Scientific and Technical Merit

The proposed study has several strengths. First, the investigators provide strong justification for a study of a primary prevention intervention to reduce lead burden in young children living in the inner city. The effects of elevated lead levels on the child are well documented as are the costs of lead abatement and its potentially disruptive effect on low-income families. The need for a primary prevention strategy to be implemented in the target community is also thoughtfully argued by the investigators.

Second, the intervention has been generated from the community and assessed for its cultural appropriateness by the investigators. Focus groups have been conducted among Asian Americans, Hispanic Americans, African Americans, and Anglo-Americans to determine the best educational approach for each group. The investigators were solicited by the community to conduct an evaluation of the intervention; the Phillips Neighborhood Lead Collaborative has been established and the investigators have become members. Preliminary studies have also been conducted to assess the relationship between lead levels of children in the Minneapolis inner city, some of whom reside in the Phillips neighborhood, and measures of their intellectual functioning.

Third, the plausibility of an intensive educational intervention is proposed by the investigators. They argue that one-on-one intensive education is more effective than less personal approaches. A well-defined conceptual framework is provided to examine how changes in parent knowledge will affect changes in behavior with regard to sanitation and hygiene and the nutritional status of the child. These changes, in turn, are expected to result in lower lead burdens among children whose mothers receive the intensive educational intervention.

Fourth, the measurements of lead levels, lead exposure in the environment, the mother's knowledge base concerning lead exposure and its prevention, and assessment of the nutritional status of the child are well described in the study proposal. Fifth, the choice of a randomized controlled trial to test the effectiveness of the intervention is appropriate. Stratification by race/ethnicity and clinic of origin in the selection of the sample will ensure that these two potential confounders will be adequately addressed in the design of the study. Moreover, the investigators are aware of the potential education contamination that may occur in the study because of the relatively tightly knit racial/ethnic groups within the community. They have weighed various alternatives to the current study design and have concluded that it offers the best approach, given the logistic, theoretical, and financial constraints.

Sixth, the research team appears to be capable of conducting the project. They have already done a good deal of work in preliminary studies and in reviewing the literature on previous work in the area. The principal investigator has amassed a study team that appears very knowledgeable in the field of environmental toxicology and childhood lead exposure.

Despite the reasoned and articulate discussion of the conceptual and methodological components of the study, some omissions in the proposal may affect implementation of the study. First, recruitment of subjects and their assignment to study groups could have been more completely articulated. The exact clinics from which subjects will be recruited and the number expected from each site are not provided in the project narrative. Moreover, the random method that will be used to assign study subjects to the intensive and basic education groups is not specified. Assignment of these subjects in permuted blocks within racial/ethnic and clinic groups should be considered. Preterm and low birthweight infants as well as infants affected by excessive alcohol or cocaine exposure would be potentially excluded from the sample only if a companion grant on the effect of lead burden on development is funded. These exclusions would seem appropriate, regardless of whether the companion grants were funded.

Second, the educational intervention has not yet been fully developed. An outline of its overall objectives and the content to be covered during each session is presented, but the detailed content for each racial/ethnic group has not been completed. The

timeline indicates that it will be completed prior to the start of the funding period.

The investigators state that the intervention they will design will be modeled after the Expanded Food and Nutrition Education Program (EFNEP) of the U.S. Department of Agriculture. This is a community health education program designed to assist low-income families in improving their diets. The authors cite a number of reports claiming important benefits of this program, though none has appeared in peer-reviewed, scholarly publications. The principal investigator notes that nutrition is important in preventing lead burden; beyond this connection, however, there is little explanation of the manner in which the proposed intervention will benefit from the EFNEP experience.

The proposal includes points where the investigators indicate that they will collect data if a given condition occurs; for example, lead exposure in the family's environment will be assessed upon enrollment in the study and will be assessed again only if the family moves or their home undergoes lead abatement. It would be preferable to measure this exposure again during the study period, perhaps at the end of the first year, to ensure that exposure has not changed for a child whose family has not moved or whose home has not undergone abatement. There are other examples in the proposal where measurements for all children should be considered, not just those presenting with problems.

The major weakness of the proposal is the plan of analysis. It is well organized but brief and is not adequately linked to the conceptual framework. It also does not indicate how the repeated measures of dust samples will be analyzed. More importantly, the analysis plan does not include some of the newer statistical methods that permit the investigators to take full advantage of the richness of the repeated measures that are collected over time. This is particularly true with regard to the repeated quarterly venous blood lead levels and the knowledge levels of mothers at baseline. A final problem with the analysis plan is the lack of any discussion about how the data will be analyzed by racial/ethnic group. Moreover, the power to detect differences in lead burden for each racial/ethnic group is clearly limited by the small numbers expected for some groups and the fact that the sample is already at the lower limits of an acceptable size. It may be possible to compare mean lead levels between the intervention and control groups for each racial/ethnic group, but no discussion of this strategy is presented.

A total of 560 subjects eligible for the study will be recruited through local health clinics and facilities serving children and pregnant women. The eligibility criteria are somewhat unclear. One section of the proposal states that birthweight will not be a criterion unless the companion study is funded, while in another section it is suggested that only infants with birthweights > 2,500 grams will be included in the study. This discrepancy needs attention.

One minor problem is the use of Hollingshead's measure of socioeconomic status (SES). This measure may not be useful with respect to several of the racial/ethnic groups included in the study sample. A more thoughtful assessment of measures of SES is necessary.

Although the quarterly sampling of blood from the children is desirable in many respects, the trauma involved may cause attrition of some subjects. A related issue concerns the benefits of keeping children enrolled in the study past their second birthday. There was no discussion of how many subjects will be available for group comparisons at ages 3 or 4 years, so it was impossible to evaluate power to detect modest effect sizes. Data collection might be scaled back after the children reach age 2 in order to save cost. Some discussion of this option should have been offered.

Although some effort will be made to characterize subjects who drop out of the study and those who refuse to participate, the proposal contained no discussion of how data from dropouts will be handled. In general, this data ought to be retained in the analysis.

A final problem with the proposal is the budget. The costs for year 1, for example, appear excessive, given the plans outlined in the proposal.

The proposed research was judged to have numerable strengths, particularly the involvement of the community. Questions were raised about the budget, process of randomization, potential exclusion of subjects, possible contamination of the control group, the use of the Hollingshead measure, the uncompleted content of the intervention, and the lack of connection between the data analysis plan and the conceptual framework driving the study. The recommendation was for approval following a site visit to clarify questions raised.



Does Lead Burden Alter Neuropsychological Development?

Grantee

University of Minnesota School of Medicine

Investigator

Elsa G. Shapiro, Ph.D.
 School of Medicine
 Box 486 UMHC
 420 Delaware Street, SE
 Minneapolis, MN 55455
 (612) 625-7466
 (612) 625-7950 fax
 shapi004@maroon.tc.umn.edu

Project Number MCJ-270302

Project Period 12/1/1995-8/31/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	207,047	53,832	260,879
Year 2	243,616	58,578	302,194
Year 3	273,572	65,781	339,353
Year 4	307,180	73,862	381,042
Year 5	207,355	49,859	257,214

Year 2000 Objectives

2.10, 8.3, 11.4

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

Infants, Toddlers, Preschool-Age Children

Race/Ethnic Focus

African-American, Asian (Asian overall), Hispanic (Hispanic overall), Native American

Summary

Statement of the Problem

Prospective studies, as a whole, demonstrate that low levels of lead have an effect on intellectual development. While the effect (a decrease of 4 to 8 I.Q. points) may not make a profound difference on an individual level, it has been shown that a downward shift of 4 I.Q. points in the population places four times as many children within the lower tail of the distribution and results in a substantial loss within the gifted range as well.

The effects of lead on I.Q. have been demonstrated in several cross-sectional studies of older children and in prospective studies of global cognitive development in young children. However, controversy surrounds the validity of those findings, due to methodological difficulties. Effects of lead on specific neuropsychological functions have not been well documented and several questions remain unanswered.

First, could deficits in component neuropsychological functions, such as attention and memory, which are important to intelligence test performance, result from lead burden? Second, are there windows of time during which children are at greater risk for long-term or specific neuropsychological deficits due to the state of the maturing nervous system at the time the child was first burdened with lead? Third, are findings dependent on the method of measuring neuropsychological

outcome? Fourth, have all confounding factors been accounted for, or might lead burden coexist with other factors that could influence neuropsychological development? Specifically, do the factors of nutrition and iron deficiency influence the relationship between lead burden and attention and memory?

Answers to these questions have implications for health care delivery and educational intervention for children affected by lead. Greater understanding of the contribution of other health risks to lead burden sequelae (such as nutrition and iron deficiency) has implications for delivery of primary care focusing on nutrition education for parents of children at high risk for lead burden. Greater understanding of the interaction of developmental factors and lead burden on attention and memory will help focus the diagnostic and intervention efforts of schools attempting to understand curriculum and special education needs of burdened children. In addition, should attention in lead-burdened children be found deficient, medical intervention (namely, administration of stimulant medication) may prove to be an effective method of addressing an important neuropsychological deficit in affected children.

Research Questions or Hypotheses

The purpose of this investigation is twofold: (1) Ascertain the effects of age when first burdened with lead, duration of lead burden, and magnitude of lead burden on children's development of attention and memory from 12 to 48 months of age; and (2) explore the relationships between lead and attention and memory as a function of the method of measuring these areas. The research will also address how early nutrition and iron status influence the relationships between lead and attention and memory.

Study Design and Methods

All children will receive a baseline developmental assessment at 8 months of age. Children will then be seen 11 times between 12 and 48 months of age to complete the Bayley Scales of Infant Development-II or the Wechsler Preschool and Primary Scales of Intelligence, neuropsychological and experimental measures of memory, or experimental measures of attention. Different measures will be administered at each testing session to achieve six time points for developmental status, attention, and memory domain assessments.

The neuropsychological and experimental measures will be administered by trained technicians indigenous to the community and representative of the ethnic makeup of the neighborhood. In addition, electrophysiological measures of attention and memory will be administered to a subgroup of lead-burdened children and controls (matched for age, race, sex, and an average of Bayley scores prior to lead burden) at approximately 8-month intervals from the time of initial lead burden. It is expected that 30 percent of the sample will be identified as having lead burden over the course of the study.

Population and Sampling Plan

Approximately 560 children from an ethnically diverse inner-city neighborhood of low socioeconomic status will comprise the study sample for this research.

Analysis Plan

Using hierarchical linear models, analyses will be conducted to relate the observed development of attention and memory functions to lead-related variables, including age when first burdened with lead, duration of burden, and severity of burden. Correlational analysis will be conducted to explore differences in the relationship between lead burden and attention or memory function, depending on method of measurement.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This proposal will provide valuable information on the effect of lead burden on cognitive development in young children.

Regional and National Significance

Lead exposure among young children is of national concern, thereby making the results of this study of regional and national significance.

Scientific and Technical Merit

This is a revision of a proposal previously reviewed and recommended for disapproval. The research is now focused on measures of attention and memory in relation to age of first lead burden, magnitude of lead burden, and duration of lead burden.

The proposed research has a number of important strengths. The investigators provide an excellent literature review and rationale for the study. The investigators will perform frequent blood lead sampling using reliable collection methods and atomic absorption spectroscopy. This is the first longitudinal study investigating attention, learning, and memory using a multimethod approach. The investigators plan to measure a large number of potential confounders but will reduce the number that will actually be used in the analysis to avoid over-correction for lead-related variance. Finally, the study sample will include children from an entire community with ethnically diverse backgrounds, with careful attention to the potential differences that may be found between participants and nonparticipants.

A second strength of the proposed research is the study design and sampling plan. The study will include repeated measures not only of the blood lead levels of the children but also of memory and attention. This design will permit the investigators to develop growth curves that can be used to determine whether the pattern of growth and development differs from the normal pattern even before changes in levels of memory or attention are noted. Thus, the more subtle effects of low levels of lead burden can be investigated. As noted previously, the study sample allows for the study of these effects in an ethnically diverse population.

The investigators present detailed and reasonable plans regarding recruitment and tracking of study subjects. The use of indigenous community workers to collect data is also a strategy that may increase compliance with the study.

The investigators have an excellent working relationship with the community. In fact, the investigators were solicited by the community to conduct an evaluation of an intervention to reduce lead levels among children in the community. The community has established a Phillips Neighborhood Lead Collaborative, which includes the investigators as members.

The investigators also present a detailed description of the study instruments. The measurements of lead levels, attention and memory, nutritional status of the child, and potential confounding variables are well described in the study proposal.

Moreover, the use of multiple approaches to measure memory and attention is an important strength of the proposed study.

These approaches include experimental, neuropsychological, observational, and physiological measures. In addition, the investigators will measure blood lead levels, the age at which lead burden was first noted, and the duration of this burden. Each of the variables to be developed from the study instruments, and the ages at which they will be obtained, are clearly described.

The research team is clearly capable of conducting the project, and the collaboration with the prevention study is a major strength of the proposed work. The investigators have already done a good deal of work in preliminary studies, particularly in developing study instruments and reviewing the literature on previous work in the area. The investigators have shown considerable creativity in developing instruments from previously established ones and adapting them for use with the study sample.

A final strength of the proposal is the plan of analysis, which is well thought out and clearly described. This plan is carefully integrated with the study questions and hypotheses and includes a clear and reasonable discussion of the advantages of using hierarchical linear modeling as the statistical method of preference in the analysis. The investigators were careful to avoid over-correcting for lead-related variance by including multiple correlated confounding variables.

In addition to retaining the strengths of the original proposal, the current plan also retains some of its weaknesses. It was noted previously that at least four separate fundable studies were embedded in the project. Essentially, the principal investigator has dropped one (neuropsychological functioning after chelation therapy) and eliminated some of the variables from the others. There remains an ambitious series of testing, including serial measures of overall developmental functioning (using the Bayley Scales of Infant Development and the Wechsler Preschool and Primary Scale of Intelligence), attention (with at least five different measures), memory (with at least four different measures), lead, iron, Home Observation for Measurement of the Environment (HOME) interviews, and other parent interviews—in addition to measures of confounding variables such as parental I.Q., socioeconomic status, family configuration, family size, substance use, parental psychopathology, birthweight, Apgar scores, gestational age, perinatal complications, and anthropometric measures of nutritional status of the children.

The principal investigator has not addressed the issue of how the coexisting educational intervention study will impact on the generalizability of the current study's results. Since one of the goals of the intervention study is to break the relationship

between poverty, parental education, and lead poisoning, the relationships between these variables may affect the current analyses. Although one might argue that the educational intervention will not interfere with all assessments of the relationship between elevated blood lead level and event-related potential (ERP) measures of attention and memory, certainly the role of the confounding variables will be different in this sample than it would be in almost any other inner-city sample. This issue has yet to be addressed in the present proposal.

In response to the previous review, revised power calculations are presented in the present proposal. Although power is good for the analyses that are based on the entire sample (approximately 450), power is relatively low for analyses involving the subsample of 50 burdened children and their matched counterparts. For example, power is less than 80 percent to detect a correlation of .30 between lead and attention with this sample size, according to the calculations presented in the proposal. The use of community workers to collect neuropsychological data, while a strength in terms of fostering good working relationships with the community, may not yield optimal data for some of the measures. For example, the Bayley Scales of Infant Development usually require considerable training to administer, and it is not clear whether 50 hours of training will be enough to train the technicians in the administration of all of the instruments. Another issue involves confidentiality of the test results. While the investigators indicate a set of reasonable procedures to ensure confidentiality of the results, including blinding the technicians to lead levels and remedial services, some plan for careful monitoring of the community technicians may be necessary, at least at the beginning of the study.

Another potential problem involves the invariant ordering of the tests to be done at each session. This ordering may lead to poorer quality data for the tests performed at the end of a session because of fatigue. A better strategy would be to randomly order the tests to ensure that errors due to fatigue will be randomly distributed across the tests.

Although the plan of analysis is conceptually sound, there is no discussion of racial/ethnic differences or of the treatment effects that may result from the inclusion of subjects in the educational intervention in the prevention study.

The investigators have not stated the reasons why they will repeat, in year 4, some of the baseline measures taken in year 1. This strategy is not optimal because it coincides with the last measurements of lead levels and memory and attention and does not permit the investigators to take full advantage of longitudinal collection of data. Collection in year 3 would be preferable because the data could be used in the analysis of the repeated measures of levels and attention and memory measures.

The proposed study is well thought out and includes an excellent design to answer the study questions. The recommendation is for approval.



Early Child Care Study of Children with Special Health Needs

Grantee

University of Washington

Investigator

Cathryn L. Booth, Ph.D.
 CHDD, 106 South Building
 Box 357920
 Seattle, WA 98195-7920
 (206) 543-8074
 (206) 685-3349 fax
 ibcb@u.washington.edu

Project Number MCJ-530640

Project Period 4/1/1994-3/31/2001

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
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

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

Year 2000 Objectives

8.3

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

Infants, Toddlers, Preschool-Age Children,
 Parents/Families/Mothers/Fathers (Adolescent
 Parents)

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

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 (30 month visit only). The 45-month assessment will be conducted by telephone and in the laboratory.

Population 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 are 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 Caucasian.

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 backwards 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 backwards 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 backwards 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 analyses of 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) covariate 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. In other words, the relation 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.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This research should make a major contribution to our understanding of the effects of out-of-home child care on the development of young children at risk and those with identified disabilities.

Regional and National Significance

The research proposed in this application addresses a subject about which very little is known. With the increasing number of dual-worker families and single-parent households, child care for young children, including those with special needs, has become an increasingly important issue. Thus, this study is of regional and national significance.

Scientific and Technical Merit

This is a revision of an application previously reviewed and disapproved. This application, like the previous one, is well written and the investigators have been responsive to reviewers' previous comments.

One of the concerns noted in the first review was the omission of early intervention services as a potential source of influence on child and family outcomes. Early intervention effects were neither included in the literature review and model nor addressed in the data collection plan. The revised application reviews the literature on the impact of early intervention and includes potential effects of these services in the theoretical model. Early intervention is expected to have maximum effects on child outcomes when it is extensive over time, includes family involvement, and includes communication between the early intervention program and the child care provider. Early intervention is hypothesized to interact with the effects of alternate child care, with the alternate care effects as the more powerful of the two influences.

Data will be collected on numerous aspects of the child's and family's involvement in early intervention programs. The content of the Individualized Family Service Plan (IFSP) will also be analyzed and the range of services noted. These revisions satisfy the concerns expressed by the original review panel and significantly strengthen the potential contribution of the work.

Concern was also expressed in the initial review about the appropriateness of the strange situation attachment measure for the theoretical model used in the study and for the sample of children to be studied. This measure has since been dropped from the research protocol. A new mother-child observational measure, in which three toys are presented in separate boxes, will be substituted. This observational situation seems more appropriate for the purposes of the study.

The first application included insufficient information concerning the characteristics of the sample. This section has been strengthened, though it still lacks detail. The potential for overlap between the disability and risk groups still exists, given that the main factor separating the groups is the agency from which they are recruited, rather than nonoverlapping subject criteria.

The original review suggested that more information would have been helpful concerning how certain research procedures (such as the play observation) would be adapted for children with physical disabilities. This was not addressed in the revision. And, although the revised application provides additional information justifying the choice of the Bayley Scales of Infant Development as a developmental outcome, this justification is still not strong, particularly given the ambiguity in administering the Bayley Scales to children with cerebral palsy and other physical disabilities.

The question in the initial review concerning the type of child care environment experienced by children with disabilities has been satisfactorily addressed, with the description of service systems that provide generic inclusive child care for children with disabilities and special health needs. Although the researchers plan to oversample families who have placed their children in child care by 15 months of age, it is not clear what proportion of children with disabilities are in alternate care

settings by that age. Information is needed on the use of child care settings in the Seattle area by children with identified disabilities at that early age.

Resources appear adequate for the project, and the researchers are well qualified to conduct the proposed study. The budget is very high, given the workplan.

Approval is recommended with sizable reductions in budget and contingent upon the researcher's providing the Maternal and Child Health Bureau with data demonstrating that the number of children with disabilities and chronic illnesses being served in child care by 15 months of age is sufficient to constitute the sample for this study. This information is needed to assure that the study design can be implemented with a sample that meets the specifications of the power analyses.



Effect on Breastfeeding of Pacifiers and Bottle Feeding

Grantee

University of Rochester

Investigator

Cynthia R. Howard, M.D.
 School of Medicine, Department of Pediatrics, Box 238
 1425 Portland Avenue
 Rochester, NY 14621
 (716) 336-3926
 (716) 336-3929 fax
 cindy_howard@viahealth.org

Project Number MCJ-360752

Project Period 10/1/1996-9/30/2001

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	132,951	38,556	171,507
Year 2	170,475	49,438	219,913
Year 3	116,907	33,903	150,810
Year 4	3,002	1,441	4,443
Year 5			

Year 2000 Objectives

2.11, 14.9, 20.9

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Infants, Neonates

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Healthy People 2000 goals state that 75 percent of women will initiate breastfeeding and 50 percent will continue to breastfeed at 5–6 months. Currently, about 59 percent of women initiate breastfeeding and as few as 20 percent are still breastfeeding at 6 months. Proper sucking technique is believed to be critical in establishing breastfeeding and preventing early breastfeeding problems. Observational studies of pacifier use indicate a possible association with shorter breastfeeding duration; however, the effects of pacifier use and artificial nipple use during bottlefeeding or breastfeeding have not been evaluated using rigorous scientific methods. Given the numerous health benefits of breastfeeding, scientific investigation of the effect of early artificial sucking experiences on the ability of newborns to successfully breastfeed is of profound relevance and importance to maternal and child health in the United States.

Research Questions or Hypotheses

The specific aim of this study is to minimize obstacles that prevent the successful establishment of breastfeeding. This study is designed to ascertain the effect of artificial nipple experiences (pacifier use and bottlefeeding) on the successful

establishment of breastfeeding. Interaction between exposure to artificial sucking experiences and successful breastfeeding are hypothesized to occur, placing infants who experience both early pacifier use and bottlefeeding at highest risk and those exposed to later pacifier introduction and no supplemental feeding at lower risk for adverse outcomes.

The specific hypotheses addressed by this study are as follows:

1. Early pacifier use (within 2–5 days of birth) compared to no pacifier use by breastfed infants is associated with reduced breastfeeding duration and increased breastfeeding complications during the first month of life. Specifically, it is hypothesized that early pacifier use (a) decreases the duration of exclusive breastfeeding; (b) decreases the duration of overall breastfeeding; (c) increases the incidence of maternal breastfeeding complications including nipple trauma and engorgement; (d) increases the incidence of infant breastfeeding complications, including increased postnatal weight loss, increased time until birthweight is regained, and incidence of feeding-related hyperbilirubinemia; (e) decreases the chances that the mother will attain her personal breastfeeding goal; and (f) increases the incidence of early supplemental feeding during the first 2 weeks of life.
2. Early pacifier use (within 2-5 days of birth) compared to late pacifier use (after 4 weeks of life) by breastfed infants is associated with reduced breastfeeding duration and increased breastfeeding complications during the first 6 months of life. It is hypothesized that early pacifier use (a) decreases the duration of exclusive breastfeeding; (b) decreases the duration of overall breastfeeding; (c) increases the incidence of maternal breastfeeding complications including nipple trauma and engorgement; (d) increases the incidence of infant breastfeeding complications, including increased postnatal weight loss, increased time until birthweight is regained and incidence of feeding-related hyperbilirubinemia; and (e) decreases the chances that the mother will attain her personal breastfeeding goal.
3. In breastfed infants who require early supplemental feedings, bottlefeeding as compared to cup feeding is associated with reduced breastfeeding duration and increased breastfeeding complications. It is hypothesized that early supplemental bottlefeeding in breastfed infants (a) decreases the duration of exclusive breastfeeding; (b) decreases the duration of overall breastfeeding; (c) increases the incidence of maternal breastfeeding complications including nipple trauma, engorgement, early breastfeeding cessation (while in the hospital), and longer postpartum length of stay; (d) increases the incidence of infant breastfeeding complications, including increased postnatal weight loss, increased time until birthweight is regained, increased incidence of feeding-related hyperbilirubinemia, lower rates of full breastfeeding at discharge, and increased rates of required early followup (within 48 hours); (e) decreases the chances that the mother will attain her personal breastfeeding goal; and (f) increases the incidence of early supplemental feeding, increasing the numbers of supplemental feedings required in the hospital and during the first 2 weeks of life.

Study Design and Methods

This randomized, single-blinded, clinical trial seeks to evaluate the effects of artificial nipple exposure in breastfed infants on the incidence of breastfeeding complications and breastfeeding duration. Healthy breastfed infants of participating women will be randomized to two pacifier study groups: (1) Pacifier use beginning after hospital discharge (within 2-5 days of birth) or (2) pacifier use beginning during the fifth week of life. Participating infants who require supplemental feedings as part of their newborn care will be randomized to the supplemental feeding intervention. Supplemental feedings will be administered by cup or bottlefeeding. Interviews conducted during postpartum hospitalization, feeding observations, chart reviews, and 6 months of prospective followup will be used to ascertain differences in breastfeeding complications and duration.

Population and Sampling Plan

Pregnant women will be recruited prenatally to participate, and informed consent will be obtained. Approximately 20 percent of the women participating in this study are being recruited from minority and/or impoverished populations.

Analysis Plan

Descriptive statistics will be prepared, and normality of continuous variables will be checked. Comparability of the intervention groups will be analyzed using the chi-square test, Fisher's Exact Test, Student's *t*-test, and the Wilcoxon test as appropriate. Variables for the comparison will be prespecified. Three primary outcome comparisons will be made: (1) The effect of cup feeding versus bottlefeeding on the duration of breastfeeding among those who required supplemental feeding while in the hospital; (2) the effect of early versus late pacifier introduction on the duration of breastfeeding to 6 months; and

(3) the effect of early versus no pacifier introduction on the duration of breastfeeding to 1 month (early group versus the late group in which pacifier use does not begin until the fifth week). Survivorship methods including the Kaplan-Meier regression model and the Cox proportional hazards model will be used to adjust for possible confounding variables. Secondary analyses will examine the effects of both interventions simultaneously.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

Rates of breastfeeding initiation and continuation are disappointingly low in the United States. This project is designed to address one reason for poor continuation of breastfeeding: "Nipple confusion," brought about by the early (in the first few days of life) introduction of pacifiers and/or bottle feedings. The investigators postulate that under these circumstances an infant learns improper sucking techniques, which interferes with breastfeeding. The infant is then less able to empty the breast effectively, which may lead to difficulty in establishing an adequate milk supply or other complications. When this happens, the infant may be given more supplemental feedings, which may only exacerbate the problem, leading to early cessation of breastfeeding. This biological mechanism makes intuitive sense and is in accord with clinical experience.

Regional and National Significance

The United States is far from achieving the Surgeon General's targets for breastfeeding initiation and duration, and the trends are actually worsening. Research that might improve breastfeeding success is important to public health and Maternal and Child Health Bureau (MCHB) goals. Therefore, this project has regional and national significance.

Scientific and Technical Merit

The proposed randomized, factorial design is the appropriate experimental procedure for testing the investigators' hypotheses. Randomization will be stratified by insurance source to ensure that differences in socioeconomic status are accounted for in the treatment groups. The research design is attractive because it requires minimal interference with usual practices (only half of the parents will have to delay the introduction of pacifiers, and alternative ways of comforting their infants will be provided). No change in parental behavior is required for the bottle/cup portion of the study, because this applies to supplemental feedings given by hospital staff.

It is important to remember that there are numerous other reasons for early cessation of breastfeeding. These include lack of cultural support for breastfeeding, lack of adequate maternity leave, lack of child care at or near the workplace, and lack of facilities for pumping breast milk in the workplace. These other reasons may be as or more important than "nipple confusion," and the investigators must detect an effect of their treatments within this generally unsupported milieu. Power calculations are provided, but unfortunately no data are provided to support the expected differences described for the supplementation or the pacifier. This renders these calculations less persuasive than they could be.

It is not clear why secondary analyses are required for investigating the postulated interactive effects. Such effects can be obtained as part of the overall data analysis strategy by simply categorizing the infants by their exposure to supplemental feeding and the type of supplemental feeding (nested design).

The single-blinding is questionable. How can the interviewer be blind when the subjects are asking questions about supplemental feeding and breastfeeding? The sample size is well-justified. However, crossover may decrease the expected differences among the supplemental feeding groups and early and late use of pacifier groups.

The research will be carried out in a community hospital with 2,800 deliveries each year. This hospital includes a high proportion of women who deliver healthy infants and choose to breastfeed them. The data collection forms are already available. The principal investigator has developed these for another ongoing research project; thus, no investment is needed for their development.

The principal investigator, Dr. Cynthia Howard, is a pediatrician with additional training in public health. The other members of the proposed staff are well-qualified for their roles.

The personnel commitment for the statistical analysis seems excessive for a project that is essentially a chart review plus several brief telephone interviews to ascertain whether and to what extent breastfeeding is continuing. Similarly, the personnel commitment for "vision" and general "consultation" seems excessive.

There are no concerns regarding the use of human subjects. Subjects will receive normal pediatric care. Those instructed to delay the introduction of a pacifier will receive instructions in comforting a crying baby.

This study has a plausible, biologically based hypothesis and an appropriate, realistic design. Study findings will likely lead to a change in hospital practice and how parents are counseled about comforting their infants. These changes may result in an improvement in the duration of breastfeeding. The major weaknesses of the study are the excessive budget and the lack of persuasive power calculations. Nevertheless, the recommendation is for approval.



EICS Phase IV: Adolescence

Grantee

Boston College

Investigator

Penny Hauser-Cram, Ed.D.
School of Education
Developmental Psychology
Campion Hall
Chestnut Hill, MA 02167
(617) 552-8664
(617) 552-1981 fax
hausercr@bc.edu

Project Number R40MC00135-01

Project Period 3/1/1999-12/31/2002

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	154,673	70,518	225,191
Year 2	155,602	75,002	230,604
Year 3	171,951	46,709	218,660
Year 4	159,772	37,081	196,853
Year 5			

Summary***Statement of the Problem***

Contemporary early intervention services, guided by Part H of the Individuals with Disabilities Education Act (IDEA) (renamed, Part C of the re-authorized IDEA), are designed to enhance the responsiveness of the caregiving environment in a way that is assumed to have an impact far beyond the early intervention experience. Little longitudinal research has been conducted to evaluate the relations among services provided in early intervention programs, and child and family outcomes during the adolescent period.

Research Questions or Hypotheses

The broad project goals are to: (1) locate key points of change, and potential points of intervention, in the developmental trajectories of children and families between early childhood and adolescence; (2) focus on the differential impacts on maternal and paternal well-being and on the particular roles of fathers in parenting an adolescent with disabilities; and (3) examine the relation between adolescents with disabilities and the health care system. The study also aims to elucidate

Year 2000 Objectives

1.14, 16.14, 28.4

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

Adolescents

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

predictors of long-term vulnerability and resilience among recipients of early intervention services in order to inform policy decisions regarding long-term service planning for children with special health needs and their families.

Study Design and Methods

This study is a continuation of an observational, prospective, noninterventional, longitudinal investigation funded by the Maternal and Child Health Bureau: MCJ- 250644, Early Intervention Collaborative Study: Age 10 Follow-Up (July 1, 1994 through June 30, 1997), MCJ-250583, Early Intervention Collaborative Study: Preschool Phase (April 1, 1989 through Dec. 31, 1993) and MCJ-250533, The Early Intervention Collaborative Study: Phase One (Jan. 1, 1986 through June 30, 1989). Seven waves of in-home and school-based assessments have been completed for an initial sample of 190 children and families from their entry into an early intervention program (mean age 10.6 months) through age 10. Early study outcomes included aspects of children's cognitive and social development and family adjustment.

Follow-up home-based child and family assessments and school-based data collection are being conducted at age 15. Core adolescent outcomes included three aspects of social competence: social connectedness, autonomy, and efficacy. Core family outcomes include four aspects of parent well-being: depressive symptoms, parenting stress, parent-child relationship, and perceived senses of competence as a parent.

Population and Sampling Plan

The sample is comprised of 148 children who had early developmental delays or disabilities (Down syndrome, motor impairment, or developmental delay of unknown etiology) and their families who received early intervention services from community-based programs in Massachusetts and New Hampshire between 1985 and 1991. At age 10 (the last data collection point for which we have complete data), 62.2% were mentally retarded. The majority of the participating families are Euro-American (92.5 %); 36.9% of families have income below the U.S. median; 62.8% of mothers are employed. Race or ethnicity is not a focus of this project. At age 10, 90% of the children received special education services. The mean cognitive composite at age 10 (on the Stanford-Binet Intelligence Scale) was 63.0 (SD=30.2) and the mean adaptive behavior score (on the Vineland Scales of Adaptive Behavior) was 52.3 (SD= 21.8).

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This project seeks funding for its Phase IV investigation into adolescence of a cohort of children and families who participated in the EICS. The proposal represents the next logical step in the longitudinal research related to the EICS program by this investigative group. The worth of the research overall is dependent upon the longitudinal questions that are involved. Importantly, little research has addressed the adolescent period to which the EICS now will turn its attention.

Regional and National Significance

The EICS has been a premier research program supported by the Maternal and Child Health Bureau, and the volume and quality of the work that has emerged from this study speaks to its significance. The proposed work will begin to fill an important void in the field of developmental disabilities, magnifying the national significance of this project.

Scientific and Technical Merit

There are several strengths apparent in this work. The sample remains intact and the sample subjects are interested in continuing their involvement. The availability of nearly 140 children and their families is an incredibly valuable resource that could not be easily duplicated. The investigators have articulated a conceptual framework that guides their choice of measurements. The framework offers a number of intriguing possible explanations of competence and well-being outcomes, the measurements appear well selected to represent reliable indices of the constructs of interest, and the basic data analytic strategies to be employed are appropriate to questions at hand. Finally, the Project Manager continues to be a staff member present from the inception of the EICS. The investigative team is exceptional and there is little doubt that excellent work

will continue to emerge from this ongoing investigation.

The hypotheses reflect a rich use of the data available from earlier data collections in the project as well as the data to be collected in this phase. The research focus that addresses developmental trajectories of the adolescents with developmental disabilities incorporate an array of mediated relations and growth trajectories that can be explored and provide a more comprehensive view of the processes that are likely involved. The same is true for the second focus on parents and families. Lastly the research focus on health status of the adolescent remains a particular strength of the work to be accomplished.

Attrition will influence study power and the analysis plans, but does not suggest that the work cannot be accomplished. The plan is now 10%, which seems reasonable given the level of involvement families have had with this project. The PI also presents strategies for re-contacting, re-acquisition, and maintenance of the sample.

Discussion about the characteristics of the available sample families, particularly in relation to fathers and siblings, suggest that a sufficient number of fathers and siblings are available for study. Also, plans are made in the procedures for collecting questionnaire data so that information between parents will not be shared (eliminating possible collusion), and the PI presents a table in which the measurements and their formats are listed.

Finally, the PI has added a teacher report index of children's social competence. This will obviate the issue that all the child assessment data came from a single source ("within family").

The principle investigator, along with the rest of the team, is exceptionally well qualified to conduct this work. They have worked together productively for some time and will no doubt continue to do so.

The budget seems appropriate to the work scope.



Evaluation of Hawai's Healthy Start Program - Phase Two

Grantee

Johns Hopkins University

Investigator

Anne K. Duggan, Sc.D.
 Division of General Pediatrics, Research Center
 1620 McElderry Street, Room 203
 Baltimore, MD 21205-1903
 (410) 614-0911
 (410) 614-5431 fax
 aduggan@jhu.edu

Project Number MCJ-240838

Project Period 4/1/1998-3/31/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1			
Year 2			
Year 3			
Year 4			
Year 5			

Year 2000 Objectives

6.14, 7.4, 7.14, 8.3

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Parents/Families/Mothers/Fathers (Adolescent Parents)

Race/Ethnic Focus

Filipino, Hawaiian Native, Japanese, Pacific Islander

Summary

Statement of the Problem

Hawaii's Healthy Start Program (HSP) is a well-established outreach program that provides community-based screening to identify newborns at environmental risk for child abuse and neglect. HSP also provides for home visiting by paraprofessionals to promote healthy family functioning and child development through role modeling, education, and linkage with pediatric primary care and other needed community resources during the child's first 3-5 years of life. Nationally, home visiting programs (in general) and HSP (in particular) receive strong endorsement. Efforts to establish community-based home visiting programs, however, have been impeded by several unresolved issues: (1) The mixed results of past evaluations, (2) the limited study of nonnurse home visiting, (3) the evaluation of demonstration projects rather than established programs, (4) the little research on the types of families most likely to benefit, (5) the uncertain cost benefits of home visiting, and (6) the lack of information on the impact of home visitation on the fathers' role in parenting. These issues render evaluation findings essential for informed policy and program development.

Research Questions or Hypotheses

As described in the abstract titled "Evaluation of Hawaii's Healthy Start Program," which is in this publication, Phase One of the evaluation addresses the following four questions:

1. How closely does program implementation mirror program design?
2. How successful is the program in achieving intended benefits for children and families?
3. How does fidelity of implementation influence program achievement of intended benefits?
4. How do achieved benefits compare to direct and indirect program costs?

Phase Two of the evaluation addresses two additional questions:

1. How does the HSP affect paternal functioning and maternal perceptions of it?
2. How does the HSP affect the concordance of fathers' and mothers' parenting attitudes and beliefs?

Study Design and Methods

This ongoing, community-based, randomized trial is the largest, most rigorous study of the HSP model. The study's goals are to measure program process, assess program impact on family functioning and on child health and development, relate process to outcome, and determine cost benefits. In the original study, family functioning is operationally defined in terms of maternal parenting attitudes, beliefs, practices and self-perception, life course, and psychological well-being.

From November 1994 through December 1995, we recruited 684 at-risk families of newborns. We randomly assigned them to HSP or control groups, and we are monitoring them until the infants are 3 years old. We collected baseline and annual followup data through HSP record review, structured maternal interview, and several strategies that focused on the index child: Observation of the home environment and mother-child interaction, child developmental testing, review of pediatric medical records, analysis of health-care-use files, and review of Child Protective Service records.

Although not part of the original workplan, we collected detailed information on fathers through maternal interviews during baseline and annual followup assessments. Thus, we have longitudinal data on several aspects of the father's role as follows: (1) His relationship with the mother; (2) his prenatal involvement; (3) the mother's desires and expectations for his involvement in parenting during the child's first 3 years of life; (4) her report of his accessibility, engagement in child rearing, and sharing of parenting responsibilities during the child's first 2 years of life; and (5) her report of his educational and vocational course, substance use, and approaches to resolving conflicts with her.

As noted earlier, the HSP aims to improve family functioning. To this end, services are offered to both parents and to extended family members, not just to the mother. Phase Two allows us to assess HSP effects more fully by measuring impact directly on both parents, not just the mother.

Phase Two involves interviews with fathers and direct observation of father-child interaction. Measures were selected on the basis of demonstrated validity and reliability, appropriateness for the Hawaiian population, objective assessment, and prior use in studies of home visiting.

Parenting behaviors are measured in several ways. Abidin's Parenting Stress Index assesses parental distress, parent-child dysfunctional interaction, and the parent's perception of the child's temperament. Using Lamb's typology of accessibility, engagement, and responsibility as domains of parenting, we developed items to measure the father's desire, expectations, and reported behavior in each area. Observed parent-child interaction is measured by using the teaching scale of the Nursing Child Assessment Satellite Training Scales. Caldwell's observational Home Observation for Measurement of the Environment Scale is used to measure the home environment. Parent employment and education interview items are drawn from existing national surveys. Psychological well-being is measured using the short form of the Rand Mental Health Inventory (MHI). The MHI focuses on two aspects of general mental health: Anxiety and depression. Substance use, stages of use, treatment, and consequences of use are measured using several existing scales, including quantity and frequency of consumption, symptoms, and consequences of use items drawn from the Addiction Severity Index; the AUDIT, CAGE, S-MAST, and T-ACE; and Prochaska and DiClemente's Stages of Change Model (e.g., contemplation to stop or modify use, action to seek formal or informal treatment, maintenance of nonuse or relapse).

Population and Sampling Plan

The target population is families of newborns at environmental risk for special health needs. The accessible population was families of newborns on Oahu who were identified as being at risk during study recruitment. A family was eligible for the HSP if the family (1) lived in an HSP catchment area, (2) was assessed as being at risk, and (3) was not already known to Child Protective Services. A family was eligible for the evaluation if the following applied: (1) The family was assessed eligible for the HSP, (2) the mother did not need a translator (less than 3 percent need a translator), (3) the family was

assessed at the time of the infant's birth (less than 20 percent are prenatal referrals), and (4) the family had never been enrolled in the HSP. About half of the study parents were married or living together at the time of the index birth. Phase Two is limited to these families because the HSP targets services to these fathers.

Early identification (EID) assessment and study recruitment activities were integrated. Families were recruited by EID workers by using the usual HSP protocol to identify at-risk families of newborns at each hospital on Oahu. By protocol, all families in HSP target areas were screened and assessed. If the family was at risk, the EID worker described the HSP and the evaluation and asked for a signed informed consent. After obtaining consent, the EID worker called the study fieldwork office to learn the family's group assignment and then shared this information with the parents. The fieldwork director made the assignment by adding the family's name to a log with preassigned study numbers. Subsequently, a study interviewer, who was unaware of the group assignment, conducted the baseline maternal interview at the hospital.

The intent-to-treat model is our main approach for assessing program effectiveness, but the study is designed to assess program efficacy as well. By design, we assigned a larger proportion of subjects to the HSP group to compensate partially for sample losses from program attrition and to increase statistical power to assess family and agency influences on engagement. All study families are followed for 3 years, regardless of whether they stay in the HSP. Program effectiveness is assessed by using the intent-to-treat model (i.e., outcomes are measured with regard to family assignment to the HSP, regardless of the intensity of services a family receives through the HSP). However, to measure program efficacy (impact under ideal conditions) and dose-response effects, we used a group-allocation ratio weighted toward the experimental group. Families are followed from the infant's birth through his or her third birthday, with baseline and annual data collected (for intervention and main control groups) for key outcome variable indicators. The paternal assessments are conducted in conjunction with the final maternal and child followup assessments.

Analysis Plan

HSP's "Impact on Paternal Functioning and Maternal Perceptions of It: Phase Two" allows us to test two hypotheses of HSP's effects on both parents' assessments of the father's role. For each of these outcomes, the null hypothesis of no differences among members of the HSP and the control groups is tested. The outcome variables that are measured are of three basic types: Binary (e.g., any involvement by the father in child-rearing responsibility), counts (e.g., the number of pediatric visits in which the father participated), and indexes or scales (e.g., the father's Center for Epidemiologic Studies depression scale score, measures of father-child interaction). For each study group, the scale variables are analyzed to determine appropriate transformations and groupings. The methodology used is that of exploratory data analysis in the context described by Hoaglin, Mosteller, and Tukey. Internal consistency of composite scores for scaled indexes is investigated using Cronbach's alpha.

The techniques of generalized linear models are used to investigate the relationships between each basic outcome and the covariates. Depending on the nature of the outcome measure, logistic, log-linear, or linear regression is used.

For HSP's "Impact on Concordance of Fathers' and Mothers' Parenting Attitudes and Beliefs," we will measure concordance by the kappa statistic and the intraclass correlation coefficient and their associated 95 percent confidence intervals.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

The proposal addresses a timely and important topic. The number of vulnerable families appears to be increasing in the United States, but the best means by which to address their needs remains uncertain. The Healthy Start Program is a widely replicated program that attempts to meet the needs of at-risk families, and is especially noteworthy because of the central place that evaluation has assumed since the program's inception. The randomized trial currently being conducted with support from the MCHB reflects an unusual and innovative attempt to evaluate the 'real-world' implementation of a government-supported social program. The trial will provide extremely important information about the effectiveness of home visiting programs, such as the Healthy Start Program.

The proposal currently under consideration will expand the clinical trial by providing additional data pertaining to fathers, thereby allowing an assessment of the program's impact on both parents, not just the mother. The proposal will also provide comparative data from not at-risk families.

The proposal addresses several issues listed as part of the MCHB research agenda, including 3.7.2, the differentiation of maternal and paternal care giving roles, 4.4.1, the evolution of the father-child relationship and its affect on mother-child and father-mother relationships, and 5.6.1, the role that minority fathers play in promoting their children's health and development. More generally, the Healthy Start Program embodies the Healthy People 2000 guiding philosophy and specific recommendations.

Regional and National Significance

The number of at-risk families in the United States continues to grow. The problems that they face have assumed national significance, because of the burden they place on public agencies and the health care system. If a home visiting program could promote better functioning and improve the health status of parents and their children, and especially if it did so with attendant savings in the social costs that they would otherwise incur, it would warrant widespread implementation. The proposed research has the potential to influence policy and programs designed to meet the needs of at-risk families.

Scientific and Technical Merit

This is a well-written proposal that has a number of strengths. The statement of the problem is clear and concise. The review of the literature is comprehensive without being discursive. Concepts and working definitions are well explicated. The study's design and methodology are described in adequate detail, and the study's hypotheses are linked closely to the variables to be measured.

The proposal also has several shortcomings. First, the preliminary results are somewhat discouraging. The retention rate for participants in the Healthy Start Program was somewhat lower than expected, with only 50% of the families still active at 1 year. Moreover, the effects of the intervention have been clinically significant for only a few outcome measures, and the effect sizes for those measures have been modest, so that their clinical significance is uncertain. The low retention rate and modest effects of the intervention, at least based on the first year of data, raise concerns about the value of the expanded proposal that are not addressed by the researchers.

The proposal also suffers from structural flaws that result in occasional failures to distinguish clearly between the current study and the proposed expansion. For instance, the hypotheses that are specific to the expanded proposal are described as part of the statement of the problem. They are presented separately from the central hypotheses guiding the overall program evaluation. The two sets of hypotheses are not linked or integrated very well. Similar gaps appear elsewhere in the proposal. As a consequence, the relationship between the larger study and the proposed expansion, as well as the differences between them, is not always clear.

Several measurement issues are of concern. First, the use of the Stanford Binet Intelligence Scale to assess developmental status is fraught with problems in young children, especially those who are at-risk. The scale has a very restricted range of items for younger, lower-functioning children, and can therefore result in significant floor effects. Second, the researchers suggest that they will administer the HOME independently with mothers and fathers. The HOME, however, was not constructed to provide separate ratings for different parents. Indeed, several of the scales on the HOME do not reflect parental behavior, and would presumably provide exactly the same scores. Thus, there is a lack of independence in the resulting measurements.

The researchers also provide relatively little rationale for the recruitment of a sample of not at-risk families. They do not indicate how they plan to contact the families, many of whom presumably will have moved or otherwise be lost to follow up in the interval since they were screened. They do not provide any support for their anticipated rate of participation, and apparently have made no preliminary attempts to contact not at-risk families to ascertain their willingness to participate. The specific variables and measures that will be assessed in the not at-risk families are also unclear. The researchers do not indicate whether all of the outcome measures and dependent variables that are being collected with regard to the at-risk participants will be available for the not at-risk families. In any case, data regarding variables such as the adequacy of health care and the use of community resources would be obtained retrospectively rather than prospectively, and would therefore be

of significantly less quality than the data collected in the original cohort.

Finally, the description of data analysis is relatively sketchy, and is not presented in a fashion that makes clear precisely how the specific sub-hypotheses presented will be tested. Instead, the description is often guided more by the general study hypotheses. For instance, the researchers mention longitudinal data analyses, although the data that will be collected as part of the expanded proposal and used to address its specific hypotheses is largely cross-sectional, so that the relevance of their comments is unclear. Similarly, the researchers characterize the statistical power of the analyses based on the total sample size. They do not discuss the power of the analyses that will be conducted using the data collected specifically as part of the expanded proposal. The power of those analyses will be less than that described because data collection will be restricted to parents who were married or living together at the time of study enrollment, and hence will include only about 50% of the current sample.

The proposed study will be conducted under the auspices of the Johns Hopkins School of Medicine, in collaboration with the Hawaii Medical Association and the Hawaii State Health Department. The history of cooperation between these institutions is one of the strengths of the proposal.

Overall, the research team is well suited to the conduct of the project. The principle investigator is currently an Associate Professor in the Department of Pediatrics at Johns Hopkins University School of Medicine. She is an experienced investigator with numerous publications listed in her Biographical Sketch, although there are relatively few for which she is the primary author. She will be joined by two co-principal investigators who will oversee the fieldwork activities subcontracted to the Hawaii Medical Association and coordinate program evaluation activities as they involve the Healthy Start Program facilities and the Hawaii State Health Department. The study will also have several collaborators at the Johns Hopkins University, including the project's health economist, and statistician, as well as a psychological expert.

The budget is rather large for a 2-year addition to an ongoing project. In general, workload projections are not presented to justify personnel needs. It is not clear why the principle investigator is requesting support for an additional 25% time during the first year, when both the current and expanded proposal will be in effect. It also is not easy to determine exactly why personnel costs at the Johns Hopkins site double in year 2. The salaries for interviewers at the Hawaii site are rather high, and it is not clear why they are paid more than research assistants. The request for funding for both an administrative assistant and a secretary at the Johns Hopkins site is not well justified, particularly when they are in addition to a full-time project director. Administrative and secretarial support should ordinarily be provided by the university.

Human subjects protections appear to be adequate, and IRB approval has been obtained.

Evaluator 2

Originality and Importance

This application requests funding for an expansion of a MCHB-funded study of the effectiveness of Hawaii's Healthy Start Program. The researchers plan to expand the sample and add to the variables assessed in the Wave 3 of family follow-up. The proposed expansion would focus on the MCHB research priorities related to studying the role that fathers play in the health, growth, and development of children and identifying factors that support or undermine fathering for different groups in different circumstances. The researchers wish to assess the extent to which fathers become engaged in the Healthy Start Program, the family and community factors influencing their level of engagement, and the program's impact on their role as parents. The currently funded study is a large, rigorous investigation of the effectiveness of the Healthy Start Program model.

Regional and National Significance

The researchers argue that much is still to be learned about home visitation, including the effectiveness of paraprofessional visitors, the effectiveness of programs that have gone to scale, the types of families that benefit most, and the effect of visitation on the father. Although not part of the funded work plan, the researchers have been collecting information on fathers through maternal interviews at baseline and in the Waves 2 & 3 follow-up. Maternal reports are available on the

following: the father's relationship with the mother, his prenatal involvement, the mother's desires and expectations for his involvement in parenting in the child's first three years, his accessibility, engagement in child rearing and sharing of responsibilities in the child's first two years of life, and his educational/vocational course, substance use and approaches to resolving conflicts with her. The broad objectives of the expansion are 1) to determine how personal, familial and cultural factors influence paternal engagement in home visitation, 2) to assess the impact of home visitation in supporting effective fathering, and 3) to determine how the father's engagement in visitation influences program effects for the mother, child, and family.

Scientific and Technical Merit

The aims of the expansion form two clusters. These will be addressed separately. The first cluster relates to an expansion of the data protocol for existing study families, adding measures of paternal engagement in the program, interviews with and observations of fathers, and expansion of maternal interviews to better measure their perceptions of fathers parenting attitudes, beliefs, and competence. Parents are either married or living together in about half of the study families (373 intervention families and 311 controls). The father component of the study would be based on Lamb's topology of accessibility, engagement, and responsibility. The expanded data protocol is exciting and important because it would allow researchers to collect data directly from fathers, including observations of father-child interaction. This is an important addition to the study, which will substantially increase the contribution of the research to our knowledge.

The second expansion cluster involves recruiting a new sample of not at-risk families to provide normative information on fathers in Asian/Pacific islander populations. This component of the expansion is less compelling. Hawaii Healthy Start services are provided to both parents and to the extended family. The rationale for this component of the expansion is sound, but the description of the sample and data collection/analysis strategies are not well developed. It would seem that this attempt to obtain normative data is a study in its own right and should be submitted, and evaluated, as a separate research project, rather than as an add-on to the existing trial. Enthusiasm for this component of the expansion is low.

The existing study is making good progress.

This is a strong research team.

IRB approval has been received. There are no human subjects concerns.



Evaluation of Hawaii's Healthy Start Program

Grantee

Johns Hopkins University

Investigator

Anne K. Duggan, Sc.D.
 Division of General Pediatrics, Research Center
 1620 McElderry Street, Room 203
 Baltimore, MD 21205-1903
 (410) 614-0911
 (410) 614-5431 fax
 aduggan@jhu.edu

Project Number MCJ-240637

Project Period 5/1/1994-4/30/1999

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	71,590	17,898	89,488
Year 2	81,145	20,286	101,431
Year 3	94,178	18,136	112,314
Year 4	104,866	20,435	125,301
Year 5	88,126	19,620	107,746

Summary

Statement of the Problem

Hawaii's Healthy Start Program (HSP) is a well-established outreach program that provides community-based screening to identify newborns at environmental risk for child abuse and neglect. HSP also provides for home visiting by paraprofessionals to promote healthy family functioning and child development through role modeling, education, and linkage with pediatric primary care and other needed community resources during the child's first 3–5 years of life. Nationally, home visiting programs (in general) and the HSP (in particular) receive strong endorsement. Efforts to establish community-based home visiting programs, however, have been impeded by the following unresolved issues: (1) The mixed results of past evaluations, (2) the limited study of nonnurse home visiting, (3) the evaluation of demonstration projects rather than established programs, (4) the little research on the types of families most likely to benefit, and (5) the uncertain cost benefits of home visiting. These issues render evaluation findings essential for informed policy and program development.

Research Questions or Hypotheses

Year 2000 Objectives

6.14, 7.4, 7.14, 8.3

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates, Infants, Toddlers, Preschool-Age Children, Parents/Families/Mothers/Fathers (Adolescent Parents)

Race/Ethnic Focus

Filipinos, Japanese, Hawaiian Native, Pacific Islanders

This evaluation addresses four questions:

1. How closely does program implementation mirror program design?
2. How successful is the program in achieving intended benefits for children and families?
3. How does fidelity of implementation influence program achievement of intended benefits?
4. How do achieved benefits compare to direct and indirect program costs?

Study Design and Methods

This project, which began in May 1994, is being conducted over 5 years. At each hospital, HSP early identification (EID) workers follow the usual screening and assessment protocol to identify infants born into environmentally at-risk families. All families living in HSP catchment areas are screened and assessed. Those who score 25 or less on Kempe's Family Stress Checklist are defined as being at risk. If the family is at risk, the EID worker describes to the family members the HSP and this evaluation project according to a standardized informed-consent protocol and invites the mother to participate in the evaluation.

If the mother agrees to participate, the family is randomly assigned to a HSP intervention group, a main control group, or a testing control group. Each intervention group family is referred to the HSP site serving its community and is offered home visiting services that follow the usual HSP protocol. Each control group family is referred to other community programs as usual. Members of the testing control group differ from the main control group because they are interviewed at baseline and at year 3 only. By comparing the testing control group with the main control group, we can assess the effects of repeated measurement of outcomes.

Families are followed for 3 years with baseline and annual data collected (for intervention and main control groups) for the following six key outcome variable indicators: Adequacy of pediatric health care, coordinated use of community resources, parent functioning, child health, child development, and school readiness.

Adequacy of pediatric health care is operationally defined as achievement of primary care and adequacy of preventive care. This is measured through a review of medical records for first contact with primary care, longitudinality, comprehensiveness, and coordination of pediatric health care, as well as adherence to American Academy of Pediatrics guidelines for well-child care visits and immunizations. Coordination of community resources is measured through medical records and social services reviews of the use of community resources. Parent functioning is also examined and is defined by (1) problem-solving ability (measured by the Wasik Problem Solving Rating Scale), (2) parent-child interaction (measured by the Nursing Child Assessment Satellite Training Scales), and (3) home environment (measured by Caldwell and Bradley's Home Observation for Measurement of the Environment Scale).

Child health is defined as general health status, measured by the Rand Health Inventory Scale. Additionally, morbidity is measured by determining emergency room use, hospitalizations, illnesses and injuries, and abuse and neglect reports from Child Protective Services, and by administering the Conflict Tactics Scale. Data also are collected on child development, which is measured by the Bayley Scales of Mental and Psychomotor Development and the Stanford-Binet Intelligence Test. School readiness, which is the final outcome variable indicator, is defined by (1) language development (measured by the Zimmerman Preschool Language Scale) and (2) social development (measured by the Vineland Adaptive Scales). Additionally, data on maternal characteristics, maternal and paternal employment, maternal social support, maternal health and psychological well-being, maternal health care, child health care, maternal and paternal substance abuse, paternal characteristics, and family income are collected at baseline and followup interviews.

Population and Sampling Plan

The target population is families of newborns at environmental risk for special health needs. The accessible population was families of newborns on Oahu who were identified as being at risk during study recruitment. A family was eligible for the HSP if the family (1) lived in an HSP catchment area, (2) was assessed as being at risk, and (3) was not already known to Child Protective Services. A family was eligible for the evaluation if (1) the family was assessed eligible for the HSP, (2) the mother did not need a translator (less than 3 percent need a translator), (3) the family was assessed at the time of the infant's birth (less than 20 percent are prenatal referrals), and (4) the family had never been enrolled in the HSP.

EID assessment and study recruitment activities were integrated. Families were recruited by EID workers by using the usual HSP protocol to identify at-risk families of newborns at each hospital on Oahu. By protocol, all families in HSP target areas were screened and assessed. If the family was at risk, the EID worker described the HSP and the evaluation and asked for a signed informed consent. After obtaining consent, the EID worker called the study fieldwork office to learn the

family's group assignment and then shared this information with the parents. The fieldwork director made the assignment by adding the family's name to a log with preassigned study numbers. Subsequently, a study interviewer who was unaware of the group assignment conducted the baseline maternal interview at the hospital.

The intent-to-treat model is our main approach for assessing program effectiveness, but the study is designed to assess program efficacy as well. By design, we assigned a larger proportion of subjects to the HSP group to compensate partially for sample losses from program attrition and to increase statistical power to assess family and agency influences on engagement. All study families are followed for 3 years, regardless of whether they stay in the HSP. Program effectiveness is assessed by using the intent-to-treat model (i.e., outcomes are measured with regard to family assignment to the HSP, regardless of the intensity of services a family receives through the HSP). However, to measure program efficacy (impact under ideal conditions) and dose-response effects, we used a group-allocation ratio weighted toward the experimental group. Families are followed from the infant's birth through his or her third birthday, with baseline and annual data collected (for intervention and main control groups) for key outcome variable indicators.

For the racial/ethnic composition of the sample, the mothers report their primary racial/ethnic affiliation as follows: 20.3 percent Native Hawaiian, 19.7 percent Filipino, 12.9 percent Pacific Islander, 11.8 percent white, 8.8 percent Asian, and 26.5 percent multiracial with no primary affiliation. More than half (57 percent) of the mothers were adolescents (19 years old or younger) at the time they gave birth to their first child. Forty-eight percent of the families experience some form of partner violence. Fifty-five percent report either maternal or paternal substance abuse.

Analysis Plan

Comparability between study participants and nonparticipants is examined using standard techniques for the types of variables measured (e.g., Student's *t*-test for normally distributed variables after necessary transformations, chi-square tests for binary and count data) through measures available for all at-risk families at the time of the child's birth. In the same way, the initial comparability of the HSP and the control groups is assessed for these measures and for baseline interview variables.

Overall program process estimates are derived from sample statistics (proportions, means) and 95 percent confidence intervals. Fidelity of implementation is assessed by determining whether interval estimates span program process standards. Summary process measures are compared among HSP sites, parent agencies, and population subgroups by using standard tests of significance (e.g., chi-square, analysis of variance).

There are three basic types of outcome variables that are measured in this study: Binary (e.g., any emergency room use), counts (e.g., number of emergency room visits), and scales. The methodology employs exploratory data analysis in the context described by Hoaglin, Mosteller, and Tukey. Internal consistency of composite scores for scaled indexes is investigated as well.

For each of the basic outcomes, the techniques of generalized linear models are used to investigate the relationships between the outcome and the covariates. Depending on the nature of the outcome measure, logistic, log-linear, or linear regression is used for the analysis. To investigate relationships over time, the methods of longitudinal data analysis for generalized linear models developed by Liang and Zeger are used.

Within both the HSP and the control groups, families are categorized in terms of baseline characteristics; these include family ethnicity, initial risk assessment score, family substance abuse, family violence, and maternal age. For each outcome, multivariable models are used to test for differences in outcome between the HSP and the control groups by controlling for differences in initial risk score and other important covariates. For normally distributed outcomes, the general linear model is used; for dichotomous outcomes, the logistic model is used; and for low incidence outcomes measured as counts, the log-linear model is used.

Results of the process assessment are used to categorize the families in the HSP group by the intensity and adequacy of services received compared to program standards of care. As described above, generalized linear models are used to relate program outcomes to the adequacy of services provided.

Within both groups, levels of use and associated costs are measured for health services, Child Protective Services, police and legal services, and other community services. For families in the HSP group, direct program costs also are measured. Tests for significant differences in total costs per child between the HSP and the control group families are computed using **t**-tests; controls for other factors influencing costs can be introduced by regression analysis. Alternative statistical tests also may be applied if the distribution of the cost data does not allow for transformation to normality. Significance of cost differences are tested for the specific cost categories listed above and for portions of cost paid directly by Government sources.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

The results of the study should contribute substantially to our knowledge base regarding both process and outcome evaluation of the Healthy Start Program and should provide direction for further research as well as policy formulation.

Regional and National Significance

Since Healthy Start is a well-established national program, the proposed study may have implications for Healthy Start programs across the Nation. Therefore, this study is of major regional and national significance.

Scientific and Technical Merit

This is a well-written document outlining a multi-institutional funding approach to the evaluation of the Hawaii Head Start Program. The need for evaluating this outreach and paraprofessional home screening program is well justified. The process evaluation, as designed, allows for the assessment of program implementation. The outcome evaluation measures the program's success in achieving its intended benefits. The relationship between process and outcome permits identification of benefits in relation to the program inputs. An analysis of costs and benefits completes the proposal.

Measurable process indicators—including population coverage, service provision, and quality of care—are sound, well defined, and appropriate. Outcome indicators such as adequacy of pediatric health, coordinated use of community resources, parent functioning, child health and development, and school readiness are appropriate and targeted to the long-term goals of the program. The literature review is thorough, critical, and supportive. Proposed tests and measurements are valid and the timing of measurements is appropriate. The relationship between The Johns Hopkins University and investigators in Hawaii is well described, as is the conduct of fieldwork. The study design is a randomized assignment of at-risk families into three groups: The Healthy Start group, the control group, and the testing control group. Baseline measurements are obtained in all groups and subsequent measures are obtained at years 1, 2, and 3 for the Healthy Start group and the control group. The testing group will be measured again only at year 3 to assess the effect of testing. The strengths and weaknesses of the design are carefully laid out. It is doubtful that the interviewers can be kept blinded, but if outcomes are assessed by nonsubjective tools, bias should be minimized. Methods of randomization are well designed.

The interventions in the Healthy Start and control groups are well described, as are the goals of the Healthy Start Program. The study population, with inclusion criteria, and the estimates of the number of families available for study are carefully described. Attrition rates are also estimated. Study power estimates seem appropriate for the measures determined. Subpopulations at risk are defined and power estimates seem appropriate, though power in detecting differences in proportions is somewhat questionable. The data analysis methods proposed are appropriate.

The investigators are well qualified and are not overly involved in other projects. The timetable is appropriate, though somewhat brief. The funding proposal is a good example of shared financing. The budget is carefully prepared, and the level of time and effort seems appropriate; The John Hopkins University will subcontract with the Hawaii Medical Association. The costs are carefully prepared by year and funding source.

The recommendation is for approval pending clarification of the questions raised at the study section discussion. The native component of Hawaii's population appears to be overrepresented in the at-risk families, and this is likely to present problems in terms of a suitable fit between the native culture and the nature and content of the intervention. Was the possibility of stratifying according to native/non-native ethnicity considered, along with random assignment within each group to the three treatment groups? Could the design have been more multifactorial by including age, education, marital status, employment status, and native/non-native ethnicity? Were these alternatives considered? Does the study, as designed, allow for determining why the intervention did not work? The study relies on scores derived from the Kempe's Family Stress Checklist to classify families according to risk status, but its appropriateness could be questioned. Thus, intervention could be a poor indicator with intervention effects restricted to subgroups.tart Program. The need for evaluating this outreach and paraprofessional home screening program is well justified. The process evaluation, as designed, allows for the assessment of program implementation. The outcome evaluation measures the program's success in achieving its intended benefits. The relationship between process and outcome permits identification of benefits in relation to the program inputs. An analysis of costs and benefits completes the proposal.

Measurable process indicators—including population coverage, service provision, and quality of care—are sound, well

defined, and appropriate. Outcome indicators such as adequacy of pediatric health, coordinated use of community resources, parent functioning, child health and development, and school readiness are appropriate and targeted to the long-term goals of the program. The literature review is thorough, critical, and supportive. Proposed tests and measurements are valid and the timing of measurements is appropriate. The relationship between The Johns Hopkins University and investigators in Hawaii is well described, as is the conduct of fieldwork. The study design is a randomized assignment of at-risk families into three groups: The Healthy Start group, the control group, and the testing control group. Baseline measurements are obtained in all groups and subsequent measures are obtained at years 1, 2, and 3 for the Healthy Start group and the control group. The testing group will be measured again only at year 3 to assess the effect of testing. The strengths and weaknesses of the design are carefully laid out. It is doubtful that the interviewers can be kept blinded, but if outcomes are assessed by nonsubjective tools, bias should be minimized. Methods of randomization are well designed.



Factors Associated with Nutritional Intake in Adolescents

Grantee

University of Minnesota

Investigator

Dianne Neumark-Sztainer, Ph.D.
 School of Public Health
 1300 South Second Street
 Suite 300
 Minneapolis, MN 55454-1015
 (612) 624-0880
 (612) 624-0315 fax

Project Number MCJ-270834

Project Period 10/1/1997-9/30/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	125,644	59,053	184,697
Year 2	183,471	86,231	269,702
Year 3	180,669	84,914	265,583
Year 4			
Year 5			

Summary

Statement of the Problem

Dietary patterns developed during adolescence may contribute to obesity and eating disorders and may increase the risk of several important chronic diseases later in life. Therefore, a number of Nutrition Health Status and Risk Reduction Objectives described in *Healthy People 2000: Midcourse Review and 1995 Revisions* have relevance for youth. These objectives include the following: Increased consumption of fruits and vegetables; increased consumption of calcium-rich foods; decreased consumption of fat; the use of sound dietary practices and physical activity; and decreased prevalence of overweight.

Existing data strongly suggest that these objectives will not be reached among adolescents by the year 2000. Furthermore, the prevalence of overweight has increased significantly, particularly among minority youth and among youth from low socioeconomic backgrounds. To address these growing problems, it is essential to identify the groups of adolescents that need to be targeted for intervention and to identify the factors that need to be addressed in the interventions. However, there are large gaps in our understanding of the factors associated with nutritional intake, physical activity, and weight status among adolescents.

Year 2000 Objectives

1.2, 1.3, 1.4, 1.5, 1.7, 2.3, 2.5, 2.6, 2.7, 2.8, 15.9, 15.10, 15.11, 16.7, 16.8, 17.12, 17.13, 22.4

Study Design

Observational

Time Design

Cross-sectional

Care Emphasis

Noninterventional

Population Focus

Adolescents, Parents/Families/Mothers/Fathers (Adolescent Parents)

Race/Ethnic Focus

African-American, Hispanic (Hispanic overall), Native American, Pacific Islander

Research Questions or Hypotheses

Following are the main research questions to be addressed:

1. Are adolescents meeting the *Healthy People 2000* Nutrition Health Status and Risk Reduction objectives? Which groups of adolescents are at greatest risk for not meeting these objectives and thus need to be targeted for intervention?
2. What are the direct and indirect overall contributions of socioenvironmental, personal, and behavioral factors to the explained variance in nutritional intake and weight gain status? Are similar associations found among adolescents from different socioeconomic, age, gender, and racial/ethnic groups?
3. Which specific socioenvironmental, personal, and behavioral measures are associated with the targeted behaviors outlined in the *Healthy People 2000* Nutrition Health Status and Risk Reduction objectives? Are similar associations found among adolescents from different socioeconomic, age, gender, and racial/ethnic groups?

Study Design and Methods

The study will include three separate but integrated components: (1) Focus groups with 150 adolescents; (2) survey completion and anthropometric assessments of 5,500 adolescents in grades 7 and 10; and (3) parental telephone interviews with 900 parents of the adolescent respondents.

Population and Sampling Plan

Those eligible to participate are students in grades 7 and 10 who attend schools in St. Paul with at least 25 students in each of those grades. Students will be drawn from 14 schools with 7th- and 10th-grade classes. These grades were selected in part because mandated health education training occurs in these grades. It is estimated that 90 percent of the eligible students will participate. Based on school enrollment data, the sample is likely to include five racial/ethnic groups: African Americans, whites, Native Americans, Asian American/Pacific Islanders, and Hispanics. Telephone interviews of approximately 900 parents of the surveyed students will be conducted after the in-class surveys. These parents will be selected by a randomization procedure.

Analysis Plan

The proportion of adolescents meeting the *Healthy People 2000* objectives (e.g., percentage of overweight adolescents) will be analyzed with chi-square tests. Logistic regressions will be used to examine independent associations between sociodemographic variables and outcome measures. Questions concerning mean levels of dietary intake (e.g., daily servings of fruits and vegetables) will be addressed with *t*-tests. Analysis of covariance will be used to compare means among subgroups of the population. Structural equation modeling (SEM) will be used to test models describing the relationships between socioenvironmental, personal, and behavioral factors and each outcome measure. Hierarchical regression will be used to identify specific constructs (from within the socioenvironmental, personal, and behavioral factors) associated with body mass index and with nutritional behaviors targeted in the *Healthy People 2000* objectives.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This study aims to identify socioenvironmental, personal, and behavioral factors associated with nutritional intake and weight status among adolescents, as outlined in the *Healthy People 2000* nutrition objectives. The findings will lead to the development of more effective interventions aimed at improved eating behaviors among youth. This is an important, well-designed study. The details of implementation are explicitly articulated, the goals of the research are consistent with the data to be collected, the researchers are experienced in the areas of investigation, the contributing colleagues are appropriately trained for their roles, and there is indication that the necessary collaborations will occur.

Regional and National Significance

The need to identify and understand the factors associated with nutritional intake in adolescents is an issue of national significance that should be addressed. This review makes clear that the proposed study is a logical next step that will advance the state of knowledge related to adolescent nutrition. The materials generated from this study will permit examination of a wide array of issues related to beliefs and practices of adolescents concerning diet and exercise/physical activity.

Scientific and Technical Merit

This revised application was reviewed at the November 1996 review cycle, at which time action was deferred pending additional information. The application proposes a three-stage study of the factors associated with nutrient intake and body weight in adolescents. The investigators have responded carefully to comments by the study section. Initially, the investigators plan to draft a questionnaire and a set of questions for use in focus groups. These materials will then be examined and assessed by an established advisory board at the University of Minnesota; the board includes 10-15 adolescent members. The revised materials will be used in the next step of the research.

During the subsequent stage of the study, 150 adolescents will participate in tape-recorded focus group sessions lasting approximately 1 hour. The participants in this phase represent three 7th grade and three 10th grade health education classes selected from one junior and one senior high school in St. Paul, MN. Guided by the questions developed in the earlier stage of the study, students in the focus group sessions will describe and discuss their food choices, physical activities, and the factors they believe may influence their consumption of specific healthful foods or their level of physical activity. These open discussions will be followed by a period of debate, in which half of the participants will take roles as "resistors" and the others will attempt to convince them to change behaviors; the students will then change roles. The same groups of students will also complete the draft questionnaire.

The data from the focus group sessions will be coded and analyzed for themes related to factors affecting nutrient intake and physical activity; factors enhancing activity and the consumption of more healthful foods; and the benefits and barriers related to these behaviors. Coding reliability will be tested on a subset of transcripts. The findings will be used in modifying the student survey and in a parental telephone interview for the next stage of the project. Test-retest reliability of the survey will be determined by repeating the process 1 week after initially administering the survey.

After these developmental sections of the study are completed, the revised materials will be used in surveying approximately 5,500 adolescents, who will also have weight and height measurements recorded. These students will be recruited from 7th and 10th grade classes in 14 schools, and an estimated 90 percent of the eligible students are expected to participate. Based on school enrollment data, the researchers anticipate the formation of five ethnic groups: American Indian/Alaska Native, Asian American/Pacific Islander, Hispanic, African American, and white.

The issue of informed consent remains a concern. In the revised application, as in the previous versions, a letter of consent is to be "sent home to all parents . . . and returned to the school with their child" if they do not want the child to participate. Presumably, the letter is to be delivered by the student, but that is not specified. This is problematic because failure to deliver the letter could result in student participation without true parental consent. Participating students complete a consent form at school. If parents of participating students are later contacted to participate in the parental interview component of the study, they may be unaware and justifiably disturbed that their child participated in the study without their consent.

Therefore, the research review committee recommends that the letter of consent be mailed directly to the parents' home. A stamped, return-addressed postcard should be provided so that parents who decline participation can indicate this easily. Furthermore, since the Hmong subsample does not speak English, the mailed consent form probably should be stated in English on one side and in Hmong on the other, unless the Hmong parents can otherwise be identified.

The recommendation is for approval with the following conditions: (1) The informed consent letter for parents should be mailed directly to the home; (2) the mailing should include a stamped, return-addressed postcard; and (3) the budget should be reduced by 15 percent.



Health Care Utilization: Pediatric Organ Transplantation

Grantee

University of California, Los Angeles

Investigator

Margaret Stuber, M.D.
Neuropsychiatric Institute
760 Westwood Plaza
Los Angeles, CA 90024-1759
(310) 825-5213
(310) 206-4446 fax
mstuber@mpimain.medsch.ucla.edu

Project Number MCJ-060839

Project Period 10/1/1997-9/29/2002

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	103,729	52,860	156,589
Year 2	98,596	51,270	149,866
Year 3	102,540	54,346	156,886
Year 4	106,641	56,520	163,161
Year 5	117,536	62,294	179,830

Summary

Statement of the Problem

Organ transplantation has transformed a number of previously fatal childhood illnesses into chronic conditions. In exchange for survival, children must commit to a lifetime of immunosuppressive medications; they then become vulnerable to the side effects of these medications and to infections. Long-term adherence to medications and other medical followup care is extremely challenging for these children and their parents; this is further complicated when families have substantial obstacles to care. Such obstacles include restricted or insufficient coverage by health insurance, lack of transportation for medical appointments, and inadequate fluency in English.

These obstacles to care are common within culturally and socioeconomically diverse patient populations and are addressed at most transplant centers through additional support that is provided by a combination of social workers and nurse coordinators or case managers. However, concern about costs in the current, highly competitive health care market has eroded the availability of many concrete supportive services. There is growing evidence that such cutbacks may prove to be shortsighted. Reduction in psychosocial support services may lead to increases in more costly medical service use. For example, researchers have demonstrated that use of a case manager on a kidney transplant service can decrease medical utilization (e.g., a shorter length of hospitalization). Cutbacks in such services can result in a loss of these cost savings.

Year 2000 Objectives

6.3, 6.5, 6.13, 6.14, 17.14, 21.2, 21.3, 21.4, 21.6

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

Preschool-Age Children, School-Age Children, Adolescents, Parents/Families/Mothers/Fathers (Adolescent Parents)

Race/Ethnic Focus

Mexican-American

A complete psychosocial assessment of the child and parents is routinely included in the pretransplant evaluation of potential organ recipients. If specific family psychosocial factors can be identified throughout the course of treatment as predictors of long-term health care utilization, targeted psychosocial interventions might result in cost savings. Clinicians note that adherence appears to diminish over time, particularly after the first 2 years posttransplant. The prevention of a single, significant rejection episode represents considerable financial savings (hospital and medication costs), as well as preservation of the donor organ, which is a scarce resource. Such preventative interventions could also result in substantial savings in terms of human suffering and future years of life for the child.

Research Questions or Hypotheses

This study would provide the basis for the development of supportive psychosocial interventions for pediatric kidney-transplant, heart-transplant, and liver-transplant recipients who are identified as high risk. This could affect cost savings by reducing medical services utilization while maintaining or improving functional outcome. The primary objectives of this study are:

1. To identify nonmedical factors that predict high utilization of medical and psychosocial services for pediatric kidney-transplant, heart-transplant, and liver-transplant recipients in the second, third, and fourth years posttransplant;
2. To identify nonmedical factors that predict poor functional outcome for pediatric kidney-transplant, heart-transplant, and liver-transplant recipients and their parents in the second, third, and fourth years posttransplant; and
3. To develop an assessment instrument that could be used to predict medical and psychosocial service needs of pediatric kidney-transplant, heart-transplant, and liver-transplant candidates.

Study Design and Methods

This study is conceived as a longitudinal study that uses multivariate statistical techniques to determine the amount of variation in treatment costs and outcomes accounted for by parent or family psychosocial indicators. Subjects and their families will be enrolled in the study at 12 months posttransplant and tracked for the subsequent 36 months. A research team member in a face-to-face or telephone interview will administer questions in either English or Spanish. This will require approximately 60 minutes per family assessment. A research assistant will be available at all times to answer questions about the questionnaires. At the completion of each of the three assessment points of the study, the parent will receive \$40 for participation (a total of up to \$120 for participation in the entire study).

1. Psychosocial predictors (independent variables): All of the psychosocial predictor variables will be assessed by self-report data from the organ recipient's mother. If the child does not live with his or her mother, data will be collected from the primary caregiving adult. These measures will be administered at entry into the study and 24 and 36 months after.
 - a. Concrete resources will be assessed by using a brief checklist that has been designed for this study and will be administered verbally. The checklist, which has strong face validity, is designed to be similar to the social work assessment that is a part of each pretransplant assessment. The items will be totaled to result in a numerical concrete resources score.
 - b. The Social Support Survey that was created for the Medical Outcomes Study will be used; this 26-item self-report measure assesses emotional or informational, tangible, affectionate, and positive social interaction for adults.
 - c. Socioeconomic status (SES) will be represented by the widely used Hollingshead-Redlich two-factor rating formula that is based on the parents level of education and occupational status.
 - d. Acculturation will be assessed by using a standardized measure titled the Marin Short Acculturation Scale for Hispanics that is designed for use with Spanish-speaking immigrants. These four questions briefly assess acculturation by evaluating the degree to which the individual prefers the use of Spanish or English in various areas of life.
 - e. Information regarding type of insurance is readily available. For purposes of data analysis, all payers will be categorized as (1) MediCal or (2) other. (We recognize that all renal-transplant patients will also be eligible for Federal medicare.) This data may provide an opportunity to separate the effect of insurance type from the effect of SES or concrete resources. The most current type of insurance will be used in each assessment period.
2. Treatment outcome: Treatment outcome will be assessed by the following:
 - a. Child functional outcome: The Child Health Questionnaire measure, which is available in a 50-item parent-report version, will be used for all subjects. This is fully applicable for children ages 5 years and older. Parents of younger children will complete only the portions that are applicable to their children. Additionally, at 24, 36, and 48 months posttransplant, the teacher questionnaire will be mailed to the index patient's classroom or homeroom teacher and returned in a postage-paid envelope.

- b. Parent functional outcome: A widely used self-report measure will be used to assess parent functional outcome. The Psychosocial Adjustment to Illness Scale is a 46-item self-report instrument that was initially designed to assess the adaptation of adult patients to major or chronic medical conditions. Additional measures include the State Trait Anxiety Inventory, the Beck Depression Inventory II, the Posttraumatic Stress Diagnostic Scale, and the Impact on Family Scale.
- c. Medical service utilization costs: This variable will be based on the need of hospitalizations, emergency care, and major medical procedures by the index patient in the second through fourth years posttransplant. These needs will include (but not be limited to) additional surgical procedures, radiographic and imaging evaluations, and endoscopies. Utilization information will be obtained from Current Procedural Terminology codes on payers' billing records and converted to dollar amounts using conversion figures for medicare cost data.
- d. Patient compliance: Patient compliance will be assessed by the treatment team through a brief questionnaire that has been developed for this study

Population and Sampling Plan

All pediatric patients (ages 1–18 years at the time of transplant) who receive liver, heart, or kidney transplants and who survive for more than 24 months posttransplant will be eligible for inclusion in the study. We anticipate that approximately 150 families will agree to participate in the study. Patients are expected to range in age from 3 to 20 years at the time of entry into the study. Based on the overall pediatric transplant experience at this center, it is anticipated that the sample will be closely divided evenly between males and females. The racial/ethnic distribution of the sample will reflect the general treatment population of the Mattel Children's Hospital at the University of California, Los Angeles, which is approximately 60 percent non-Hispanic white, 30 percent Hispanic, and 10 percent a mix of African-American, Asian, and other racial/ethnic groups. Only families in which the primary caregiving parent is fluent in English or Spanish will be eligible for participation. We anticipate that less than 1 percent of the otherwise eligible subjects will be excluded on the basis of this criterion. Given the age, gender, and racial/ethnic diversity of this sample, the findings of the proposed study will be generalizable to other pediatric solid-organ transplant populations.

Analysis Plan

The primary goal of this research is to assess the relationship between key predictors (concrete resources, social support, SES, acculturation, and insurance status) and outcome variables (medical and psychosocial utilization costs and patient and parent functional outcomes). Several potential confounding factors (type of organ transplanted, patient age at transplant, type of illness, and severity of complications during the first 2 years posttransplant) will be controlled for. The measurement of outcomes at three points in time enables us to investigate (1) the average outcome across all three points in time, (2) a linear contrast that captures the degree to which outcomes are trending upward or downward across all three points in time, and (3) a quadratic contrast that captures the extent to which changes across the three points in time are nonlinear. Because the primary outcome variables in this study are being measured with composite instruments that can be thought of as producing measures on an underlying continuous scale, multiple linear regression analyses can be used. The primary tests of significance for the study can be framed as multiple regression analyses. For each of the four primary outcomes (medical service and psychosocial utilization costs and patient and parent functional status), a group of social and psychological factors are included as predictors in a model with other potential confounding factors that are intended to control for background differences among subjects. The latter predictors are type of transplant (heart, liver, or kidney), age group (categorized as 0–5, 6–11, and 12–18 years old), type of illness (congenital vs. acquired), and severity of complications during the first 2 years posttransplant (mild, moderate, or severe). For each outcome variable, we plan three tests—one for each contrast of interest (average outcome and linear and quadratic trends in outcome across three points in time). The primary test of interest for each contrast will be to see whether the predictors of interest (concrete resources, social support, SES, acculturation, and insurance status) collectively predict a substantial amount of variability in the outcome of interest. A multiple regression *F*-test can control for the confounding factors noted above.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

The goal of this study is to identify posttransplant psychosocial factors that predict increased medical and psychosocial health care utilization or poor functional outcomes. Investigators hope to demonstrate the link between psychosocial services and improved functional outcomes for children with organ transplants. By defining the predictive factors of interest, investigators seek to develop a standardized psychosocial screening instrument to identify families at risk, as well as supportive or compensatory psychosocial interventions for these posttransplant families.

Regional and National Significance

The systematic assessment of psychosocial predictors of utilization and functional outcomes among children and adolescents with organ transplants is a crucial and growing area of research. Reviewers judged the research topic to have both regional and national significance.

Scientific and Technical Merit

The project's focus on families from diverse demographic backgrounds and on the risk factors that are amenable to preventative interventions suggests that findings will be generalizable and have practical significance for organ recipients, their parents, and health care providers. The principal investigator and research team are highly qualified to conduct the research.

Although this revised proposal has considerable strengths, a number of concerns still need to be addressed. If one of the goals of this study is to provide posttransplantation data on populations from diverse cultural and economic backgrounds, the small number of participating Hispanic, African-American, and Asian-American transplant recipients and their families may not constitute an adequate sample size. Although the power analysis suggests that a sample of 118 participants would be sufficient to detect statistical differences, and the investigator hopes to recruit a total of 150 participants, the anticipated sample size with respect to racial/ethnic populations raises additional questions. If the sample size is inadequate, the proposed multivariate analyses would not be possible and the generalizability of the findings would then be compromised. This problem is further compounded by the fact that the attrition estimates may be overly optimistic. Retention may be especially difficult among families of low socioeconomic status who have transplant recipients not yet enrolled in school. One possible strategy would be to oversample members of these groups to ensure sufficient numbers.

The specific variable, ethnic group membership, does not appear in any of the variable lists. How will the cultural differences between groups be factored into the data analysis plan?

Additional questions involve ratings of functional outcome. Teacher ratings of a recipient's functional status will be obtained at 24, 36, and 48 months. Presumably, these data are intended for cross-validation. The proposal makes no reference as to how this will be accomplished or how these data will be used. If there is disagreement between parents and teachers as to the functional status of the recipient, how will this be resolved? The proposal states that each parent will complete ratings of both the recipient's and the parent's functional outcome. In cases in which both parents cannot complete ratings, will the mother be selected as the informant? How will the data from two-parent households be compared with the data from single-parent households?

Although the data analysis strategy states that the longitudinal design enables the investigator to capture outcome trends and nonlinear changes, it is not clear how the causal relationships between the predictors and outcome variables will be ascertained. In the study design diagram, it is suggested that predictor variables "cause" functional outcomes. However, the current literature on social support recognizes that the distress of poor outcomes can also have a negative impact on adequacy of support. Given the fact that the data will be available to assess the bi-directional nature of support and outcomes, it seems appropriate to address this issue as part of the overall scope of the project. Exploring causal relationships more precisely seems especially important because this study is intended to provide the groundwork for future psychosocial interventions.

Although one of the major purposes of the study is to develop a standardized psychosocial screening instrument to identify families at risk, there is no direct description of the procedure to be used in developing such an instrument. How will the validity of this instrument be demonstrated? How will sensitivity and specificity be established? This issue was raised in the original review and remains a concern.

The cultural differences between the groups to be studied were only superficially addressed in the original application. The treatment population at the University of California, Los Angeles (UCLA) Medical Center includes a large Spanish-speaking subsample. The reviewers commented that cultural differences needed to be addressed in the study's conceptual framework, research questions/hypotheses, study measures and methodology, and data analysis. To assist with these issues, Dr. Carole Browner, an anthropologist with expertise in working with Spanish-speaking populations, served as a consultant for the revised application. The Marin Short Acculturation Scale has been added, and measures have now been selected based on

their use with Spanish-speaking populations. Inclusion of this population is a strength of the research, since so little is known about pediatric transplant predictors and outcomes for this group of families. The revised application, although considerably improved, still needs refinement. However, given the potential significance of the study, approval is recommended, with the following stipulations prior to funding: (1) Dr. Browner is to be hired as a paid consultant to the study; (2) analyses are to be restricted to the use of descriptive approaches with confidence intervals estimation; and (3) concerns raised in this summary review statement are to be clarified.



Home Nursing to Avoid Pediatric Hospitalization

Grantee

University of Rochester

Investigator

Kenneth McConnochie, M.D.
 Medical Center, Box 777 Pediatrics
 601 Elmwood Avenue
 Rochester, NY 14642
 (716) 273-4119
 (716) 256-1809 fax

Project Number MCJ-360831

Project Period 10/1/1997-9/30/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	413,807	244,146	657,953
Year 2	352,455	207,948	560,403
Year 3	212,773	124,356	335,129
Year 4			
Year 5			

Year 2000 Objectives

8.12, 11.1

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Infants, Toddlers, Preschool-Age Children, Adolescents

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Hospitalization accounts for almost 50% of child health expenditures. Adverse psychosocial effects of hospitalization are broadly recognized. Studies indicate that hospital admission is often highly dependent on physician discretion and that services provided to many children hospitalized could be delivered in alternative settings. The study team proposes a home nurse enhancement of primary care (HNEPC) as a new alternative to hospitalization for common illnesses in children.

Research Questions or Hypotheses

The purpose of this study is to evaluate the home nursing program in Monroe County, New York. Specific questions to be addressed in the main study phase are as follows: 1) What is the potential for implementing HNEPC on a community-wide basis?; 2) How well will HNEPC be accepted by families and providers?; 3) What is the net impact of HNEPC on hospitalization of episodes eligible for randomization and on overall community hospitalization rates?; 4) What will be the cost of care for episodes randomized to different groups?; and 5) Will quality of care for illness episodes in the treatment group be equal to or better than those in the control group?

Study Design and Methods

Essential characteristics of HNEPC design are: 1) capacity to deliver services comparable to those provided to hospital inpatients for selected, common illness episodes; 2) immediate accessibility; 3) ability to adjust to the unique and changing needs of different families and illnesses; 4) unique opportunity in home-based interventions to promote health enhancing behavior; and 5) integration in both primary care and hospital care systems.

Phases of this study include preparation (in which the intervention will be piloted), research pilot, main study, and analysis. Preparation phase funding has been secured.

During the research pilot, 66 additional episodes will be cared for with HNEPC and research instruments will be piloted in field situations and refined.

During the main study phase, 1590 acute illness episodes presenting to the Emergency Department (ED) will be randomized either to the treatment or control group. HNEPC will be one option available for the management of episodes in the treatment group, whereas only the usual options, inpatient or family home care, will be available for the control group.

Outcome variables measured to address the efficacy and effectiveness of the intervention regarding quality of care include: number of illness days, time to return to normal activity, medical record review, impact of illness on family, family/nurse/provider satisfaction with quality of care, and subsequent hospitalization utilization. Potential confounding variables to be assessed include socioeconomic variables and severity of illness.

Population and Sampling Plan

Of the expected 9399 cases presenting to the ED in the likely clinical groups of the appropriate age (from aged one month to 19 years), 1767 will be eligible for randomization based on meeting the inclusionary criterion. Of these 1767 cases, after accounting for refusals, 795 cases will be assigned to each of the treatment and control groups. Once in the randomization arm of the study, the patient's care will be determined as a joint decision of the provider and the family. Only in the treatment arm of the study will HNEPC be available.

Analysis Plan

Data analysis plans include descriptive analyses, cost-benefit analyses, plus bio-equivalence, ANOVA, and logistic regressions for the randomized clinical trial component.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This proposed 3-year study would evaluate Home Nursing Enhanced Primary Care (HNEPC), an intervention that would be implemented in place of inpatient hospitalization. The researchers propose to conduct an extensive evaluation of potentially avoidable pediatric hospitalizations. The issue is of particular importance in light of the current emphasis on cost savings.

Regional and National Significance

The project has national significance because of the large number of potentially preventable hospitalizations each year. Since the research findings could have a major impact on the management of pediatric illnesses, this study also has clear implications for maternal and child health policy.

Scientific and Technical Merit

The current proposal has incorporated a number of revisions, and the pre-award commentary reflects the fourth review of the application. At the November 1996 review committee meeting, the application was deferred pending a site visit (April 1997); after the visit, a review committee team suggested additional changes to strengthen the revised proposal.

The project is designed to evaluate a fundamental question: How much of the current pediatric inpatient care for common childhood illnesses can be replaced with HNEPC? The investigators propose that the HNEPC intervention will be evaluated in four phases: (1) The preparation phase, for which funding has already been secured; (2) the research pilot phase, which would take place during the first 4 months of the proposed project and would serve to refine procedures and instruments in

field situations; (3) the main study phase, in which the randomized clinical trial would take place, and (4) the data analysis phase. Primary outcomes of interest are the comparative costs of the two treatments, and the quality of care.

The researchers cite previous studies to support their belief that HNEPC can provide a low-cost, effective alternative to pediatric hospitalization. They report that a significant percentage of pediatric hospitalizations are (in retrospect) judged avoidable, that repeated pediatric hospitalization increases the likelihood of vulnerable child syndrome and other childhood developmental problems, and that home nursing has been shown to be relatively safe and effective for moderately severe illnesses.

The following issues were of concern to the committee: (1) The project staff's lack of sufficient expertise and experience in clinical trials; (2) unclarified budget issues, specifically with respect to what costs would be paid by private insurers for the medical treatment, and what costs would be supported by the Maternal and Child Health Bureau for the research and evaluation component; and (3) the appropriateness of the "alternate days" design with respect to potential confounding when evaluating the efficacy of the proposed intervention.

Responding to the first and third points, the research team proposed a scientific advisory board consisting of specialists and experts in four main areas: Community and preventive medicine, nursing, biostatistics, and health services—economic decision analysis. Furthermore, two consultants would be added, a biostatistician with expertise in clinical trials, and a specialist in community and preventive medicine. The proposed scientific advisory board would provide an additional oversight mechanism to ensure that the research protocol is followed faithfully throughout the project period, especially in light of the uncertainty regarding third-party payment for home nursing care.

Responding to the second point (the alternate days design), the research team proposed an alternative design that addresses a concern expressed by a number of the reviewers. The new design would incorporate randomization by episode rather than by day. Proposed strengths of the new design include unbiased estimates of both the quality of the intervention and the communitywide costs. Furthermore, classification of the patient's condition at presentation can be done by emergency department providers blinded to the patient's control or intervention status. Although some reduced power to detect effects can be expected for any given question, the preliminary estimates provided suggest a rather minimal loss, given the greater range of questions to be addressed.

Issues of financial responsibility for the proposed intervention were discussed by hospital administrators and financial officers, several of whom strongly indicated their commitment to seeing this project come to fruition. The investigators have been informed that the National Institute of Nursing Research has agreed to fund the proposal at a level of support in direct costs for 3 years, and would consider joint funding with the Maternal and Child Health Bureau. This is an important study in a priority area of maternal and child health; approval is recommended.



Home Versus Group Visits After Early Postpartum Discharge

Grantee

Kaiser Permanente

Investigator

Tracy Lieu, M.D.
Division of Research
3505 Broadway
Oakland, CA 94611-5714
(510) 450-2063
(510) 450-2071 fax

Project Number MCJ-060838

Project Period 10/1/1997-9/30/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	175,795	54,997	230,792
Year 2	176,535	57,435	213,970
Year 3	55,799	17,031	72,830
Year 4			
Year 5			

Summary*Statement of the Problem*

Hospital discharge of mothers and newborns 48 hours or less after uncomplicated delivery is now standard throughout the United States. Recently enacted legislation only mandates reimbursement for routine stays up to 48 hours. However, it is essential that the newborn and mother be examined on the third postpartum day, when jaundice peaks and lactation begins. Providers vary in how follow-up examinations are offeredæ as home visits, individual clinical visits, or group visitsæand there is scant evidence to compare the effectiveness and costs of these practices.

Research Questions or Hypotheses

The purpose of this randomized trial is to test the hypothesis that low-risk mothers and newborns will be at reduced risk of adverse health outcome if assigned to receive a home visit rather than a group clinic visit on the third post-partum day.

Study Design and Methods

Low-risk mothers and newborns will be identified before hospital discharge. These study subjects will be enrolled,

Year 2000 Objectives

14.14

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates, Infants, Other-Postpartum Women

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

interviewed, and randomized either to a home visit (intervention) or to a group clinic visit (usual care) on the third day postpartum. Outcome data from telephone interviews with mothers will be obtained from computerized utilization data bases at Kaiser Permanente. An adverse health outcome will be defined as any of the following during the first 14 days postpartum: An urgent clinic visit by the newborn or mother, discontinuation of breastfeeding, maternal depression symptoms, or rehospitalization of the newborn and/or mother.

Population and Sampling Plan

The study team will randomize 1,780 women into the 2 study groups. With estimated attrition, a total of 1,646 women are expected to complete the study (823 in each group). Health outcomes will be assessed at 2 and 12 weeks postpartum.

Analysis Plan

Outcomes between the usual care group and the intervention group will be compared and analyzed. Power analysis indicates that the study has the power to detect a 20 percent difference (from outcome estimates based on the Kaiser Permanente data set) in urgent clinic visits by the newborn and in a summary measure that combines all of the outcomes except hospitalization of the mother or the newborn. This study will provide information needed to guide health policy recommendations for the general population of mothers and newborns in the United States.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This once-revised application addresses an important problem: Options for followup postpartum care, given the typically brief hospital stays for mothers and newborns after delivery. This research study proposes to use a randomized controlled design to test two approaches to postpartum followup: Individual home visits by a health professional, or group visits to the prenatal care site by the mother and newborn. It is intended that similar material will be covered during both types of visits. The findings will provide significant information about the effect of these two approaches on urgent clinic visits for the newborn or mother, the effects on breastfeeding cessation, maternal depression symptoms, and rehospitalization of mother or infant. The proposal is thoughtful and thorough, and the investigators are well qualified to conduct the investigation.

Regional and National Significance

Brief hospital stays for newborns and their mothers after delivery have become the norm in this country, and the well-being of these mothers and infants is an issue that must be addressed. This well-written proposal covers important issues relevant to the mission of the Maternal and Child Health Bureau, and thus has both regional and national significance.

Scientific and Technical Merit

There are two problems with the proposed study. First, the study as designed would evaluate home visits vs. group clinic visits. A companion study in Sacramento evaluates home visits vs. individual clinic visits. It is likely that home visits will prove more effective—but more costly—than either group or individual clinic visits. The relative effectiveness and cost of group vs. individual clinic visits (the two alternatives most likely to cost less) will not be established. The investigators have argued that the companion study could not have included an arm of group clinic visits since such visits were not standard practice at that Kaiser Permanente site. It is unfortunate, at best, that a practice that is standard at other Kaiser Permanente sites could not have been tested in this other study, as it would have produced a much more parsimonious design.

The second problem with the proposed study is the lack of adequate justification for the second interview. As presented, the second interview appears essential only for determining breastfeeding continuance. It is possible that data on preventive health visits may also be collected for use in assessing health outcomes, but that is not explicitly stated. Since a significant part of the telephone interview costs involve the second interview, the use of the resulting data should be made clearer. Aside from these limitations, some of the measures have not been tested for validity, such as the measure for breastfeeding discontinuation (defined in the proposal as providing formula equal to more than half of the daily average intake of a

reference infant of the same age). In addition, no mention is made of the significance of the investigators' observation that only 80 percent of women come for the group clinic visit. This factor needs to be considered both in deciding the sample size and in estimating effectiveness and cost.

The investigators have presented a carefully reasoned and thoroughly described research project, including the purpose, rationale, and significance of the proposed work. The investigators demonstrate a clear grasp of the measurement and analytic issues. Most of the materials to be used in the study have already been pretested in another study comparing home visits to individual clinic visits.

The persons responsible for each task are designated, and the procedures for staff training, subject randomization, data management and analysis, and maintenance of data integrity and confidentiality are explicitly indicated and of high quality. All investigators and project staff seem qualified and appropriately trained and supervised in their specific study tasks. However, the project is heavily staffed. Although staff roles are justified, it is clear that it would be possible to do the work proposed with a smaller team of professionals. The cost remains high in this revision, and it is clear that is not possible for these researchers to do the three-way comparison (i.e., home visits, individual clinic visits, and group clinic visits) that would have been ideal.

Nevertheless, the reviewers considered the research question important, and the application protocol well written and technically strong. The concerns identified in the prior review were judged to have been addressed aptly. The recommendation was for approval with a 15-percent reduction in the overall budget.



Improved Prenatal Detection of the Fragile X Mutation

Grantee

Research Foundation for Mental Hygiene, Inc.

Investigator

Edmund C. Jenkins, Ph.D.
 W. Ted Brown, M.D., Ph.D.
 Institute for Basic Research in Developmental Disabilities
 1050 Forest Hill Road
 Staten Island, NY 10314
 (718) 494-5236
 (718) 494-1026 fax
 JENKINEC(a)NYSOMR.EMI.COM@MISSIVE

Project Number MCJ-360587

Project Period 9/1/1989-8/31/1999

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	64,356	36,678	101,034
Year 2	60,700	38,603	99,303
Year 3	70,684	40,770	111,454
Year 4	74,079	42,538	116,617
Year 5	77,642	43,237	120,879

Year 2000 Objectives

14.3, 21.6

Study Design

Quasi Experimental

Time Design

Mixed

Care Emphasis

Noninterventional

Population Focus

Pregnant Women

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Fragile X syndrome is the most prevalent inherited form of mental retardation. Progress made during an earlier phase of the study (Sept. 1, 1989–Aug. 31, 1994), also funded by the Maternal and Child Health Bureau, included the following: Developing a variety of cell culture modifications in combination with multiple fragile site induction systems and quality assurance strategies to optimize fragile X detection prenatally; applying DNA linkage studies, where possible; accounting for occurrence of a false negative result; applying direct DNA and polymerase chain reaction (PCR) testing to prenatal detection; and demonstrating that female fetuses with low fragile X chromosome frequencies are reliably detected, have increased frequencies postnatally, and are the usually affected individuals.

Additional progress has been made in developing molecular procedures. The investigators now consider the combination of PCR and Southern analysis of fragile X mental retardation-1 (FMR-1) status to be reliable not only for amniotic fluid samples but also for chorionic villus samples (CVS). Therefore, cytogenetic prenatal or postnatal testing for fragile X is no longer recommended. In contrast to cytogenetic laboratories and laboratory settings in which maternal cell contamination is excluded, not one instance of a false negative or false positive result has been recorded with the use of the molecular testing

procedures. A summary of results through 1996 is provided in the following table.
Results of 111 Prospective Prenatal Studies of FMR-1 by a Combination of PCR and Southern Blot Analyses
Insert table from Active Projects FY 96 & 97 Research book p. 141

Note: AF = atrial fibrillation.

*One normal female confirmed with cord blood sample.

Research Questions or Hypotheses

This phase of the study completes the development and validation of the present protocol for fragile X detection. Specific aims are to: (1) Assess the reliability of the present protocol for detecting fragile X mutations in additional cases; (2) further improve the PCR protocol to reduce both the quantity of the sample required and the turnaround time; (3) continue trials to miniaturize the Southern blotting procedure so that cells do not have to be grown in culture for 2–3 weeks in order to generate sufficient DNA for the procedure; and (4) test and develop monoclonal antibodies specific for the FMR-1 gene product (FMRP) to further improve prenatal detection of the fragile X mutation by indirect protein product assay.

Study Design and Methods

This continuation of an earlier phase of the study will test and validate significant new modifications in the protocol or combination of protocols, so that prenatal fragile X detection will approach 100 percent reliability with minimal turnaround time. Research in the prior funding period indicated that cytogenetic approaches alone are not sufficiently reliable—some 10 to 20 percent of the fragile X cases did not show the fragile X chromosome even under the most stringent fragile site induction conditions.

Fetal cells will be simultaneously tested using PCR and direct DNA testing (Southern hybridization and analysis) and will be retrospectively analyzed with monoclonal antibodies, which are able to indicate the full mutation. Retrospective study is necessary to validate the protocol and to pinpoint the earliest possible gestational time that absence of FMRP may be detected in CVS material.

Population and Sampling Plan

Subjects will be pregnant women who are carriers of the FMR-1 mutation and thus have a very high risk of giving birth to affected children. These subjects will be recruited through continued referrals by geneticists across the country.

Analysis Plan

The overall goal of this project is to improve the technology used to detect the fragile X mutation prenatally. The study will continue to revise and develop both current and new protocols based on emerging technology. Presently, new PCR, Southern analysis, and monoclonal antibody technology is being developed/tested (using the present combination protocol of PCR and Southern hybridization testing as the gold standard) by determining the sensitivity, specificity, false positive and false negative rates, and predictive value positive and predictive value negative of these new protocols. If any false negative or false positive results are observed, studies will be conducted to attempt to correct the problem and prevent recurrence.



Improving Health/Development of Low Income Pregnant Women

Grantee

Spectrum Health

Investigator

Lee Anne Roman, Ph.D., R.N.
Healthier Communities Department
100 Michigan N.E., MC-94
Grand Rapids , MI 49503
(616) 391-2627
(616) 391-1305 fax

Project Number MCJ-260743

Project Period 10/1/1996-9/30/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	232,116	60,350	292,466
Year 2	291,903	75,895	367,798
Year 3	316,164	82,203	398,367
Year 4	129,464	29,777	159,241
Year 5			

Summary

Statement of the Problem

Most reported trials of interventions targeting low-income pregnant women have been closely linked to the provision of prenatal care by professional health care providers. Nurse home visiting is a well-tested strategy with positive maternal and parenting effects during the prenatal and postnatal periods. Yet this intervention often fails to reach those most at risk: Women who break appointments, refuse services, or are chronically "not at home" to home visitors. Further, these studies have not addressed the high incidence of depression, stress, mistrust, and powerlessness among low-income pregnant women; these concerns may need to be ameliorated before health and developmental outcomes can be affected.

The sole use of traditional professional interventions limits the number of families that can be helped, propagates a costly dependence on paid providers, and fails to invest in building informal supportive environments. Ultimately, these interventions do not take advantage of the strength that exists in low-income communities: the expertise of women with limited economic resources who prevail and whose children thrive despite difficult life circumstances.

One strategy receiving increased attention is the use of community health workers (CHWs) to bridge sociocultural differences and gain access to and establish relationships with hard-to-reach women. Yet current research efforts are primarily descriptive or focused on determining the effects of nurse interventions versus CHW interventions. However, a model that teams CHWs with nurses and integrates team services with prenatal care, maternal support services, and welfare initiatives could provide

Year 2000 Objectives

6.5, 6.13, 14.14, 21.3, 21.5

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates, Infants, Pregnant Women,
Other-Postpartum Women

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

the greatest opportunity for reaching low-income mothers. This team strategy for reaching low-income pregnant women has not been tested in controlled studies comparing such models with traditional nurse home visiting. Analyses of costs and of Government expenditures for such models are also needed as communities face increasing pressures related to the allocation of scarce resources.

Research Questions or Hypotheses

The aim of this research is to test the efficacy of a CHW-nurse team intervention targeting low-income pregnant women. CHWs include low-income paid health advocates and volunteer neighborhood women. The efficacy of the team intervention will be tested through a comparison of low-income women who have been randomly assigned to receive either State entitlement maternal and infant support services that include nurse home visitation (control group) or the CHW-nurse team services (intervention group). The two groups will be compared in relation to women's stress and stress responses (perceived stress, depression, and health risk behavior); psychosocial resources (social support, self-esteem, and mastery); and life course development (education, family planning, job participation, and use of community resources). The study will also explore the more remote effects of the intervention on birth outcomes, parenting skills, and infant development between the two groups. Finally, the study will compare differences between the control and intervention groups regarding the costs of using maternal and child health care services and the Government costs of this care.

Study Design and Methods

The study is designed as a controlled, randomized, multicenter clinical trial with two experimental groups. Women who meet all inclusion criteria and consent to participate will receive either the CHW-nurse team intervention (intervention group) or the traditional professionally delivered State entitlement maternal and infant support services (control group). The CHW-nurse team intervention program maintains weekly contact with the pregnant women at clinics, in their homes, and in a variety of community locations, and provides continuing support over the first 12 months of the infant's life. Four prenatal clinics providing care to the underserved and willing to adhere to the randomization process will be the source of care: The Butterworth Hospital Clinic (approximately 550 women), Cherry Street Health Services (approximately 200 women), Blodgett Memorial Medical Center Clinic (approximately 200 women), and Clinica Santa Maria (approximately 100 women).

Population and Sampling Plan

A total of 580 low-income women from 4 different clinic sites will be randomly assigned to the CHW-nurse team intervention or to the control group. To be included in the study, a woman must be eligible for medicaid, reside in Kent County with no plans to move, read or understand English or Spanish, request prenatal care at one of the four clinic sites, and enroll by 24 weeks' gestation. Criteria for exclusion include treatment within the past 2 years for various psychiatric disorders.

Data will be collected at time of enrollment, at 32–35 weeks' gestation, at delivery, and at 6 weeks and 6 and 12 months postpartum. At the two prenatal data collection points, measures of stress, depression, social support, life course development, health risk behavior, and self-esteem and mastery will be collected. In addition, measures of parenting and infant development will be collected at 6 and 12 months postpartum. At delivery, data on birth outcomes and medical risk will be collected. An additional brief psychosocial assessment will be collected prior to the mother's mandated welfare work participation at 3 months postpartum.

Analysis Plan

The study will evaluate differences between the two groups in maternal stress and stress responses, psychosocial resources, and life course development. Effects of the intervention on parenting skills, birth outcomes, and infant development will also be assessed. Further, the cost and use of maternal and child health services and the Government costs of this care will be examined between the two groups. Descriptive, nonparametric confidence intervals, repeated measures, analysis of variance (ANOVA), multiple regression, and other appropriate statistical methods will be used.

All tests of hypotheses will be two-sided with a significance level of 5 percent. Initially, the adequacy of the randomization will be tested by comparing all baseline characteristics of the two groups of women. These variables include age, race,

highest educational level attained, marital status, gestational age, and parity (nullipara, primipara, or multipara). If significant differences exist in these prognostic variables, they will be controlled for in subsequent analyses of outcomes.



Increasing Safety Seat Use Among Preschoolers

Grantee

Children's Hospital Medical Center Research Foundation

Investigator

Victor F. Garcia, M.D.
 3333 Burnet Avenue
 Cincinnati, OH 45229-3039
 (513) 636-4453
 (513) 636-7657 fax
 garcv0@chmcc.org

Project Number MCJ-390805

Project Period 10/1/1998-9/30/2001

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	171,779	77,301	249,080
Year 2	224,183	100,882	325,065
Year 3	136,548	61,447	197,995
Year 4			
Year 5			

Year 2000 Objectives

9.12.1

Study Design

Quasi Experimental

Time Design

Mixed

Care Emphasis

Interventional

Population Focus

Preschool-Age Children,
 Parents/Families/Mothers/Fathers (Adolescent
 Parents)

Race/Ethnic Focus

African-American

Summary

Statement of the Problem

Crash-related fatalities remain the leading cause of injury and death for children between the ages of 1 and 4 years. The arguments for use of a child safety seat (CSS) for all preschool children are compelling. Risk of death or serious injury can be decreased approximately 71 percent by use of a CSS. However, usage rates among preschool children are very low; the rates range from 6 to 43 percent. Preschool children who are restrained in safety belts are at risk for severe or fatal head, intestinal, and spinal injuries. Minority and disadvantaged children are at particularly high risk for injuries resulting from car crashes. Use of a CSS is very low in this population, and crash-related fatality rates are twice as high among low-income children. High rates of misuse have been observed among the small number of preschool children who do ride in a safety seat, which may degrade the protective effect of the seat. Several injury-prevention approaches have addressed low CSS usage. However, legislation and short-term educational, incentive, and give-away programs have not been successful in increasing CSS usage among preschoolers.

The intervention is a preschool passenger safety curriculum coordinated with a parent educational program that will be implemented in nine preschools and child care centers in Hamilton County, OH, throughout the 1999–2000 school year. The children's curriculum is taught by the classroom teacher, who incorporates the passenger safety messages and activities into all areas of the classroom. The parent intervention, which is based on the tenets of the Health Belief Model and Social

Learning Theory, will provide modeling and positive reinforcement to increase parental competence in dealing with CSS-related issues.

The parent program will address the barriers to consistent CSS usage identified by three focus groups that will comprise parents of preschoolers; the focus groups will be conducted during spring 1999. The parent program will also disseminate to other parents the behaviors and activities identified by focus group participants as facilitators to CSS usage.

Research Questions or Hypotheses

This study will address the following hypotheses:

1. A multidimensional child passenger safety program based on the principles of Social Learning Theory and integrated into the curriculum throughout the school year will result in increased usage of safety seats among preschool children;
2. CSS usage will demonstrate a larger increase among families with less income and lower parental educational attainment when perceived barriers to usage are addressed;
3. Use of safety belts will increase significantly among parents as a result of the program; and
4. Specific educational messages developed for parents and children will result in significantly more children riding in a rear seat position in vehicles equipped with passenger-side air bags.

Study Design and Methods

The purpose of this study is to evaluate the effectiveness of an innovative, preschool-based child passenger safety program to increase the prevalence of CSS usage and the rates of correct installation and proper harnessing of the child. Two secondary objectives are to increase the use of safety belts among parents and to increase the percentage of children riding in the back seat of vehicles equipped with passenger-side air bags. Tertiary objectives include increased parental and teacher awareness, attitudes, and knowledge related to child passenger issues and self-reported motor-vehicle restraint use. A quasi-experimental, pretest-posttest control group design will be used to evaluate the intervention.

Injury prevention efforts may have an impact along a continuum that progresses from awareness of risk, knowledge of how to prevent or minimize injury, and, ultimately, to behavioral change. The program evaluation includes assessment of all three areas in order to determine the impact of the program on each.

Behavioral change (i.e., using a CSS, wearing a safety belt, positioning a child in a rear seat) is the ultimate goal of the program. Measurement of program effectiveness on the primary and secondary objectives will be assessed through direct observation during the arrival times for children at both the intervention and control schools. Observation and a brief driver interview will be conducted by blinded interviewers from the University of Cincinnati Institute for Policy Research. Observation will be conducted in the fall before the introduction of the program and again in the spring.

Measurement of the tertiary objectives will be conducted through questionnaires administered to parents and teachers before the introduction of the program and again in the spring. These questionnaires will assess awareness of and attitudes toward personal use of restraints, safety seats for children, and other injury-prevention devices. The questionnaires will also measure knowledge of specific CSS issues and knowledge of State law related to child passenger safety.

Additional measures include weight and height information for each child. These measures will be taken in the classroom, and suggestions for selection of an appropriate safety seat will be provided to the parent.

Process measures for the program will include monthly teacher activity diaries. Because program materials and activities will be employed in the classroom at the discretion of the teacher, it is not feasible to accurately observe the degree of compliance with the program in all intervention school classrooms throughout the school year. To obtain some estimate of the degree of implementation, each month the teachers will complete a diary that describes how often specific materials were available in their classrooms and how often they conducted program-related activities.

Population and Sampling Plan

Preschools were obtained from a list of all licensed preschools and child care centers operating in Hamilton County. They were stratified into high-tuition, middle-tuition, and low-tuition level groups. Within each tuition tertile, schools were randomly selected and contacted until the demographic and sample size requirements for that stratum were met. Each parking situation was assessed to ensure that observation could be safely conducted at the school. Schools that agreed to participate and that met the study criteria were allocated to the intervention or control group through a coin toss. Seventeen

schools are participating in the study, nine as intervention sites and eight as control schools. The estimated total number of children enrolled for September 1999 is about 1,400. There are approximately 500 African-American children and 900 white children. African-American children are overrepresented in the sample to permit analysis of socioeconomic interactions within race. With an alpha of $p=0.05$, the statistical power to detect a difference in CSS usage from preprogram to postprogram levels is greater than 90 percent.

Analysis Plan

Because child-specific information (age, standing and sitting heights, weight) will be linked to observation data, the unit of analysis is the individual passenger. However, within tuition tertiles, preschools were randomly assigned to intervention or control status. To control for the potential violation to independence introduced by using the school as the unit of randomization, the general estimating-equation-logistic approach will be used for the following primary outcome variables: CSS usage, parental safety belt usage, and rear seating. Covariates will be considered for inclusion in the equation by using a modified stepwise procedure. Key variables (study group, tuition tertile, school, and race) will be forced into the model. Questionnaire data will be analyzed by using frequency counts, univariate analysis, and Mantel-Haenszel chi-square techniques.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This study is important in two respects. Its objective is of intrinsic interest to anyone interested in improving children's health. Perhaps more importantly, the study's approach has relevance to a more generic problem: how can one increase the use of relatively inexpensive interventions that clearly benefit both individual users as well as society as a whole? The study is an example of how the use of rigorous quantitative methods can be used to assess interventions that might be considered "soft" or "hard to pin down."

This study's subject area - prevention of child injury, child death, and increasing the use of safety belts - is an issue of major scientific importance, which clearly falls in an area of critical importance for the MCHB Research Program and is in synchrony with the Healthy People 2000 goals.

Regional and National Significance

The study is significant, particularly from a methodological standpoint. If successful, it could be a model for 1) the incorporation of rigorous quantitative approaches to the measurement of community-based interventions, 2) improving the overall quality of community-based interventions, and 3) increasing the links between researchers and the ultimate beneficiary of their work - the community.

Scientific and Technical Merit

This proposed study has several strengths. The authors have performed a thorough review of the literature. This thoroughness is evidenced in that their study design clearly incorporates others' work and is grounded in a coherent conceptual framework (Health Belief Model and Social Learning Theory). The authors also have a fairly clean analytic design with very clear delineation of independent and dependent variables. Moreover, their key outcome variables are readily quantifiable and it is reasonable to anticipate that final data analyses can be straightforward.

Additional strengths of this project deserve special mention. The first is that the authors have conducted and learned from a pilot study. Their pilot study is important in that 1) it shows that it is possible to make an impact on this problem, 2) it identified key outcome variables which have guided the design of this proposed study, and 3) it identified key factors that need to be considered if one is to increase use of car seats. In particular, the pilot study highlights the importance of an intervention that does not separate parental use of seat belts with the use of child safety seats in pre-schoolers.

The second major strength of this project is that the authors clearly demonstrate knowledge of how to reach their target populations. The educational materials they provide in the appendix are of very high quality and evidence a very thoughtful team. Material provided by the authors also evidences that this team is comfortable working outside a strictly theoretical environment.

The major remaining problem with the revised proposal relates to the process whereby this project's findings become generalizable. While it is true that they now describe various schemes that will attempt to "tease out" the relative contribution of specific project components (e.g., educational videos), the actual mechanism for this involves a rather weak design (asking teachers and parents what they thought worked the best). There is scant description of how this rich body of data will be transformed into an "inexpensive, self-contained module." In fairness to these investigators, this problem is not fatal.

The locale for this study is ideal. The population is readily available and recruitable. The investigators also demonstrate that they do have access to leaders in the community and that they have performed an extensive amount of preparatory work (e.g., identifying centers that will need to be randomized and established links with local community leaders).

The principle investigator is highly qualified to lead this study. He has conducted significant research in many of the areas required. These include pediatric trauma, as well as injury prevention. He has also used the prestige of his position and research to "leverage" community interest, which is important for this study. Dr. Zins is a psychologist who is also well qualified and who has published extensively in areas relevant to this project. Dr. Rivara is a political scientist with experience in- survey research, data management, questionnaire development, and opinion polling. He is a valuable member of this team. The addition of Dr. Tuchfarber significantly improves the team's analytic capability. Susan Laurence will be the project coordinator and will be responsible for the day to day management of this project. Kathryn Clark will provide administrative support and consultation for the project. She is also well qualified to perform this task. Data collection for the key outcome measures will be performed by professional interviewers who will be hired on a contract basis.

Some of the key data collection for this study does need to be performed by individuals at a high level of training (Zins, Rivara, Tuchfarber). The other costs listed are appropriate; they form part of the "nuts and bolts" of this project where contact with centers and families is concerned. The key issue with this project's budget is teasing out which project analytic costs are intrinsic to the project and which are for the poorly defined process whereby study findings will be transformed into an "inexpensive, self-contained module" suitable for national dissemination.

Protection of the rights of human subjects in this study is adequate.

Evaluator 2

Originality and Importance

This proposal is designed to assess the prevalence and reasons of inadequate use of age-appropriate restraint devices for preschool children in automobiles. The project includes development of an injury prevention program to increase use of child safety seats and booster seats, particularly among high risk, disadvantaged families. It also includes evaluation of the effectiveness of the program by comparing changes in the use of child safety seats among parents whose children attend control preschools with those attending preschools participating in the injury prevention program. The prevention of injuries among preschool age children is an important research priority of MCHB and the Healthy People 2000 directive.

Regional and National Significance

Inappropriate and/or lack of use of child safety seats among preschool children is widespread and well documented in the 1990s despite mortality and injury statistics for this age group due to automobile collisions without use of appropriate restraining devices. The problem is worse among the disadvantaged and minority children. Why this injury prevention strategy is ineffectively used by large numbers of parents despite federal efforts to encourage the use of child safety seats remains unclear. This projects proposes to identify barriers and facilitators of child safety seat use, determine the prevalence of inappropriate and lack of use of child safety seats, and develop an effective community-based program that increases use of

child safety seats and booster seats among preschool children and the use of seat belts among parents. The project will also evaluate the effectiveness of this injury prevention program. Each facet of this program can be generalized to other communities nationally and therefore has national significance.

Scientific and Technical Merit

The literature is clearly cited and provides compelling figures describing the magnitude of the problem and the potential number of lives that could be saved and injuries reduced. It includes direct observations made by the principal investigator in his community. It also includes explanations as to why adult restraint devices are not effective for preschool children. The reasons why previous injury prevention programs in this area have not worked are also cited.

The concepts explained are the Health Belief Model for why people practice prevention behaviors and the Social Learning Theory as a means to help people change behaviors. The specific principles of these theories are cited and provide rationale for the structure of the proposed injury prevention program.

The hypotheses are clear and measurable although the techniques to measure effects of the intervention are largely through parental self-reporting. Outcome variables are use of child safety seats for the children, seat belt for the parents, and rear seat child safety seats positioning. Whether the program increases child safety seat use more among families of lower socioeconomic status will also be measured. The test measurements will be self-reporting behaviors through interviews and surveys and actual use of restraining devices by drivers and children arriving at preschools. Use of restraint devices per preschool is the unit of analysis; schools will agree to receive the intervention or act as controls.

The fact that the author has completed a pilot of the project and subsequently refined the content of the education program adds considerable strength to the current proposal. The use of focus groups has been improved with resubmission of this proposal. A mechanism for setting priorities regarding parent-based barriers and facilitators of child safety seats use is inherently selective, i.e. the modifications/suggestions that can be included in the prevention program. However, a mechanism for identifying the order of importance of parent issues is now in place. An additional strength of the methodology is the stratification of focus groups by socioeconomic status. However it is unclear how components among the three focus groups will be prioritized among groups, particularly if increasing child safety seats use among lower socioeconomic families is a priority of the project. Whose input is most important?

The data based on direct observation of child safety seats use by parents arriving at school by car with children is strengthened by the prior training of the observers and assessment of inter-observer variability during training sessions. Observers will be blinded to the allocation of the school in the intervention or control group. It is unclear if the interviewees will be blinded to the observations recorded by the interviewers. Secondary outcomes will be measured with parent surveys using a pretest-post-test design to discern differences due to the intervention and changes will be compared between groups of parents from control and intervention groups of schools. Poor response rate to parent surveys may still represent a limitation of the design despite additional incentives to schools for parents to participate.

The frequency of carpooling and its impact on the utility of observation data remain problematic. It will be helpful to know the frequency of car pooling for each school and between groups of schools in the intervention and control groups. How will parent survey responses and parent behaviors be correlated using child safety seats? Is child safety seats use proportional to number of children in the car, i.e. are there enough child safety seats in the car? This data should also be reported and perhaps a separate description of use of child safety seats and booster seats as a function of car pooling is in order. Finally, it would be interesting if the education intervention had a differential effect on car pooling parents vs. single driver parents.

The educational intervention has multiple components for both parents and children using a variety of methods (e.g., videos, newsletters, parent education sessions, and classroom role-playing). No single component will be judged for effectiveness as the project is now written. Focus groups among the schools that experienced the most improvement in use might be helpful to further evaluate the intervention's educational components.

How will the investigators alter their approach if the parent participation (as measured by frequency of video checkout?) is particularly low in certain schools after 6 months?

Enrollment of schools will be done with number of children per school and tuition for school in mind in order to assure balanced representation of socioeconomic groups in both the control and intervention groups. No attrition of schools is anticipated. Number of schools and students to be enrolled exceeds power calculations to assess an increase in child safety seats by 50%. Data will be analyzed by linear regression techniques accounting to three tiers of tuition and two racial groups balanced among control and intervention groups of schools. Changes in survey responses pre- and post-intervention will be tested with a chi-square procedure.

The time schedule seems appropriate. Analysis of the initial focus group input will need tight time controls in order to refine the educational program and initiate it at the onset of the school year. There are no collaborative financial arrangements.

The investigators are most qualified to conduct this project given their previous publications regarding injury prevention and the previous experience of the team in conducting a pilot project in Cincinnati. Resources are adequate for feasible completion of the study. The project has been approved by the Children's Hospital Medical Center Institutional Review Board.



Infant ETS Exposure: Clinic-Based Maternal Counseling

Grantee

San Diego State University Foundation

Investigator

Melbourne F. Hovell, Ph.D.
9245 Sky Park Court, #230
San Diego, CA 92123
(858) 505-4770
(858) 505-8614 fax
hovell@mail.sdsu.edu

Project Number MCJ-060634

Project Period 6/1/1996-5/31/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	141,573	62,912	204,485
Year 2	175,572	86,030	261,602
Year 3	178,040	87,240	265,280
Year 4	154,894	75,898	230,792
Year 5			

Summary

Statement of the Problem

Babies' exposure to environmental tobacco smoke (ETS) is a significant problem because ETS is an etiologic factor in lower respiratory disease including otitis media, asthma, and bronchitis, and is associated with an increased risk of sudden infant death syndrome (SIDS).

Research Questions or Hypotheses

This study tests a behavioral counseling intervention designed to reduce ETS exposure among babies under age 1. Specific aims are to (1) determine the effects of clinic-based behavioral counseling on ETS exposure among babies of low socioeconomic status (SES), as measured by mothers' reports and babies' urine cotinine analyses; (2) validate parent-reported ETS exposure measures using urine cotinine assays and environmental nicotine monitors; (3) determine the effects of participation on the mothers' smoking rate and the proportion of mothers who quit smoking; (4) explore health outcome measures associated with decreased ETS exposure; and (5) identify possible determinants of ETS exposure.

Study Design and Methods

Year 2000 Objectives

3.4, 3.6, 3.8, 15.12, 16.6, 16.10

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Infants, Toddlers,
Parents/Families/Mothers/Fathers (Adolescent
Parents)

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

A two-group repeated measures design with random assignment will be used. After baseline measures are collected, mothers and babies will be assigned at random to the experimental counseling or "usual care" control group. Clinic personnel (health educators, registered nurses, and medical assistants) will serve as counselors for the experimental group, conducting three face-to-face and four telephone sessions over 6 months. Counseling will incorporate contingency contracting and problem-solving negotiations.

Population and Sampling Plan

A total of 150 English-speaking and Spanish-speaking mothers will be recruited from patients seen for well-baby visits through the California Department of Health Services' Child Health and Disability Prevention Program (CHDP) at North County Health Services and East County Community Health Services, two of the largest community clinic systems in San Diego County. Outcome measures will be obtained from both groups at 3 months (midintervention), at 6 months (posttest), and at 12 and 18 months (followup).

Analysis Plan

Differential change in ETS exposure between experimental and control groups will be evaluated using repeated measures analyses of mothers' reports of ETS exposure and babies' urine cotinine results. The group by time interaction in each model will be assessed. Hierarchical multiple regression analyses will be used to explore correlates of ETS exposure and health. If effective, this intervention could be incorporated into CHDP-funded well-baby care throughout the State of California and in other well-baby care settings across the country.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

A major feature of the proposed intervention is that it can be applied in a "real world" setting. Moreover, the intervention will be tested within the context of such a setting. The investigators have the cooperation of one of the largest community health systems in San Diego County to undertake the work. In addition, they have developed contingency plans if they find that there are not enough subjects in the clinics.

Regional and National Significance

The problem of infant exposure to environmental tobacco smoke (ETS) is significant. ETS exposure may be an etiologic factor in the rates of respiratory disease in children who live in households with adults who smoke. An intervention to reduce this exposure that can be implemented as part of routine pediatric care may have widespread application and would be of national and regional significance.

Scientific and Technical Merit

The proposed analyses are a natural extension of the previous work of the investigators. They have several years of experience in studies of ETS exposure and clinical trials of preventive interventions.

The research team is very strong in terms of both research and clinical background. The proposal is also well-written. Another strength of the proposal is its use of validation measures for parental reports of ETS exposure. The investigators will use the Centers for Disease Control and Prevention (CDC) laboratories to analyze the urine cotinine levels of infants. These laboratories have the most sensitive tests available for urine cotinine.

The study design appears to be appropriate to answering the study questions, and the investigators are aware of the potential limitations of their work. The objectives of the study are clearly stated and linked to the study hypotheses. The study hypotheses are also clearly specified, and a rationale and a list of variables are provided for each. Power calculations are presented for each hypothesis. These indicate that, given the proposed sample size, the investigators will have adequate power to test the hypotheses.

Although the proposed studies have many strengths, they also have a number of weaknesses. First, it is unclear why the investigators need to do the two studies simultaneously. The natural study to pursue first is the one in the white population

that addresses whether counseling by telephone has an effect on reducing ETS exposure among healthy infants. The investigators are introducing two new elements to their previous work: The telephone contact and the healthy population. It is not clear that face-to-face counseling would have an effect on children who are free of respiratory disease. The second study is predicated on the evidence from the first study. Moreover, the second study needs a separate rationale and a set of retention methods and counseling approaches that differ from the first study.

A second weakness of the proposed study is that other investigators may not be able to replicate the intervention. The proposal contains a lengthy discussion of the counseling and what it might involve, but presents no clear guidelines for counseling. More standardization of the intervention appears to be needed before it can be replicable.

A third weakness is that although the investigators state they are using social learning theory to guide the intervention and the data collection, they never indicate which theory or how it directly relates to the interventions. The literature review provides a graphical representation of the relationships among variables, but the proposal does not mention these relationships again.

The investigators may be overly optimistic about the success of their followup of subjects. They project counseling points that coincide with well-child visits, but they do not indicate what they will do if a mother does not bring in her child for a visit at the proposed times. A 15-percent attrition rate over the course of the 18-month followup seems very low.

The investigators propose to use a biomarker to validate the ETS exposure data reported by the parents, but the biomarker may not be a valid measure of exposure. Is there a reason to estimate biomarker levels if they are of questionable validity? One measure, environmental nicotine levels, will only be estimated for 20 percent of the sample due to the cost of measuring these levels. It is likely that either the data on morbidity will not be useful or the sample size will be too small to detect differences in the incidence of more severe lower respiratory illnesses. Thus, it is not clear whether the study will obtain valid data on outcomes for the entire sample.

Power calculations predominate in the analysis plan. The plan is difficult to follow because it is too succinctly written, does not clearly indicate the independent variables for the analysis, and suggests methods (such as correlation for the determinants of ETS exposure) that may not be the best approaches. The inclusion of a dummy variable for group membership may not account for differences in the effect of the independent variables on ETS exposure between the intervention and control groups.

The literature review primarily includes the previous work of the investigators. The investigators indicate that very little work has been conducted on reducing ETS exposure in children. However, there have been a number of clinical trials on smoking cessation among pregnant women that may provide information about the best strategies for intervention. Some acknowledgment of this literature would seem appropriate. One important finding in these studies is that, despite higher quit rates in the experimental group, the effect of the intervention on infant birthweight was small.

The behavioral counseling program for nonsmoking Latino mothers is described as being culturally tailored. In this study, counseling will be directed toward the mother to reduce the child's exposure to the father's tobacco smoke. Although the program will be delivered in Spanish or English (according to the family's preference), the potential for marital/family conflict poses a serious threat to the participants' well-being and their ability to remain in the study. What counseling and retention procedures will be implemented in the event of increased marital problems? Will the nature of these marital conflicts and their resolution be documented? In what ways will conflict-resolution counseling be culturally tailored? In addition, many Latinas live in extended families, which create complex intervention situations. Will counselors whose professional expertise is limited to OB/GYN and birth control be sufficiently prepared to address complex extended-family issues? Although the proposal contains evidence that Latino mothers are likely to get fathers to cooperate, the data presented are based on a relatively small number of families. To reduce infant ETS exposure in this group, it would be worth considering ways in which the father and other household members might be actively involved in the intervention. Direct and personal involvement by fathers may also decrease the potential for conflicts with the mothers.

Clearly, the use of independent measures of ETS exposure is a strength of this study. However, as the principal investigator suggests, a potential weakness of the study design is the lack of an "attention control" group. If the present study shows a significant decrease in ETS exposure levels, how will the reactivity threat be handled?

It is not clear how the attrition rate was estimated. The investigators' previous experience is limited to working with parents of children with respiratory disease and face-to-face (as opposed to phone counseling) interventions. In this proposed study, participants and their infants have characteristics that may increase the attrition rates considerably beyond the estimates. The dropout rate among controls could be lower because of fewer study demands.

The study timeline appears to give the investigators sufficient time to recruit the sample, collect the data, and analyze it. The problem of infant exposure to ETS is a significant one. Exposure may be an etiological factor in the rate of respiratory disease in children who live in households with adults who smoke. An intervention to reduce exposure that can be

implemented as part of routine pediatric care may have widespread application. Unfortunately, the investigators have not made a good argument for doing both studies. The recommendation is for approval of Study 1 only, with the stipulation that prior to funding the investigators comply with the following conditions:

1. Support the estimated rate of attrition given in the application protocol;
2. Address the possibility that participation in the study may lead to spousal and/or family conflict, and specify the measures that will be taken to address this problem if it does occur; and
3. Submit a data analysis plan and revised budget that is restricted to the activities proposed for Study 1 only.



Infant Temperament: Neonatal–5 years in Rural Appalachia

Grantee

Marshall University

Investigator

Margaret Fish, M.S., Ph.D.
School of Medicine, Department of Family & Community Health
1600 Medical Center Drive, Suite 1400
Huntington, WV 25701-3655
(304) 696-7194
(304) 696-7048 fax
fishm@marshall.edu

Project Number MCJ-540635

Project Period 6/1/1996-5/31/2001

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	58,387	22,771	81,158
Year 2	56,497	22,034	78,531
Year 3	50,110	19,543	69,653
Year 4	53,011	20,674	73,685
Year 5	43,882	17,114	60,996

Summary***Statement of the Problem***

The lack of cross-sectional and longitudinal data on individual differences in developmental trajectories in the rural Appalachian population has hampered efforts to design culturally relevant interventions for this population. More information is needed on the strengths of this rural population to disentangle the role of poverty versus culture in examining variables of interest. It is important to learn more about protective factors that promote good outcomes in rural families of low socioeconomic status (SES) as well as to understand whether risks identified in infancy and preschool have effects once children enter school.

Research Questions or Hypotheses

Two research questions will be addressed by this study. First, what continuity is there from certain temperament and mother-infant relationship qualities in infancy to preschool behavior problems and early school adjustment? Second, how do concurrent environmental factors such as poverty and low parental education levels, cultural values regarding education and

Year 2000 Objectives

6.3, 22.4, 8.3

Study Design

Observational

Time Design

Mixed

Care Emphasis

Noninterventive

Population Focus

Preschool-Age Children, School-Age Children, Parents/Families/Mothers/Fathers (Adolescent Parents)

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

achievement, and individual differences in temperament and mother-child relations interact to influence early school adjustment and performance?

The following hypotheses will be tested:

1. Difficult temperament is a risk factor when combined with a less optimal or less supportive caregiving environment. Children who showed continuity in high negative emotionality during the first year will be higher on preschool behavior problems and less sociable, positive, and persistent at age 4 if their mothers also had one or more of the following characteristics: Higher scores on negative personality traits, lower sensitivity during interaction, and low social support.
2. A positive, socially responsive temperament and a secure relationship with the primary caregiver are protective factors against global risk conditions such as poverty. Children who remain high or increase in positive emotionality/social responsiveness during the first year and those who have secure attachments to their mothers at 15 months will be lower on preschool behavior problems, higher on persistence and problem solving, and more likely to remain securely attached at age four.
3. The major child outcome variables from each age in this study (15-month attachment and verbal communications skills, 4-year behavior problems, attachment, temperament, and verbal skills, 5-year measures of social and cognitive functioning) will contribute significantly to variation in kindergarten adjustment. Continuity in positive factors and more optimal characteristics beyond infancy will best predict good school adjustment.
4. Parental expectations/aspirations will interact with child and family characteristics to influence school adjustment. Higher parental aspirations for the child and higher value placed on education, in combination with strengths such as child positive/social temperament, high social support, and stable, satisfying parental relationships are expected to predict higher teacher-rated adjustment in kindergarten.

Study Design and Methods

This is a continuation of a previously funded project on infant temperament. This project will conduct assessments at the age of 4 years, immediately before entry into kindergarten, and during the kindergarten year. At the age of 4 years, the laboratory assessment includes child free play with the mother and a stranger (a preschool version of the strange situation), a clean-up task, two puzzles of increasing difficulty, and the PLS-3 scale of language development. Mothers will repeat social support and relationship satisfaction measures that were given prenatally and will also complete measures of child-rearing values and attitude toward spanking. Before entry into kindergarten, the child and both parents will engage in free play and clean up; then the parents will be interviewed on aspirations and expectations for the child and their feelings about education while the child repeats the PLS-3 and plays counting, sorting, and completion games and is given a resistance-to-temptation task. During the spring of the child's kindergarten year, the kindergarten teacher will complete the classroom behavior inventory with scales that measure both social behavior and academic performance.

Child variables to be assessed include the following: Standard measures of attachment and behavior problems (age 4 years); a number of ratings of temperament and social functioning such as positive and negative emotionality, sociability, persistence, focused attention, and compliance (ages 4 and 5 years); concepts and language skills needed for school (ages 4 and 5 years); and a standardized measure of classroom functioning (kindergarten).

For parents, variables to be assessed include the following: Repeated measures of family demographics, maternal social support, and relationship satisfaction (age 4 years); parenting attitudes (age 4 years); ratings of parent-child interaction (ages 4 and 5 years); and attitudes toward education and hopes and expectations for the child (age 5 years).

Population and Sampling Plan

This longitudinal sample will consist of 95 rural Appalachian, white, mother-child pairs with children 4 years old (all of those who completed the first phase of the project). The mean age of the mothers is 27 years, and the majority are married (68 percent) or living with a partner (10 percent). The mothers' and fathers' average level of education is 10.8 years; 46 percent of the parents are not high school graduates. About 70 percent of the families report annual incomes of less than \$10,000 and receive public assistance. The children are 53 percent male, and 72 percent are second-born or later. It is estimated that 85 mother-child pairs will be retained through the kindergarten data collection.

Analysis Plan

Multiple regression and path analyses will be used to determine which child and caregiving environment variables best predict behavior problems, temperament, cognitive functioning, and school adjustment. At each age, the outcome measures are expected to relate to individual differences in prior child temperament, attachment, and cognitive functioning, and relate to concurrent mother-child interaction and characteristics of the caregiving environment in a process model that reflects both direct and indirect influence. Discriminant function analysis will also be used to identify predictors that best distinguish groups who are secure and insecure in attachment, high and low in behavior problems, and problematic vs. functioning satisfactorily in cognitive measures.

The goals of data analysis are twofold. First, the study aims to increase understanding of the developmental processes that lead to more and less optimal socioemotional functioning and adjustment in both family and school contexts for rural, low SES children. Second, the study aims to identify specific risk and protective factors in this population. Achieving both of these goals will lead to increased ability for early identification of children who may be at risk in order to provide appropriate, culturally relevant, intervention programs.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This well-written and well-designed research proposal will provide more information on an understudied, high-risk group of Appalachian women and their infants. The observations already obtained by the study, combined with a lack of cross-sectional and longitudinal data on individual differences in the developmental trajectories of this population, argue for continuation of the study. As the investigators acknowledge, additional information is required before culturally relevant interventions can be designed for those at risk.

Regional and National Significance

There is little current research on the Appalachian population. The project will assist the MCH community in better understanding the developmental trajectories of this population and will provide additional information about designing culturally relevant interventions. Therefore, the project has regional and national significance.

Scientific and Technical Merit

As in the prior application, the design and methods are well-described and appear appropriate for longitudinal followup of this population. Although the mothers in this sample are socioeconomically disadvantaged and have low self-esteem, they do not have lower maternal self-efficacy than mothers in a comparison sample.

The investigator has attempted to remedy the deficiencies of the previous proposal. Specifically, the literature review and description of the conceptual framework (as well as hypotheses and analyses) attempt to view the strengths of the rural Appalachian culture and disentangle poverty and culture in examining the variables of interest.

The investigator attempts to include fathers in this revised proposal. Specifically, at the 5-year data point, fathers and mothers will be assessed in the structured-task interaction situation. However, details of paternal involvement (i.e., anticipated numbers) are not provided, and the consent form has not been revised to reflect the inclusion of fathers.

In this revision, sample size estimates based on a power analysis are provided. The original submission proposed a sample size of 175, but no details were provided for the final sample size of 121 in phase 1. This revision provides the rationale. The original proposal was based on 1989–90 figures for the number of prenatal patients in Lincoln County. Since that time, the population has declined, resulting in fewer births. Seventy percent of eligible women were recruited in phase 1; however, 111 of 121 women had infants who met study criteria. Attrition due to mobility and other factors accounts for the additional loss of subjects and the projected sample size of 100 at the beginning of phase 2, when the infants will be 3.5 years of age. Based on the same estimate of attrition, 85 infants are expected to be included at 5 years. However, estimates of attrition are not extended to the kindergarten data point. It is probable that less than 80 subjects will be available to study at this data point.

The conceptual framework is a synthesis of attachment and risk/resiliency theories, and suggests selected variables to be included. Within this framework, the investigators perhaps have focused more on methodological rigor than cultural relevance. A paradigm that takes into account culture as well as parenting and other developmental processes may be more informative. Additionally, since attrition is expected to reduce the power needed for multivariate analytic techniques, qualitative approaches to examining major phenomena should be considered.

The principal investigator has published several articles in this area. She is well-qualified to conduct this study as proposed. The addition of team members, as suggested in the 1994 review, adds to the proposal. The budget appears to be appropriate. This is a modest budget for a 5-year study; personnel costs are the major line items. This is a clear and well-written application. The research methods are sound and the conceptualization is compelling. The investigator has responded to concerns noted in the initial review, and the revised application is stronger as a result. The recommendation is for approval.



Interparental Conflict and Adolescent Violence

Grantee

University of California-San Francisco

Investigator

Jean Marie Tschann, Ph.D.
Department of Pediatrics
Box 0844
San Francisco, CA 94143-0844
(415) 476-7761
(415) 476-7744 fax
jmt@itsa.ucsf.edu

Project Number MCJ-060702

Project Period 1/1/1997-12/31/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	193,472	90,932	284,404
Year 2	216,101	102,647	318,748
Year 3	246,116	116,905	363,021
Year 4	131,407	62,418	193,825
Year 5			

Summary***Statement of the Problem***

Although violence among adolescents is increasing, little is known about its causes. Parental marital conflict is a potentially important but understudied influence on adolescent violence. Results of this study will be useful in developing primary and secondary prevention programs for parents and for adolescents, aimed at decreasing violent behavior and victimization among adolescents. This research will also provide the basis for developing prevention programs tailored to the needs of Mexican-American families.

Research Questions or Hypotheses

The purpose of this research continuation is to determine the specific components of parental conflict that are related to violent behavior and victimization among adolescents and the processes by which parental conflict influences adolescent violence and victimization.

Study Design and Methods**Year 2000 Objectives**

6.14, 7.4, 7.7, 7.9, 22.4

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

Adolescents, Parents/Families/Mothers/Fathers
(Adolescent Parents)

Race/Ethnic Focus

Mexican-American

The proposed longitudinal research will use a cognitive/emotional model to examine how parental conflict influences adolescent peer violence, dating violence, and sexual aggression. Both violent behavior and victimization among adolescents will be examined. Multiple dimensions of parental conflict will be measured to identify aspects of parental conflict that are beneficial or harmful to adolescents. The theoretical model will be tested separately in white and Mexican-American families.

Adolescents will be interviewed about parental conflict, their emotional distress, violence, and victimization. Parents will be interviewed regarding their marital conflict. The Marin acculturation scale will be administered. Six focus groups will be held for the purposes of instrument development and refinement, with particular emphasis on the assessment of violence. The research will use a strong multidimensional approach to assessing inter-parental conflict. Six dimensions of conflict are targeted: frequency, intensity, content of the conflict, conflictual processes, conflict resolution, and child involvement in conflict. This conceptually and methodologically sophisticated approach to studying parental conflict allows the researchers to address precisely associations between conflict and child outcomes.

Population and Sampling Plan

This study will use 303 adolescents and their parents who are participating in currently-funded research as study subjects. Adolescents, aged 15-18, and their parents will be interviewed individually by telephone three times at 6-month intervals. Families will be recruited from the membership of Kaiser Permanente, a large HMO serving Northern California.

Analysis Plan

The scales developed for this research, factor analyses will be conducted, followed by Cronbach's alpha. Items for a scale will be equally weighted and combined. The hypothesized cognitive/emotional model will be tested using latent variable structural equation modeling (SEM). The model will be tested separately for white and Mexican American families. Following this, differences between Mexican American and whites will be assessed using multi-group SEM, which will test whether the same model applies to both groups and whether the coefficients for each parameter are the same across groups. The multi-group analysis will include only those scales common to both groups.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This application requests 3.7 additional years of support to extend a currently funded study. The current project is a prospective study of the relationship between aspects of marital conflict and adolescent health risk behaviors, including unprotected sex and use of alcohol, tobacco, and other substances. The proposed research would follow longitudinally the study sample, with a focus on the predictors of adolescent violence. The research is based on theories of emotion and cognitive models of stress and coping.

The purpose of the continuation study is to determine the specific components of parental conflict that are related to violent behavior and victimization among adolescents, and the processes by which parental conflict influences adolescent violence and victimization. Peer violence, dating violence, and sexual aggression, addressed in the proposed study, are all of significance and concern. The researchers make a convincing argument that parental conflict is a relatively unexplored but potentially powerful influence in the development of adolescent violence. In addition, the researchers' focus on studying culturally relevant aspects of family conflict and adolescent violence is an important strength of the proposed research.

Regional and National Significance

The involvement of adolescents in violence, both as perpetrators and as victims, is a major national public health issue. The study's results should make an important contribution to our knowledge of risk behavior and violence among white and Mexican-American youth. The information obtained from the study could be useful in developing culturally relevant intervention and prevention programs. For example, programs could teach parents to develop those aspects of parental conflict that are helpful to adolescents and to reduce those conflict behaviors that are harmful.

The investigators discuss the possible development of such programs within the health maintenance organization (HMO)

system and describe how information could be used to develop educationally based interventions for adolescents, focusing on conflict management and coping with distress arising from parental conflict. Important information would be generated to better understand how to tailor such interventions to Mexican-American adolescents and their families. The topic of this project is of regional and national significance, given the importance of this issue.

Scientific and Technical Merit

The study uses a strong multidimensional approach to assessing interparental conflict. Six dimensions of conflict are targeted: Frequency, intensity, content of the conflict, conflictual processes, conflict resolution, and child involvement in conflict. This conceptually and methodologically sophisticated approach to studying parental conflict allows the researchers to precisely address associations between conflict and child outcomes.

The researchers have been very responsive to the review committee's requests for clarification and additional information. The first issue concerned the reliability and validity of data obtained through telephone interviews. The investigators provide a detailed response to this question, citing the advantages of data collection by phone rather than face-to-face interviews (namely, ease of scheduling and completion, and cost savings). Using certain sensitive questions as a basis, the investigators have analyzed their existing data collected from adolescents through phone interviews and through face-to-face interviews, and have found minimal discrepancies between the two data-collection formats. Inconsistencies averaged 1.8 percent for whites and 3.0 percent for Mexican-Americans. Extensive detail is provided on strategies to ensure the reliability and validity of telephone data, including using focus groups of parents and adolescents to develop the phrasing of questions, pretesting the interview, ensuring the adolescent's privacy during the phone interview, and building checks for internal consistency into the interview.

The most substantial questions arising from the current review concerned the conceptual framework for the study. These concerns centered on two areas: (1) The different associations between the adolescent risk behavior and the three types of violence to be studied; and (2) expectations for similar or different processes in whites compared with Mexican-Americans. The investigators address each of these areas in detail, supplying an expanded review of the literature and clarifying the data analyses to be performed.

The investigators argue that the factors determining intimate-directed versus peer-directed violence are yet to be determined. They suggest that it is not yet known to what degree peer aggression, dating violence, and sexual aggression are a function of the same factors. The planned research would investigate these associations. The researchers present a theoretical model that posits differing processes leading to peer aggression, dating violence, sexual aggression, and to victimization by each of these three different forms of violence. The model posits similar basic processes for Mexican-American and white adolescents. In addition to these basic predictions, the investigators suggest that the within-family processes of acculturation, as well as societal forces such as economic hardship and discrimination, may place Mexican-American youth at greater risk. The investigators predict that the model components of parental conflict, primary appraisal, and emotional distress will have stronger effects on adolescent violence and victimization among Mexican-American youth.

In sum, the investigators have provided a thoughtful and detailed response to the questions posed. The conceptual framework has been tightened and improved, and methodological concerns related to the phone interviews have been satisfactorily addressed. The proposed investigative staff seems well qualified and experienced in conducting studies such as the proposed project. The budget is a bit high and could be reduced by at least 15 percent. The recommendation is for approval, with reduction in budget.



Life Around Newborn Discharge (LAND)

Grantee

American Academy of Pediatrics

Investigator

Henry H. Bernstein, D.O.
Pediatric Research in Office Settings
141 Northwest Point Boulevard
Elk Grove Village, IL 60009-0927
(617) 355-7960
(617) 739-5458 fax
Bernstein_H@al.tch.harvard.edu

Project Number MCJ-250825

Project Period 10/1/1998-9/30/2001

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	457,986	152,509	610,495
Year 2	544,588	181,348	725,936
Year 3	408,857	136,149	545,006
Year 4			
Year 5			

Year 2000 Objectives

14.1, 14.9, 14.14, 14.16

Study Design

Observational

Time Design

Mixed

Care Emphasis

Noninterventional

Population Focus

Neonates, Postpartum Women

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

The immediate postpartum period is one of biological and social transition, providing an important opportunity for the health care system to identify and respond to both acute and chronic medical and social problems that families face. Insurers, managed care companies, and hospitals operating under capitation have sought to reduce costs through initiatives to shorten hospital stays, including the length of postpartum hospitalizations for mothers and newborns. With a reduction in the lengths of hospital stays and the services, opportunities to screen for medical and social risks diminish. Therefore, practitioners and parents must shoulder substantial added responsibility for monitoring during the critical neonatal period. The safety and feasibility of discharge are dependent on the medical and psychosocial needs and risk status of the mother and infant pair, together with the health care infrastructure available to monitor them after discharge. Despite the breadth of these concerns, recent studies have found seemingly contradictory conclusions with respect to identifying substantial medical harm because of decreased postpartum hospital stays. Traditionally, practitioners have judged the degree of readiness and risk and have determined suitable timing for discharge. The components of this judgment about discharge timing are complex and probably include intuitive assessments of biological and social risk, barriers to access, adequacy of education and postpartum services, and, admittedly, tradition. Economically inspired, rule-based

decision making may limit good judgment and result in unsuitable discharge timing and insufficient postpartum services for some mothers and infants. An optimal length of postpartum stay for healthy newborns and mothers is not well defined. Good judgment and available data do not tell us where services should ideally be performed, by whom, and with exactly what content or methods.

We feel the most revealing investigation will be one that examines the mothers', pediatricians', and obstetricians' judgments of readiness for discharge and that identifies the components of practitioner judgment or family readiness for discharge. We then will relate these judgments to health care utilization, health-related behaviors, and infant and maternal health status during the first month after postpartum discharge. A comparison will also be made between the supplemental services and family supports and adjustments perceived as necessary by mothers, pediatricians, and obstetricians with those that are actually delivered.

The eventual product of this and related work will be to provide the basis for recommendations for service delivery in the peripartum period; the recommendations will be based on this empirical study of the medical and psychosocial needs during the first month of life. Our project is well timed to examine scientifically the critical perinatal period and to help with the monitoring of the Newborns' and Mothers' Health Protection Act of 1996 (as required by law), which went into effect January 1, 1998.

Research Questions or Hypotheses

The study will focus on the following questions:

1. How often do mothers, pediatricians, and obstetricians agree on readiness for postpartum discharge?
2. What influences these perceptions of readiness?
3. How do these perceptions affect health care utilization, health outcomes, and health-related behaviors during the first 4 weeks after discharge?
4. How do these perceptions of readiness change over time?

Study Design and Methods

This will be a prospective, observational cohort study of 6,000 mother and infant pairs who will be followed for the first 4 weeks after postpartum discharge. These infants are healthy, term newborns who weigh more than 5 pounds and who will be followed in one of our national sample of pediatric practices. Exclusion criteria include maternal chronic illness; multiple births; mothers without a telephone; and newborns who have a major congenital anomaly, have been placed for adoption, or have been in the special care nursery for more than 8 hours for medical reasons. Each practice will enroll all eligible newborns seen consecutively for visits in the hospital nursery during a period of 8 weeks, including holidays and weekends. Data will be collected by questionnaires completed by mothers, pediatricians, and obstetricians.

Mothers, pediatricians, and obstetricians will answer self-administered questionnaires at the time of enrollment. A mother's enrollment questionnaire contains items about care received during pregnancy, labor and delivery, and time in the hospital, and about decision making during discharge planning. The discharging pediatrician's questionnaire documents prenatal problems, birth data, nursery problems, discharge data, and practitioner judgment regarding discharge and followup plans. The discharging obstetrician's questionnaire documents the obstetrical considerations about postpartum discharge, including the medical and psychosocial factors.

Beginning the first day after postpartum discharge, mothers will complete daily diaries during the infant's next 14 days of life. These diaries request information about health concerns, behaviors, and health care use for both mother and infant.

Pediatric practitioners will also complete an encounter form at each pediatric office encounter during the first 4 weeks after discharge. This form records key information about the encounter, including the articulated reason for the visit, the initiator of the visit, the disposition, and the diagnosis, as well as sufficient other information to assess the clinical context.

Four weeks after discharge, mothers and pediatricians will each complete self-administered followup surveys. The mother's survey documents maternal confidence level in her newborn's care, maternal ratings of the quality of encounters with various health care practitioners, maternal health-related behaviors, and maternal health and mental status. The pediatrician's followup questionnaire documents health care utilization including office visits, hospitalizations, outpatient procedures and referrals, infant's weight gain, and whether (in the practitioner's opinion) the mother and/or infant would have benefited from an earlier or a longer hospital stay. Finally, each mother will complete a postcard at 7–8 weeks postpartum to document the date of her obstetrical checkup. All patient questionnaires will be available in English and Spanish; the mothers' reading level is approximately fifth-grade to sixth-grade level, and the questions have been modified to insure cultural sensitivity and

relevance.

Population and Sampling Plan

The intent of our sampling plan is to obtain a heterogeneous set of community-based practices serving diverse populations. This study will be conducted in a national sample of approximately 200 pediatric practices, each with an average newborn enrollment of 30; there will be oversampling of certain practice sites, as required, to ensure that there are adequate numbers of underserved and minority subjects. Subjects will not be excluded from this study based on their race, ethnicity, or the gender of the infant. Mothers and their newborns will primarily be drawn from a geographically diverse national sample of pediatric primary care practitioners in Pediatric Research in Office Settings (PROS), a national, practice-based research network of the American Academy of Pediatrics (AAP). All PROS practices will be asked to participate. This source will be supplemented with additional inner-city practices recruited through Health Watch, a not-for-profit organization located in Brooklyn, NY, and dedicated to "improving the health and longevity of minority populations." Surveys on the structure of the practice, demographic characteristics of both the practice and each practitioner, and routines relevant to newborn discharge will be completed. A subset of these same items will also be answered by a random sample of AAP practitioners. National, practice-based research networks allow investigators to conduct studies requiring large, national primary care samples from a pool of volunteer practitioners. Although this is clearly not a random sample, repeated PROS analyses from other studies have demonstrated that PROS practitioners are similar (in a number of important ways) to random samples of AAP practitioners. Therefore, we feel our results will be appropriately generalizable. This prospective, observational cohort design provides a substantial advantage in addressing our study aims. First, this study seeks to understand patterns of practice as they occur in real-life settings; we endeavor to generalize as broadly and appropriately as possible. The use of a highly specialized population, as typically occurs in randomized trials, and the intensity of followup involved in most such trials limit the ability to generalize from findings in randomized trials. This study provides low costs per patient and per clinician as compared with randomized, controlled, multisite trials with similar numbers. Second, we seek to minimize the impact of recall bias, that is, the bias that occurs when the outcomes of interest have already occurred and shade the recollection of possible exposures. Prospective data collection is the most desirable means of limiting such bias. Third, we seek information on a broad array of outcomes; such an approach precludes the use of a design, such as case control, based on the occurrence of one particular outcome.

Analysis Plan

Analyses of the data concerning the 6,000 newborns in this study will be complicated primarily by the fact that the medical care and advice will be limited to approximately 200 practices. Therefore, it is possible that outcomes for mothers and infants seen in the same practice will be more closely related to each other than to those in other practices. This correlation will be accounted for in all of the analyses that are carried out through use of the generalized estimating equation approach to cluster data. We will assume an exchangeable correlation structure within each practice and effectively increase the standard errors of the parameter estimates to reflect the reduced amount of "independent" information. These analyses, whether linear, logistic, or Poisson regressions, will all be carried out using a public domain, Statistical Analysis System macro written to implement the generalized estimating equation approach. If we find that the sample of practitioners in our study is not representative of the national population, we will use weighted regression methods to estimate outcomes that are more representative of practitioners in general. The weights will be derived by comparing the study sample with the membership of the AAP.

Related to the issue of generalizability is the extent to which study results hold in specific subpopulations, such as minorities, primigravidas, and those of lower socioeconomic status. In addition to analyses in which these variables will be included in multivariate models as explanatory factors, we will also provide descriptive statistics on the outcomes of interest for these separate subpopulations.

The choice of measures selected to be studied fits best with our conceptualization of discharge. Statistical analyses will include summary statistics (proportions and 95-percent confidence intervals or mean, standard deviation, median, interquartile range, minimum and maximum) for all study variables of interest and for calculated derived variables. We will analyze the readiness outcome, assessing the agreement among mother, pediatric, and obstetric decisions about maternal and infant readiness for discharge, using chance-adjusted kappa statistics.

To begin to elucidate the impact of certain explanatory variables on readiness, we will use two-sample *t*-tests or Wilcoxon tests for continuous data, and we will use the chi-square or Fisher's exact test for categorical data. As described above, we

will then build multivariate linear, logistic, or Poisson models, which reflect the clustered data structure, to explore factors influencing readiness. Similar methods will be used to assess the impact of readiness on health care utilization, health outcomes, and health-related behaviors during the first 4 weeks after hospital discharge.

We will also assess changes in decisions about readiness on the part of the mother and practitioner at 1 month postpartum; this will allow us to evaluate whether changes from the time of discharge to 1 month postpartum occur more frequently with judgments of infant or maternal readiness for discharge.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

Pre-award evaluation outstanding from MCHB. Submitted second request 10/26/00, JMB.



Maternal Health and Pregnancy Outcomes Among Hispanics

Grantee

Regents of the University of Michigan

Investigator

Edith C. Keiffer, Ph.D.
 School of Public Health
 Health Behavior and Health Education
 1420 Washington Heights
 Ann Arbor, MI 48109-2029
 (734) 647-2739
 (734) 763-7379 fax
 ekieffer@umich.edu

Project Number MCJ-260842

Project Period 10/1/1998-9/30/2001

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	116,858	61,350	178,208
Year 2	120,896	63,470	184,366
Year 3	131,246	68,904	200,150
Year 4			
Year 5			

Summary

Statement of the Problem

Low birthweight is rare among Hispanic infants in the United States. Most research associated with birthweight in Hispanic communities has explored social, dietary, and behavioral aspects of traditional Hispanic culture, which is presumed to reduce the risk of low birthweight among Hispanic infants. Although sociocultural and behavioral lines of inquiry are important, the complex interplay of factors associated with birthweight must ultimately involve physiological processes. Obesity, insulin resistance, impaired glucose tolerance, and type 2 diabetes are prevalent among Hispanic women of childbearing age. The prevalence of diabetes during pregnancy is three times greater among Hispanic women than among non-Hispanic white women. Fetal exposure to maternal hyperinsulinemia is associated with fetal overgrowth and increased incidence of neonatal respiratory problems and metabolic abnormalities. Increased body mass index (BMI), upper body fatness, and blood pressure in infants, and increased risk of obesity, hypertension, abnormal glucose tolerance, and other metabolic abnormalities in adolescence and young adulthood have been documented in the children of diabetic mothers. Maternal obesity and an increasing level of screening glucose in nondiabetic mothers are also associated with higher birthweight and blood pressure, as well as other adverse neonatal outcomes. Mothers who are obese or have abnormal glucose tolerance

Year 2000 Objectives

14.5, 14.6, 14.7, 14.8, 14.9, 14.10, 14.11, 14.14, 17.9, 17.10, 17.11, 17.12

Study Design

Observational

Time Design

Mixed

Care Emphasis

Noninterventional

Population Focus

Infants, Pregnant Women, Other-Postpartum Women

Race/Ethnic Focus

Hispanic (Hispanic overall)

during pregnancy are at increased risk for pregnancy, labor, and delivery complications and type 2 diabetes after pregnancy. Given the focus on low birthweight as a major public health indicator of maternal and neonatal health, the perception of good outcomes, according to this measure, has reduced health policy, program, and research attention to Mexican American mothers and infants. The influence of maternal obesity and metabolic characteristics on Hispanic infant birthweights and on the increasing risk of obesity and diabetes that is observed among Mexican American children, adolescents, and young adults remains to be systematically assessed, along with the preventive health care needs of women and children in this population. The rising prevalence of both obesity and diabetes among young people and women of childbearing age in this country suggests that the health of an increasing proportion of mothers and infants will be affected by the processes examined by this study, particularly in immigrant, minority, and other populations undergoing lifestyle changes. Study findings should have significance for design of both policies and programs for women and infants.

Research Questions or Hypotheses

This study will describe the following: The distribution, prevalence, and relationships among maternal body fat distribution, BMI, glucose tolerance, pregnancy weight gain, and sociodemographic characteristics, including level of acculturation; the relationships among maternal anthropometric, BMI, and metabolic measures; the patterns of pregnancy weight gain, maternal sociodemographic and family characteristics, cigarette smoking, other maternal health conditions, and prenatal care therapies; and the prevalence and distribution of several measures of birthweight, gestational age, and adverse maternal and newborn outcomes in this community-based Hispanic population.

This study will also test the following hypotheses:

1. Among nondiabetic mothers, increased central body fat distribution and an increasingly abnormal maternal metabolic profile (glucose, insulin, free fatty acids, triglycerides) will be associated with increasing birthweight (adjusted for gestational age), infant BMI, birthweight ratio, and incidence of large-for-gestational age (LGA) births. The impact of sociodemographic characteristics, prepregnancy BMI, pregnancy weight gain, other maternal health conditions, and prenatal care will attenuate but not account for all of this relationship.
2. As maternal central body fat distribution increases and metabolic profile becomes increasingly abnormal, the incidence of adverse maternal and neonatal outcomes will increase, after accounting for prepregnancy BMI, other maternal health conditions, and infant gestational age.
3. Adding central body fat distribution, metabolic characteristics, and prenatal treatment variables will result in a better fitting model by which to predict birthweight and gestational age outcomes than the traditional models, which are based on sociodemographic, medical risk, and prenatal-care-use characteristics.

Study Design and Methods

This is a 3-year prospective cohort study of 700 mother-infant pairs. Data sources include medical records, metabolic assays, maternal anthropometry, and interviews. Independent variables include the following: (1) Sociodemographic and family characteristics—family (mother, father, sister, brother) history of diabetes, maternal age, parity, marital status, ethnicity, level of acculturation, maternal and paternal educational level, income, and insurance type; (2) level of acculturation (measured by ethnic identity; duration and pattern of residence in the United States, in Detroit, MI, and in a Latino community; primary and preferred language and need for a Spanish translator); (3) metabolic measures (maternal glucose, insulin and triglyceride, free fatty acid, and glucagon); (4) anthropometry (waist, hip, and upper arm circumference; upper arm skinfold; prepregnancy weight; height; and BMI); and (5) pregnancy weight gain, cigarette and alcohol use, anemia, and hypertension during pregnancy. Dependent variables include the following: (1) Birthweight adjusted for gestational age (e.g., birthweight ratio, percentages of LGA), and (2) neonatal BMI. Adverse newborn outcomes will be classified in categories to include hypoxia and asphyxia, respiratory problems, need for resuscitation, birth injuries, metabolic abnormalities, congenital abnormalities, and infection. Adverse maternal outcomes will be classified as antepartum, intrapartum, and postpartum, including labor and delivery complications, cesarean section, preeclampsia, and infection.

Population and Sampling Plan

All self-identified Hispanic women entering prenatal care between January 1999 and December 2000 at the Community Health and Social Services Center (CHASS) in southwest Detroit will be asked to participate in the study. High-risk obstetric care and deliveries take place at Henry Ford Hospital in Detroit. The final study population (allowing for patient

refusal to participate, no parental consent for some women under 18 years old, pregnancy loss, multiple gestations, and loss to CHASS or Henry Ford care before delivery) is expected to include 700 mother-infant pairs. Ninety percent of these women are expected to be Mexican or Mexican-American and have incomes at or below the poverty line. With the exception of slightly lower proportions of women under age 18, the study population is expected to include the full range of age, health status, and other characteristics of the population of Hispanic women who use this community-based health center. The entire cohort should have delivered their infants at Henry Ford Hospital by July 2001.

Analysis Plan

We will calculate descriptive statistics (including frequencies, means, standard deviations, coefficients of variation, and confidence limits, where appropriate) for the independent and dependent variables. We will describe the distribution of maternal metabolic characteristics, BMI, and central body fat distribution by degrees of abnormality. For example, increasing glucose intolerance will be described by histogram, division of the population into quartiles, and the proportion of women in categories commonly used for glucose screening and diagnosis. Measures of central body fat distribution and prepregnancy BMI will be examined as continuous variables whenever possible. However, categorical variables will also be created when they conform to categories used for clinical care decisions. We will use correlation coefficients, phi coefficients, and plots (variously depending on whether the variable of interest is categorical or continuous) to assess the relationships between pairs of independent variables that may influence fetal growth and other maternal and infant outcomes. Independent, additive, and interacting effects of these variables will also be assessed.

The distribution and confidence limits for birthweight (in grams), gestational age (in weeks), birthweight at each gestational age, newborn BMI, percentages of LGA, and birthweight ratio will be described for the whole study population and by subgroup classified by measures of maternal body fat distribution, BMI, and maternal metabolic characteristics. The incidence of adverse maternal and newborn conditions will be calculated for the whole population and by glucose level, maternal BMI, and body fat distribution category. The proportion of mother-infant pairs affected by one or more adverse outcomes will also be calculated because it is expected that the incidence of many of the outcomes will be low. The relationships between the independent variables and each of the birthweight and maternal and newborn health outcome variables will be examined using correlation coefficients, phi coefficients, and plots. We will develop multiple variable regression models of the relationships among sociodemographic characteristics, glucose level, central body fat distribution, prepregnancy BMI, and pregnancy weight gain as independent variables and the various birthweights and maternal and infant health as dependent outcome variables. Linear, logistic, and polynomial models will be used, depending on the nature of the outcome variables.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

No statement of originality and importance.

Regional and National Significance

No statement of regional and national significance.

Scientific and Technical Merit

This is an extremely well organized, well presented proposal. A very good literature review is given which supports the hypotheses to be tested, however additional information could have been provided on the incidence of adverse effects associated with high birth weight. Much preliminary work has been done and the investigators have an excellent relationship with the clinic where the patients are to be enrolled. Approximately 300 prenatal records have already been abstracted, along with partial abstraction of 125 labor and delivery obstetric and newborn records. The calculations are based on numbers from the population to be studied. The hypotheses and specific aims are clearly stated. The independent mediating and outcome variables are clearly summarized in a table. For the most part, measurement of the variables is clearly defined. Central body fat distribution, which is key, will be measured in three different ways, i.e., waist circumference, waist-to-hip ratio, and sum of trunk skinfold thicknesses to the sum of extremities skinfold thickness ratio (although whether measurements of waist

circumference are useful at 28 weeks gestation is not certain). It is not clear how they will determine the pre-pregnancy weight for mothers whose first prenatal visit weight was obtained after 10 weeks of pregnancy. The specific list of adverse maternal and neonatal outcomes to be collected is given and seems to be appropriate, although not specifically justified. However, they are excluding stillbirths and pregnancy losses from analysis since this can be associated with gestational diabetes, they may want to reconsider whether they want to include these as an outcome.

The strength of this study is the investigator's experience with this population. Although they state that most Hispanic women enter prenatal care later, this population seems to enter relatively early. They may not be a completely representative population. The study is to be integrated into the normal routines of the clinic, and very few extra or disruptive studies will be performed. Additional blood tests will be drawn, but only at the time of routine testing. The data collection forms have already been developed and pre-tested. Inter- and intra-observer reliability will be 98%. This will be measured again on a 10% randomly selected sample every 8 weeks. No plan is given for if this high level of inter- and intra-observer reliability is not maintained. The sample size seems appropriate and based on realistic numbers. They have not considered how many women will decline participation in the study. Data analysis is clearly described for each specific aim and hypothesis. A time line is given and is primarily devoted to conduct of the study. This is clearly a strength, as much as the preliminary work has already been done and the study can begin in month 2.

Financing has not been requested from other places. The budget seems reasonable and well justified. There is \$16,000 in other costs requested, which are primarily for subject incentive and laboratory tests. A strength of the study is the plan only to run a laboratory test on patients for whom outcomes are available.

Evaluator 2

Originality and Importance

This proposal is for three years of funding to investigate the impact of central body obesity and metabolic abnormalities among Hispanic women and their impact on maternal and newborn complications. The problems of obesity, impaired glucose tolerance and diabetes have not been systematically assessed, nor have the associated risks. Studies have confirmed links between increased acculturation and behavioral risk factors associated with poor fetal growth, but a direct effect of acculturation on birth weight has not been demonstrated. Studies of the impact of acculturation on birth weight have not accounted for the potential impact of maternal weight and metabolic status on birth weight. Also, despite increased risk for obesity, insulin resistance and diabetes among Hispanic women of childbearing age, very little is known about the impact of these conditions on fetal growth, birth weight, or adverse maternal and newborn outcomes. In addition studies of maternal body fat distribution have not assessed its importance on fetal growth or other outcomes. Recent studies have identified increased risk for neural tube defects among infants of obese women. The former controlled for diabetes status, but neither study measured maternal fuel metabolism. There are also gaps in research on prevalence and impact of obesity and diabetes on birth outcome.

Regional and National Significance

The results of this study can be applied to Hispanic women living in the United States, as well as other pregnant women who have central obesity and metabolic abnormalities. It is proposed that information from this study could lead to the design of appropriate treatment strategies that should result in improved care and improved perinatal outcomes.

Scientific and Technical Merit

An important strength of this proposal is that the principal investigator and her team have already collected preliminary data and are doing a pilot study on 300 Hispanic women. Also the majority of the procedures are already collected as part of their routine prenatal care.

The hypotheses are clearly stated and testable and the pertinent variables are identified. The independent, mediating/confounding, and outcome variables are clearly defined and the measures are clearly indicated. Pertinent terms and

concepts are also clearly defined. The data gathering procedures are clearly described and appear adequate and appropriate. The design is appropriate to the research problem. However, a weakness in study design is that the clinicians will not be blinded to the results of the maternal glucose tests because they need to be referred to the clinic for insulin and/or diet counseling. The sample size is adequate and allows for attrition or loss to follow-up. The subject population is well described and appropriate. The community being studied includes 60% of Detroit's Hispanic population and 80% of the prenatal patients at their clinic are Hispanic. Data analysis is presented in detail and the rationale for the sequence of steps to be taken. These plans are appropriate to the nature of the data, design and sample. The sample size is adequate for the proposed linear regression modeling.

The time schedule is set up for the three years of the study and a detailed time schedule is included. This proposal has not been submitted to any other Federal agency or private foundation for consideration. Preliminary studies of medical record data are being funded through October 1998 by the University of Michigan and the CDC Academic Prevention Research Center.

The principal investigator has been previously funded by the Hawaii State Department of Health, W.J. Kellogg Foundation, University of Michigan, and Blue Cross Shield Foundation of Michigan. She has published research on maternal diabetes on many different in ethnic groups in the United States.

The budget seems reasonable and realistic in terms of the aims and methods of the study. The consultant and staff's time will be used in a very economical and logical fashion.

The resources and facilities support the investigation. Much of the data is already being collected as part of the routine prenatal care given at the facility. The staff are from the performance sites (University of Michigan School of Public Health, University of Michigan School of Medicine/Diabetes Research and Training Center, Community Health and Social Services and Henry Ford Health System) and there appears to be appropriate coordination.

There are no concerns about the treatment of the human subjects since the majority of the materials and procedures are collected by staff as part of routine prenatal care. Investigators will remain alerted to signs of emotional, psychological or physical discomfort and attempt to identify and reduce its cause. Clinicians will not be blinded to glucose test results and will give treatment as appropriate. Patients will be given prenatal care with stringent protocols to identify maternal health problems associated with pregnancy. Follow-up care will be given, as well as education regarding obesity and glucose tolerance.

Evaluator 3

Originality Importance

This proposal addresses sections 3.1.4, 2.4.2, 2.4.3 of the MCHB Research Priority Agenda.

Regional and National Significance

No statement of regional and national significance.

Scientific and Technical Merit

The statement of the problem is comprehensible and compelling. Aims are stated clearly. The literature review is thorough and well organized. The hypotheses are derived from the aims and testable. A conceptual model illustrates the potential role of central body fat distribution, maternal fuel metabolism and the role it may play among the other well-known factors associated with adverse infant and maternal outcomes. Variables for analysis are given with justification for their use, characteristics of measurement and their role in analysis (dependent, independent, mediating variable). The study design, a prospective cohort study, is carefully justified, and the circumstances under which data will be collected and clinicians blinded. The number of Hispanic women and their socioeconomic characteristics available for study is described and about 700 mother-infant pairs are expected over two years of recruitment. The data analysis for each aim and hypothesis is carefully outlined with sample size justification.

The major problems are in the loss to follow-up and the effect it will have on the sample size and power.

The principle investigator has a number of publications in perinatal epidemiology and maternal and child health. She has active research support (20%). There is demonstrated consultant support for (1) statistical design and analysis, (2) expertise on maternal weight, pregnancy weight gain and their impact on maternal and infant outcomes, (3) quality assurance with respect to measurement and recording of neonatal outcome variables, (4) diabetes and other metabolic abnormalities and their influence on pregnancy, (5) maternal body composition and nutritional status, and (5) data management.



Maternal PKU Resource Mothers Program: A Clinical Trial

Grantee

Childrens Hospital

Investigator

Susan E. Waisbren, Ph.D.
IC Smith Building
300 Longwood Avenue, #108
Boston, MA 02115
(617) 355-4686
(617) 734-2652 fax
waisbren@hub.tch.harvard.edu

Project Number R40MC00162-01

Project Period 8/1/1999-7/31/2003

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	30,423	7,606	38,029
Year 2	176,314	102,262	278,576
Year 3	184,173	106,820	290,993
Year 4	166,657	96,661	263,318
Year 5			

Summary

Statement of the Problem

A randomized clinical trial of the Maternal PKU Resource Mothers program will assess the feasibility and efficacy of a home visitation program designed to improve outcome in maternal PKU. Women with PKU are at high risk for having babies with mental retardation, microcephaly, congenital heart disease and low birth weight. If the women are treated with a low phenylalanine diet and if they maintain metabolic control at the recommended level prior to and throughout pregnancy, their risks are greatly reduced. Nonetheless, over 70% of women with PKU achieve metabolic control after 10 weeks gestation, when damage to the fetus has already occurred. To reduce the number of late and inadequately treated pregnancies, mothers of children with PKU (who are familiar with the special diet) are trained to assist women with PKU who are preparing for pregnancy or who are already pregnant. While experiences with this program on a limited basis have been promising, it is not known whether the Resource Mothers home visitation program increases maternal metabolic control during pregnancy and hence improves offspring outcome.

Research Questions or Hypotheses

Year 2000 Objectives

No Stated Healthy People Objectives

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Infants, Pregnant Women

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

Women with PKU followed by an intervention that includes Resource Mothers compared to women with PKU followed by an identical intervention without Resource Mothers will 1) attain metabolic control sooner in their pregnancies, 2) have babies with better outcome at birth and 3) better outcome at one year of age.

Study Design and Methods

Women who contact a metabolic center for maternal PKU treatment will be randomly assigned to a group that receives Resource Mothers or a group that is treated according to the identical Maternal PKU Treatment Plan except that no Resource Mothers are involved. Resource Mothers are mothers of children with PKU who go to the homes of pregnant women with PKU and provide them with information, practical assistance and emotional support. The primary outcome variables to assess the effectiveness of the program will be the number of weeks from treatment initiation to maternal metabolic control, offspring birth head circumference, and offspring development (DQ) at one year. Secondary analyses will be performed to assess the cost of the intervention and the ways in which the Resource Mothers program affects the course of treatment. Information about pregnancy blood phenylalanine levels, weight gain, and dietary intake will be obtained. Questionnaires measuring social support and other psychosocial factors will be administered soon after enrollment and at the 7th month of pregnancy. After the baby is born, information on birth head circumference, weight, and length will be retrieved from medical records. At one year of age, the baby will receive developmental testing and the mother will be interviewed about her baby's health history.

Population and Sampling Plan

The sample of 80 completed pregnancies will be obtained from all maternal PKU pregnancies treated in the selected metabolic clinics: Children's Hospital, Boston, MA; St. Christopher's Hospital, Philadelphia, PA; Children's Memorial Hospital, Chicago, IL; University of Illinois Medical Center, Chicago, IL; Emory University School of Medicine, Atlanta, GA; Johns Hopkins Hospital, Baltimore, MD; Waisman Center, Madison, WI; Children's Hospital of Los Angeles, CA. All women with PKU at the selected study sites who are planning a pregnancy or who are pregnant will be recruited for the study. Informed consent will be requested during a clinic visit from those who require treatment, are less than 20 weeks pregnant and plan to continue their pregnancies. PKU is rare among Ashkenazi Jewish, Asian and Black populations. Based on data from previous studies, it is expected that 1% will be Black, 1% Native American, and 10% Hispanic. The study will include pregnant women and male and female offspring. The study does not address issues of gender, race or ethnic health. Secondary descriptive analyses may be possible to address issues related to ethnic background in terms of acceptability of the Resource Mothers Program.

Analysis Plan

Data analysis will proceed according to our primary model, which postulates that the independent variable (Resource Mother support) affects maternal metabolic control, the home environment and offspring outcome by way of altering the mediating factor of adherence to treatment protocol. The first step will be to test for potential biases between the randomly selected study groups in terms of the "intervening variables". Due to the random selection process, it is hoped that the groups will be comparable. If not, separate analyses may have to be performed for the subgroups. Although we expect the Resource Mothers treatment group to attain metabolic control sooner and hence have better outcomes, we will conservatively use two-tailed tests and confidence intervals in order to be able to comment on results that may occur in the opposite direction to our hypotheses. Analyses to test the specific hypotheses are as follows:

Hypothesis 1: The Resource Mothers treatment group will attain metabolic control sooner. The nonparametric Wilcoxon Mann Whitney test will be performed on the number of weeks from treatment initiation to metabolic control, since all women who achieve metabolic control prior to pregnancy receive a score of 0 weeks.

Hypothesis 2: The Resource Mothers treatment group will have babies with better outcome at birth. A T-test based on z-scores of birth head circumference, birth weight and birth length will be used. The relative occurrence of congenital heart disease and other anomalies will be analyzed by the Fisher's Exact Test.

Hypothesis 3: The Resource Mothers treatment group will have babies with better outcome at one year of age. A T-test will be used to compare the DQ, motor development, and language quotients of offspring in each group.

Hypotheses 4, 5, 6, 7: The Resource Mothers treatment group will have greater adherence to the Maternal PKU Treatment Plan, a higher percentage of recommended weight gain, a higher percentage of recommended nutrient intakes and provide a

more stimulating environment for their child at one year. These hypotheses will be tested using the Wilcoxon Mann Whitney test. We selected this statistical test over parametric tests because of concerns about distribution, especially in the measurement of the home environment. Our experience has been that a bimodal distribution often occurs. For similar reasons, nonparametric correlations will be used to determine if percent of recommended nutrition intake is related to birth outcome and development at one year.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This is an important project that has national significance. The number of infants born to women with PKU will only continue to increase as newborn screening remains in place. Strengths of the proposal continue to be qualifications of the investigators and their experience in working with mothers with PKU. Regional centers, such as those involving the six centers in the study, generally have very good follow-up of PKU patients, and in particular mothers with PKU.

The investigators have been very responsive to the criticisms raised in the previous review. Of primary concern was the number of patients who were expected to be available. It was felt that recruiting 72 patients was over-optimistic. They have now expanded the number of recruiting centers to six, extended the study to five years and now expect to have 115 pregnancies occur. This now allows 30% attrition, which is increased from their previous estimate of 25%, to reach the 36 subjects needed in each group. Power calculations were also redone using more conservative techniques and were based on two-tailed tests so that results obtained which were not in the expected direction could also be discussed. They also include an additional 10% adjustment to account for the use of the non-parametric Wilcoxon test. There was also concern previously about women entering prenatal care early enough to be included. They have now defined their recruiting gestational age cut-off as less than 20 weeks. They give evidence that the vast majority of their maternal PKU patients present for prenatal care before this time.

It is still likely that most women will present after they become pregnant. This will be taken into account by stratifying the groups prior to randomization on whether they present prior to or after conception.

Another previously raised concern was that some important information would be obtained by report from the PKU mothers, whose mean IQ as a group was given at 85. It was questioned whether the standard measures to be used were valid in women with lower IQ's. Seven of the psychosocial instruments to be administered are said to be valid in this group. The Social Support Questionnaire was "one of the best predictors of adherence to medical recommendations" in a previous maternal PKU study. Knowledge of maternal PKU has been validated on a population of women with a mean IQ of 84 and had a validity coefficient of 0.63. The Self Esteem Questionnaire, a "standard measure", had been found to correlate .95 with longer measure of self esteem, but may not have been specifically studied in individuals with lower IQ. Locus of Control, another "standard measure", is stated to have "excellent reported reliability and validity and can be administered to those with a fifth grade reading level". List of Threatening Experiences has been found to be "reliable and valid in extensive piloting", but again the group in which it was tested is not clear. The home organization scale was developed for the resource mothers program and in preliminary studies was found to be associated with economic status but not with IQ. No reliability or validity is given. The attitudes about treatment questionnaire is a revision of one used in evaluative study of the Maternal PKU Camp. It has also not been validated but uses a variable that is highly predictive in the psychosocial study and its results were not related to IQ. Investigators give a detailed plan for training the resource mothers in administration of these questionnaires. They will be trained to assist the women who may not understand the questionnaires or interview questions. Those interviews previously have shown no differences in scores related to IQ.

Similarly, there was concern about obtaining detailed food intake information from the PKU mothers, particularly attempting to have them record their food intake for three days. This three-day record is a standard part of the Maternal PKU Treatment protocol; however, acknowledging that this may be of questionable validity in the study, for those women who are not able to do this, a nutritionist will do a detailed one-day food intake history. A check-off list will be used for those women who have difficulty maintaining food records. It is felt that this will be helpful as only a limited number of foods are allowed in the PKU diet. However, I am concerned that women will be eating foods that are not allowed on the diet and that

these will not be recorded. Amount of formula consumed will be verified by comparing to the amount ordered and/or amount remaining on the woman's shelves.

A previous concern was that some information would be obtained from clinic records which might not be accurate, would not be obtained during metabolic clinic visits at the time of delivery, and would be verified by obstetrical and delivery records. Newborn data collection forms are to be sent to the birth hospitals prior to delivery and a study coordinator will ensure that these forms are filled out when delivery occurs. This system resulted in 100% success in the Maternal PKU Collaborative Study. The local coordinator will be responsible for updating each form after each assessment metabolic clinic visit, obstetric appointment, or provision of services in the community. Head circumference is still included, as it is the measurement most highly correlated with maternal blood phenylalanine levels during pregnancy and is an indicator of brain growth in-utero.

Other issues have also been addressed. There was concern that no women would maintain the target phenylalanine level below 6. This indeed may be the case, but this is the recommended level below which women should maintain their phenylalanine level. If this does not occur, the investigators will also analyze their data using a target level of 10 mg/dl. The use of paper food models has been dropped. Measures of adherence to the treatment plan by the metabolic clinic and obstetrician, including community services used, cost of medical treatment, and time spent by the metabolic center, have all been dropped. There is no plan now to do any sort of economic analysis. However, the cost of the resource mothers program will be calculated and reported, but not analyzed for this study.

More detailed plans are given for data analysis, and more conservative estimates of power have been proposed.

The budget has been completely revised. Emergency supplies of low-protein food will be available for any patients. Those with resource mothers will also use these foods for demonstration of food preparation. This remains a problem unless the availability of low protein food is a part of the standard treatment protocol. If not, it introduces an additional intervention into the model. Costs regarding the principle investigator's travel to each center one a year to monitor the progress of the study and provide supervision have been dropped, as all of the information is being made available through the Internet. The justification for including a social worker is now given and her time decreased to .15 FTE. This seems reasonable as these resource mothers may need continued support throughout the project. It is stated that she will provide a liaison between the resource mothers and patients with multiple different community agencies as needed. It does seem that the local centers should also have a person who would routinely do this. It appears that her main role should be to support the resource mothers who may be overwhelmed with the social problems of the PKU mother. The time commitment for Diane Sullivan, the trainer, has been reduced, but still seems high. She is budgeted for 40% in the first year, 35% in years 2, 3, and 4, and 25% in year 5. However, most of the training will take place in the first year or two, and why so much time is needed in the remaining years is not clear.

There are no particular human subjects concerns. IRB approval is pending from four sites. The proposal has not been submitted to any other agency for review. The group of investigators is well qualified to carry out this resource. They have extensive experience in the management of individuals with PKU, particularly maternal PKU. Dr. Waisbren is currently funded about 55% time, and there is no overlap with any of her current grants.

Evaluator 2

Originality and Importance

This application is the second revision of an application to conduct a clinical trial examining the efficacy of a resource mother intervention for mothers with PKU. The original application, which proposed a small pilot study, was deferred. The revision submitted in response to this deferral proposed a full clinical trial; that application was disapproved, primarily because of concerns related to sample size. The current application is a revision of that proposed clinical trial, specifically addressing reviewer's concerns about the sample. The reviewers expressed concern that the proposed sample was very small (36 intervention mothers; 36 controls) and stretched the capability of the participating sites to provide subjects. In the revision, the number of participating metabolic centers has been expanded (the Waisman Center and Hopkins have been added) and the study time line has been extended to include a fifth year. The application states that in 1996, 23 PKU pregnancies occurred in the 6 participating centers. At least 115 pregnancies are expected across the period of the study. The

authors anticipate that 80 of these will be completed and 72 of the women will remain in the study.

Many of the PKU mothers would be expected to have IQ's or 85 or less, which led to some concern about their ability to complete study instruments. The authors respond that all study instruments have been used previously with PKU mothers without difficulties relating to lower IQ. The authors argue that no differences in instrument scores have been detected related to maternal IQ. Mean differences in scores do not really indicate that the instruments are equally valid/reliable across groups.

The study hypothesizes that intervention mothers will attain metabolic control sooner and have babies that have better outcomes at birth and at one year of age. Pilot data, based on a doctoral dissertation, support the potential impact of the program. Secondary hypotheses focus on adherence to diet, maternal environment, and the stimulating nature of the home environment, while additional hypotheses focus on psychosocial benefits of the intervention for the mother.

The application now clarifies that key measures on the infants will be obtained by researchers, rather than from medical records. A defense of head circumference as a key outcome measure is presented, based on this measure being reported in the literature as most highly correlated with dietary control.

For the psychosocial measures, the application states that a checklist will be used to determine the percent of data collected for each variable. It is not clear what this means.

The Bayley, REEL, and the HOME will be obtained by contracting with local psychologists in the mother's home community. It seems unlikely that these practicing psychologists will be familiar with the HOME and its administration.

A nutritionist or social worker has been designated as the Study Coordinator at each metabolic center that will be enrolling patients. This person will assume responsibility for coordination, data collection, data entry and adherence to the Study Protocol. This person will participate in an initial training workshop in Boston to learn the study protocol and to learn the role of resource mothers. All nutritional assessments are to be conducted by Registered Dietitians at each clinic site, yet, these individuals do not seem to appear in the budget. It is still not clear that the researchers will be able to maintain consistent quality control of both the intervention and the data collection at the distant sites.

In the previous review, there was some confusion about the role of the project social worker. The revised application describes the social worker's role as: assisting in identifying and procuring local services for the pregnant women with PKU, including making arrangements with the pharmacy to assure that correct formula is ordered and that billing is done properly; getting approvals from insurance/Medicaid/WIC (often involving advocacy and follow-up, assistance with budgeting and obtaining low cost foods); getting prior approvals so women can be seen at metabolic centers; getting referrals for prenatal care; and developing back-up plans in case the women have difficulties attending medical appointments, submitting specimens, etc. It would almost seem that the activities of the social worker constitute an additional study intervention over and above the intervention implemented by the Resource Mothers. Do both intervention and comparison women receive all these services? If they are available primarily to women in the intervention women, they would seriously confound the test of the intervention. Are the services only available for women living in the Boston area, where the social worker is based? Do women in other clinic sites lack these services, thus lessening their intervention experience when compared with the women in Boston? These issues are of concern.

The application also states that without the guidance of the social worker. The Resource Mothers are at-risk for being overwhelmed by the needs of the young women with PKU. Does this mean that Resource Mothers working in isolation, at sites other than Boston, are at risk of being overwhelmed and quitting their positions? How are these interventionists supported. Long distance phone calls would not seem to meet the intense need for support described in the application. Also, how does this affect the generalizability of the intervention? What support system do clinics have to have in place in order to adopt the Resource Mother intervention. Is it shown to be effective?

The description of human subjects states that mothers younger than 18 will be accepted into the study if their parents agree to the participation. How will the role of the mother's parents in her dietary intake, adherence, etc. be addressed? It would seem that young women living with their parents would have their diets heavily influenced by the cooking decisions of their parents, primarily their mothers.

The application states that if there are biases between the randomly selected groups, analyses may have to be performed for the subgroups. It is doubtful that sufficient power will exist to conduct subgroup analyses. The plan to switch order of entry in hierarchical regression analyses for independent and adherence variable, for example, is based on the ability of this procedure to rule out other causative factors if the variance contributed by the independent variable disappears when it is entered second. This is not really true. Other factors may still be responsible for the effect. It mainly indicates that the independent and adherence variables are substantially correlated.

The number of participating clinics has increased by 2, and agreements are in place with these clinics.

The research team is well qualified to conduct the proposed research.

The application has received IRB approval from the main study site. Approval is pending in the other sites.

The budget appears appropriate.



National Practice-Based Network to Improve Children's Health Care

Grantee

American Academy of Pediatrics

Investigator

Richard C. Wasserman, M.D., M.P.H.
141 Northwest Point Boulevard
P.O. Box 927
Elk Grove Village, IL 60009-0927
(802) 656-4611/(708) 981-7910

Project Number MCJ-177022

Project Period 9/1/1990-8/31/2004

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	

Year 1
Year 2
Year 3
Year 4
Year 5

Year 2000 Objectives

Study Design

Time Design

Care Emphasis

Population Focus

Race/Ethnic Focus

Summary

Statement of the Problem

Standards for medical care of children are typically based on research in academic settings. Yet, the vast majority of children seen by a physician are seen not in academic settings but in a variety of ambulatory facilities that principally offer primary care. It is not clear what approaches to care and treatment are actually being used in children's care in most of these settings, nor how effective the approaches are. Where approaches may be less than optimal—either because they are based on the "wrong population" (children seen in academic settings, who may be more ill than those usually seen in primary care practices) or because the best methods of practice are simply unknown—it is important to gather information that primary care physicians can use to improve their treatment of children.

Research Questions or Hypotheses

This project, carried out by the American Academy of Pediatrics (AAP), plans to work toward the identification of more effective approaches to children's health care in ambulatory settings by meeting four objectives:

1. Gather information about pediatricians' care and treatment practices in primary care settings;
2. Provide a structure for learning more about the effectiveness of care and treatment practices in primary care settings;

3. Provide feedback to pediatricians, other physicians and primary care practitioners, and public health groups so that they may act on this information; and
4. Provide experience to a large group of primary care pediatricians concerning how to research these issues.

The major activity of this project is to maintain a national network of pediatricians in primary care practice who cooperate in studies of their own choice to enhance the knowledge base addressing important child health issues.

To develop this network, called Pediatric Research in Office Settings (PROS), interested chapters of the AAP joined as chapter-level networks. Each identified a chapter coordinator to be in charge. A steering committee, named by the AAP, oversees this project, and a research management group (RMG), located in the Department of Research at the AAP, provides research expertise.

The PROS program calls for (1) annually developing ideas of topics for study, (2) annually testing a protocol chosen by the network in a pilot study, and (3) carrying out a full study annually on a previously piloted project. The RMG manages the data collection effort and analysis of the data. This project provides for the dissemination of the information developed by the PROS network.

A study on vision screening of preschoolers has been concluded, and a manuscript describing the study results has been published. During the third year of this grant we anticipate that a study on the development of secondary sexual characteristics of young females will be completed, and, pending funding, three other studies will begin: (1) The management of febrile infants less than 2 months of age; (2) management of gastroenteritis in children under 6 years of age; and (3) management of acute asthma in children over 3 years of age. The project has applied for funding for an additional study on the management of psychosocial problems in children ages 4–15 years, to begin at the end of the project period. In order to develop future study topics for PROS, a Delphi study of PROS practitioners is also being conducted to identify critical areas requiring research. Finally, PROS will create an age/gender registry of its patients to better describe its patient population.

In addition to the PROS network, a series of periodic surveys of fellows of the AAP are planned under this grant. These surveys gather information from randomly selected AAP members on a variety of practice-related treatment and management issues. Results of the periodic surveys are disseminated through AAP publications.



Neighborhood and Family Effects on Adolescent Health Behaviors

Grantee

Johns Hopkins University School of Hygiene and Public Health

Investigator

Cheryl Alexander, M.P.H., Ph.D.
Center for Adolescent Health Promotion, Maternal and Child Health
2007 East Monument Street
Baltimore, MD 21205
(410) 614-3953
(410) 614-3956 fax
calexand@hjsph.edu

Project Number MCJ-240840

Project Period 10/1/1998-9/30/2001

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	147,890	47,324	195,214
Year 2	183,090	58,588	241,678
Year 3	110,596	35,400	145,996
Year 4			
Year 5			

Summary***Statement of the Problem***

Although health status measures for infants and young children have shown improvement over the past several years, markers of adolescent health suggest a decline in the well-being of U.S. adolescents. Low-income and minority adolescents, many of whom reside in the Nation's largest central cities, have borne a disproportionate share of these health-related problems.

Recent research suggests that some of the increases in problem health behaviors among urban adolescents can be attributed to the social environments in which they live. Neighborhoods, particularly those that are low income and socially isolated, have been linked to increasing rates of early adolescent pregnancy and criminal and violent behaviors. Yet not all adolescents who are growing up in impoverished neighborhoods become adolescent mothers or delinquents or engage in violent behavior. There is limited information about how neighborhood and family social contexts influence the onset of adolescent health-related behaviors.

This study attempts to fill the gap in research on neighborhood and family effects on adolescent problem behaviors by combining the following elements: (1) A longitudinal study of the onset of adolescent sexual activity and increased

Year 2000 Objectives

No Stated Healthy People Objectives

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

Adolescents, Parents/Families/Mothers/Fathers
(Adolescent Parents)

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

delinquency behavior, one that uses a large national data set that links adolescent and parent responses to neighborhood-level measures, and (2) an indepth study of family and neighborhood processes that uses Baltimore City neighborhoods with varying rates of adolescent births and juvenile arrests.

Research Questions or Hypotheses

The following questions will be addressed by this study:

A. Using national data, we propose to address the following three questions:

1. To what extent are neighborhood conditions directly related to adolescent sexual activity and delinquent behaviors after adjustment for neighborhood selection effects?
2. What are the ways in which neighborhood effects are mediated by family characteristics and parenting practices?
3. What are the ways in which neighborhoods interact with family characteristics and parenting practices to explain the onset of early sexual intercourse and changes in delinquent behaviors?

B. In Baltimore City, we propose to study family characteristics and parenting practices that are associated with adolescent involvement in sexual and delinquent behavior. Specifically, we will carry out the following: (1) An exploration of definitions of neighborhood boundaries by residents (i.e., adolescent and family members) and compare these definitions with the geographic definitions of neighborhoods derived from census data; (2) a description of variations in the social and institutional resources in the neighborhoods that differ in their levels of adolescent births and juvenile arrests; (3) within each neighborhood, an investigation of the mechanisms that families use to obtain social and institutional resources; (4) within each neighborhood, an assessment of the extent to which families who have and families who do not have adolescents involved in problem health behaviors differ in their responses to their neighborhoods, their use of social resources, and their parenting practices; and (5) an exploration of the role of cultural practices in forming both parenting practices and adolescent involvement in sexual intercourse and delinquency.

Study Design and Methods

The study uses a longitudinal design drawn from the National Longitudinal Study of Adolescent Health (AddHealth) to investigate neighborhood influences on the sexual activity and delinquent behaviors of 700 U.S. adolescents in the seventh or eighth grade. Outcomes will be the report of having ever engaged in sexual intercourse and scores on a 14-item measure of delinquency and aggression. Predictor variables include structural characteristics of neighborhoods (e.g., neighborhood sociodemographic status, racial and ethnic composition, residential stability, family structure), perceptions of neighborhoods, neighborhood social resources, family sociodemographic characteristics, family involvement in organizations, parenting practices, and adolescent involvement with deviant peers.

Using adolescent birthrates and juvenile arrest rates for Baltimore City, we will identify three categories of neighborhoods—those census tracts having high, medium, and low rates as defined as being one standard deviation about or below the mean rate for Baltimore. We will select three relatively contiguous neighborhoods that represent high, medium, and low rates of adolescent problem behavior. We plan to survey 300 adolescent-parent pairs, 100 pairs from each of the 3 neighborhoods, using a face-to-face interview and a self-administered questionnaire for items on sexual activity and delinquent behaviors. In addition to the measures listed above, we will ask questions about racial/ethnic identity and the racial/ethnic socialization practices of parents.

Population and Sampling Plan

Subjects for the longitudinal analyses of AddHealth data will be eligible for study inclusion if they are currently enrolled in the seventh or eighth grade in an urban-public or general-curriculums magnet school within close proximity to their residence; if they have completed two in-home interviews, a parental interview, and an in-school screening survey; and if they have school-level data provided by the school administrator.

Subjects for the Baltimore City study will be obtained through the rosters of students from the seventh or eighth grade from the Baltimore City–zone schools for the neighborhoods. Subjects will be eligible for study inclusion if they live in one of the study neighborhoods, are in the seventh or eighth grade, and have parental permission. An oversampling of 30 percent will be necessary to achieve the desired sample size of 300 adolescent-parent pairs.

Analysis Plan

Similar preliminary analyses will be conducted on both the AddHealth and the Baltimore City data. For both data sets, distributional properties of variables will be examined to make cut-point or transformation decisions, to assess the psychometric properties of study-constructed and existing scales, and to reduce the number of independent and intervening variables for the multivariate analyses.

To examine the first research question, a series of hierarchical, multivariate logistic regression analyses will be conducted to assess neighborhood and family influences on the likelihood of an adolescent having had sexual intercourse. We will repeat the analyses for delinquency and aggression using multiple linear regression models.

In order to assess the indirect neighborhood effects, we will regress the likelihood of an adolescent having had sexual intercourse on a restricted set of neighborhood characteristics, on family-level and adolescent-level characteristics, and on measures of family parenting and organizational involvement. In subsequent equations, we will regress parenting practices and organizational involvement on neighborhood-level, family-level, and individual-level characteristics. The indirect or mediated effects of neighborhoods on adolescent sexual behavior can be estimated from the product of the effects of neighborhood characteristics on measures of parenting and family organizational involvement. Analyses will be repeated for delinquency/aggression outcome.

To assess the extent to which neighborhood characteristics interact with family-level and individual-level factors to produce variations in sexual activity and delinquency outcomes, we will use multivariate regressions that include interaction terms reflecting the product of differing levels of neighborhood characteristics and levels of family processes.

For the Baltimore City data, we will assess the influence of family processes on adolescent sexual activity using an ordinal logistic regression model with an outcome of never having had sex, having had sex with one or two partners, and having had sex with three or more partners. In a second set of analyses, we will treat delinquency and aggressive behavior as a continuous variable and regress this outcome on the set of family-level, parenting, and neighborhood perceptions.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

How the context in which one develops relates to behavioral outcomes has been a major concern of psychologists for many years. The decline of our inner cities and the preponderance of health risk behaviors observed in such environments has revitalized the urgency with which such a question needs to be addressed.

Regional and National Significance

If the study is successful at identifying those family characteristics most likely to serve as protective mechanisms against increasingly risky environments then preventive measures for those most at risk would more probably be forthcoming.

Scientific and Technical Merit

The major strength of the proposal is its use of both a national data set and local data set to assess the types of neighborhood characteristics related to the onset of problem health behaviors. The two data sets are complimentary in that the national data allows for conclusions about very diverse populations, while the local data sets helps us to understand problems effecting specific types of neighborhoods. In addition, the interview process to be used with the local data set will allow for more in-depth probes, which are lost within the national data set.

Another strength is that the study proposes to go beyond the basic neighborhood description (education, employment, etc.) by taking a closer look at what types of resources are actually available in these high risk areas and to also assess how availability and use of these resources relate to adolescent outcomes. In addition, the proposed project's intent to look more closely at the reasons why individuals reside in a given neighborhood will help to further define the process by which neighborhoods come to take on certain characteristics and patterns of interactions.

Finally, looking at the interaction between parenting practices and neighborhood characteristics will help us to understand the adaptive nature of how people rear children. There is much criticism of parenting styles characterized by "excessive

control." However, if loose control of your child puts her/him at risk for early sexual activity, drug abuse and violent behavior, then control seems a good way to go.

One problem seen with the proposal is the dependent variable of sexual activity defined as # of partners. Why not a ratio of partners to times multiplied by number of partners (# of partners/# of times* # of partners) such that the researchers can account for both in one variable. The child who is having a lot of sex with a lot of partners should produce a much higher ratio than one who has a lot of sex with just one partner who would also look different than one who is having a little sex but with many partners.

The personnel and budget are well suited to conduct the study, and there are no human subjects concerns.

Evaluator 2

Originality and Importance

No statement of originality and importance.

Regional and National Significance

No statement of regional and national significance.

Scientific and Technical Merit

Using the ADDHealth data to set a national context is a great idea and should be used more often in the field of emergent adolescent behavior.

Using both ADDHealth and local definitions of neighborhood provides an excellent opportunity to evaluate the effects of methodological differences in operationalizing the concept of neighborhood.

The tests proposed for evaluating the kinds of roles (direct, mediating, and moderating) that neighborhood context plays in the development of emergent adolescent sexual activity is a welcome addition.

One issue that has not been addressed is the issue of retrospective reports of parental involvement being assessed over the last 4 weeks prior to the assessment period. This appears to be too time-limited; perhaps supplementing this with a longer retrospective period obtaining the adolescents judgment would give the principle investigator multiple methods for assessing this very important construct.

The other issue is the form of the data analysis. The principle investigator suggests that power is dependent on the extent of the intra-neighborhood correlation, which is accurate. Yet the statistical models as reported do not seem to take into account this hierarchical structure that exists, which would lead to inaccurate estimates of standard errors. The principle investigator should be clear that because of the structure of the data, methods for handling non-independent error structures must be used.



Office Systems to Improve Preventive Care for Children

Grantee

University of North Carolina

Investigator

Peter Margolis, M.D., Ph.D.
UNC Center for HPDP
255 Rosenau Hall, CB #7400
Chapel Hill, NC 27599-7400
(919) 966-2504
(919) 966-3852 fax

Project Number MCJ-97-56-97-00

Project Period 7/1/1997-6/30/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	98,975	44,044	143,019
Year 2	114,658	51,023	165,681
Year 3	45,547	20,268	65,815
Year 4			
Year 5			

Year 2000 Objectives

14.16, 20.1, 20.11, 20.14, 21.2, 21.6

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Other-Physicians

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Pediatricians spend more of their time providing preventive health care than any other single activity, yet empirical evidence indicates that even children seen in private practices have unacceptably low rates of such care.

Research Questions or Hypotheses

The objective of this project is to implement and evaluate an intervention to increase rates of prevention-oriented counseling activities in private practices in North Carolina and Oregon. There are two primary hypotheses:

1. Practices that implement an "office system for prevention" will have higher rates of four core preventive services (immunizations, and screening for anemia, lead, and tuberculosis) than practices that do not use an office system.
2. Practices that implement a more complete office system by the end of the intervention will have larger increases in rates of preventive care than practices with a less complete office system.

Study Design and Methods

With the involvement of the North Carolina Pediatric Society, the Oregon Medical Association, and the American Academy of Pediatrics, the research team will encourage physicians to develop practice-specific office systems that involve members of the office staff as a team to provide preventive care and patient education.

Practices in the intervention group will receive an assessment of their current performance of preventive services, ongoing assistance to implement an office system for prevention, materials to implement the office system tailored to the needs of the practice, and incentives to implement the system. The control group will receive an assessment of their current performance in delivering preventive services, and publicly available materials that could be used to implement an office system.

Population and Sampling Plan

This randomized trial will involve 58 practices.

Analysis Plan

In conducting an analysis of hypothesis 1, the treatment and randomization unit is the practice, but the smallest observational unit is the patient. Each chart audit will indicate whether the preventive service was carried out. Simple comparisons will be performed on the rates of each of the four preventive services. Chi-square tests will be used to test the significance of differences between groups. Because rates of preventive services are likely to be correlated between children in a particular practice, this test will be adjusted to account for the intra-practice correlation. The mean number of well-child visits between intervention and control practices will also be compared. A *t* test will be used to assess the significance of differences in the mean number of well-child visits in each group.

The analytic objective for hypothesis 2 will be to examine whether the use of more complete office systems is associated with higher rates of preventive services. The completeness of the office systems will be measured through an empirically derived scale. Initially, this index will be considered as an ordinal scale variable categorized into three broad categories. The study team will examine the extent to which differences in rates of preventive services are associated with movements of practices from one category to another, adjusting for other potentially confounding practice characteristics.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This proposed study will test the effectiveness of a thoughtful, theoretically grounded intervention that could contribute to meeting child health objectives. The provision of preventive services still needs significant attention, even in view of advances made in the last several years. The project could also contribute important understanding to the measurement of organizational variables that affect the adoption and institutionalization of management practices.

This study has the potential to contribute to both the understanding of dissemination and the increase of prevention practice. The investigators have the experience and the abilities to conduct a broadly based field experiment from which very rich data would result. The proposal clearly states how the project will be organized and conducted, and this planning produces further confidence. Despite some minor weaknesses, reviewers believe the application has sufficient strengths, and are confident that the investigative team can conduct this study as planned.

Regional and National Significance

The development of a method to substantially raise rates of pediatric preventive services could have far-reaching consequences. The proposed interventions would not be inexpensive to implement broadly, but they do have the prospect of providing benefits that would be both real and enduring. This study has clear regional and national significance.

Scientific and Technical Merit

This revised application is extremely responsive to reviewers' concerns, and considerable revision and drafting has been done. This submission is much clearer and the design tighter than that described in the earlier version. The application provides a reasonable and current literature review, including discussion of physician-, patient-, and practice-related reasons for low participation in screening, as well as previous studies of interventions. The proposal presents arguments about the generalizability of current studies to pediatric populations. The review demonstrates only adequate knowledge of the

literature on physician-behavior change; some important references have been omitted.

The discussion of physician barriers helps respond to previous questions about the need for the proposed intervention, but is nonetheless still somewhat frustrating. The application presents evidence that immunization rates are not adequate and that physicians overestimate the extent of preventive services, but this does not fully respond to the prior critique. Just what do pediatricians do? How much care delivered to infants is related to acute situations and how much is routine? Left unanswered is the question of how often routine care is devoid of needed prevention.

The point is that attempting to fix the current system would be greatly helped by analysis of just what the weaknesses are in *process,* not just in missed outcomes. Pointing out that "good intentions alone are not reliable predictors of behavior" is quite true, and exactly the same logic must be applied to the development of interventions. Identifying prevention activities that should occur is not the same as enabling those activities to be incorporated into practice. There are many potential routes to behavior and many possible barriers, even within an individual physician and practice.

The investigators suggest that educational interventions might be particularly important for disadvantaged patients, who may be more passive with doctors. It is somewhat difficult to follow this line of thought. Will education provide the motivation to act? Will educational interventions teach the patients what to do and how to do it, or will such interventions be useless unless the issue of passivity is addressed separately?

The explanation of what is meant by "office systems" has been expanded slightly beyond what was presented previously, but is still inadequate. Do these "systems" constitute anything more than a bundle of administrative tools and procedures?

There is nothing wrong with that, except the use of the word "system" implies that these components come together in an important way by which the whole is greater than the sum of the parts. The application simply asserts or assumes these sorts of things.

The description of the intervention in the methods section clarifies the issue somewhat by stating some principles on which the intervention will be based. This section also makes clear that the shared intervention is not any one package of improvements but is rather an approach to making improvements.

The project is significant in that it will test whether the documented lessons learned in adult medicine practices are generalizable to pediatric practices. The arguments outlined provide sufficient justification for scientific attention.

The concern raised in the initial review that this proposed study may not be needed has been addressed in the revision. The revised proposal asserts the following: (1) Although the evidence on the positive impact of office systems is favorable, such interventions are still evolving; (2) the magnitude of the effect reported in previous studies is probably not of sufficient strength to achieve national goals for prevention; and (3) the published studies have methodologic/design problems that compromise their internal and external validity. Some aspects of this application are particularly innovative, such as the availability of medicaid billing assistance.

The aims of the study have been readjusted to include secondary questions related to impact on counseling, as well as changes in documentation. Both are responsive to reviewer comments. Topics for counseling activities to be monitored are nutrition, safety, and fluoride. Enhanced emphasis on understanding the "performance gap" phase of adoption is also welcomed. The new emphasis on organizational development in this revision is a strength and is also responsive to reviewers' concerns. The recommendation is for approval.



Post-Traumatic Stress Disorder After Pediatric Traffic-Related Injury

Grantee

The Joseph Stokes, Jr. Research Institute

Investigator

Flaura Koplin Winston, M.D., Ph.D.
 Children's Hospital of Philadelphia
 General Pediatrics-1 Abramson Building
 34th Street and Civic Center Boulevard
 Philadelphia, PA 19104-4318
 (215) 590-3118
 (215) 590-5425 fax
 flaura@mail.upenn.edu

Project Number R40MC00138-01

Project Period 3/1/1999-2/28/2002

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	246,436	160,880	407,316
Year 2	268,776	146,893	415,669
Year 3	247,241	135,123	382,364
Year 4			
Year 5			

Year 2000 Objectives

6.3, 6.9, 6.13, 6.14

Study Design

Time Design

Mixed

Care Emphasis

Noninterventonal

Population Focus

School-Aged Children, Adolescents,
 Parents/Families/Mothers/Fathers (Adolescent
 Parents)

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Traffic-related injury is the leading cause of death and acquired disability in children in the United States. Psychosocial consequences of these injuries for the child and his/her family are common but may receive insufficient attention. Descriptive studies suggest that children and their parents may suffer post-traumatic stress symptoms after injuries, but prevalence and risk factors are not well understood. Because Post-traumatic Stress Disorder (PTSD) cannot be diagnosed until long after most injured children have completed acute medical care, early screening for PTSD risk would be a useful tool to guide secondary prevention.

Research Questions or Hypotheses

The central hypotheses of the proposed project are: 1) that the prevalence of psychological distress in children (including PTSD) after crashes is significant and warrants clinical attention; and 2) that those at risk for developing PTSD can be identified during the acute phase of care. In order to test these hypotheses, this research addresses the following specific

aims:

Determine the prevalence of PTSD in children which develops within 4 months after pediatric traffic-related injuries;
Determine the contribution of several specific risk factors (including parent PTSD) to the development of child PTSD within 4 months after traffic-related injuries; and
Develop and validate a PTSD risk assessment screening tool for use in the acute care setting.

Study Design and Methods

A prospective cohort of 360 children admitted to a Level 1 pediatric trauma center for treatment of traffic-related injury is currently being enrolled. After obtaining parent and child consent, children and their parents are interviewed in the hospital or in their home within 4 weeks post-injury, and again in 4 months. Children (and parents who directly witnessed the crash) are asked to describe the injury circumstances. In the initial assessment, parents report on the child's pre-existing behavioral and emotional functioning (CBCL), previous exposure to traumatic events (TESI-P), prior family life event stressors (LES), as well as their child's Acute Stress Disorder (ASD) symptoms (CSRC) and their own ASD symptoms (SASRQ) and social support (DSSS). Children report on their previous exposure to traumatic events (TESI-C), their ASD symptoms (CASQ), and their pre-existing anxiety or depression symptoms (MASC-10 and CDI-S). In the follow-up assessment, parents report on their own and their child's PTSD symptoms (PCL and PCL-C/PR), and other aspects of their child's emotional/behavioral functioning (DICA-R-P). Parents also report on their child's physical health status (CHQ), the impact on the family from the child's injury (IFS), any new interim traumatic events for their child, and their own social support and coping (DSSS and CHIP). Children report on their own PTSD symptoms (CAPS-CA), anxiety and depression symptoms (MASC-10 and CDI-S), as well as coping methods (KidCope) and social support (SSSCA). At each assessment point, parents and children also rate the child's experience of physical pain associated with the injury.

Population and Sampling Plan

All children (between age 5 and 17) admitted to The Children's Hospital of Philadelphia (a Level 1 Pediatric Trauma Center) for treatment of traffic-related injuries (injured as a pedestrian, bicyclist, or motor vehicle passenger) will be invited to participate in the proposed study during their acute hospitalization. Children or parents who cannot complete a verbal interview because of limited spoken English proficiency or severe cognitive impairment will be excluded from the study. Families will not be contacted if a child has died. The population of children admitted to the Hospital for traffic injuries is approximately two-thirds male, and is approximately 50% African-American, 40% White, 2% Hispanic, and 8% Other.

Analysis Plan

The analyses involve determining prevalence of PTSD, development of a PTSD risk assessment screening tool, and the analysis of a proposed theoretical model for the development of traffic injury-related PTSD in children. The main outcome for all analyses is PTSD in children measured as both the presence/absence of diagnosis and a continuous score of symptom severity. Secondly, we will explore parental PTSD in response to pediatric traffic injury.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

Originality and Importance

No statement of originality and importance.

Regional and National Significance

No statement of regional and national significance.

Scientific and Technical Merit

The theoretical model seemed to indicate that PTSD might happen without ASD, thus limiting the predictive value of the tool. However, the literature review includes a section on PTSD in children and adolescents and the developmental implications of trauma in children. The investigators note that such occurrences are rare and that ASD is a primary predictor of PTSD.

The investigators have developed a working assessment tool. The tool will be tested on the first 100 subjects enrolled and, informed by analysis of that data, the tool will be revised and re-tested on the final 160 subjects. The description of the analyses related to this process are specific.

The plans for training interviewers is described. Using both didactic and practical components, the interviewers will be jointly trained by the research team and the Response Analysis Coordination Unit. Topics to be covered will include pediatric injury, ASD and PTSD, and approaching the family. The training will also include demonstrations of interviewing by the staff and role playing practice for the interviewers. Initial interviews with study subjects will also be observed. The quality of the interviews will be reassessed over the course of the study. One of the investigators will monitor interviews and re-interview a small number of families.

The timing of the interview will be aimed to be between 2-4 days to allow for a consistent relation to the traumatic event. Variations in timing will be analyzed.

The variables to be examined as potential risk factors for and predictors of PTSD include a range of factors related to acute treatment (such as length of stay) and post-discharge treatment (such as psychological counseling). In addition, the investigators have added measures of family stress both preceding and following the injury. Coping resources for parents will be evaluated. Finally, children will be asked about their attempts to cope with the challenges of this traumatic experience.

One issue is raised in the prediction tool assessment. The investigators note that they will consider promising a PPV and NPV of >70%. As the PPV and NPV are dependent on the prevalence of the outcome, these will differ from population to population. Concentrating the evaluation of the tool on sensitivity and specificity will provide better information for generalizing results to different settings.

No other financing is being sought.

This is a highly qualified team.

The budget generally seems reasonable. It is not clear why Dr. Kassam-Adams is at 40% for all 3 years since her responsibilities relate to overseeing training of interviewers and selection of instruments to measure PTSD.

Resources and facilities are adequate.

There are no concerns with Human Subjects. The investigators have carefully considered these issues.

Evaluator 2

Originality and Importance

The current effort builds upon some of the findings that this project team has noted in their Injury Circumstances Evaluation (ICE) study, which has resulted in the creation of a pediatric injury circumstances scoring system for use in triage, care, and research for pediatric traffic-related injuries. An extension of the ICE study to estimate rates of PTSD in children and parents illustrates their ability to discuss stressful topics with parents of injured children. Moreover, the preliminary results of the aforementioned investigation support the hypothesis of the proposed study.

Regional and National Significance

Traffic related injuries among children frequently results in subsequent psychological issues. Early identification and early intervention efforts may bring about cost-saving perspectives in the future.

Scientific and Technical Merit

The proposal is well written and clearly builds upon the collective and individual expertise of co-investigators. While the ICE study enrolled 710 children, telephone interviews with 103 parents were conducted 7 to 12 months after their child's injury to obtain parent-report measures of PTSD in children and a related self-report measure of the parent's own PTSD symptoms. Of the 103 participants, 29% of the children met full diagnostic criteria for PTSD based on their parents' responses. Another 29% of the children were evaluated as having partial PTSD. Thus a total of 58% of the children experienced at least partial PTSD. Of the 102 parents who responded, 20% met full diagnostic criteria for PTSD, while another 29% reported symptoms corresponding to partial PTSD. Perhaps not surprising was that parent and child PTSD severity scores were highly correlated.

According to the investigators, the proposed study requires a survey contractor to conduct acute and follow-up interviews with families of children who are injured in traffic-related incidents. The purpose of the survey is to collect data that will help researchers at Children's Hospital of Philadelphia (CHOP) identify children most at risk for developing PTSD in the period following an injury. Response Analysis Corporation has been recommended for the subcontract. This corporation has an extensive record of collaborative working relationships with state and federal agencies, conducting the type of work that is outlined in the current proposal.

But, herein lies one of the more puzzling dimensions of the proposed investigation. Based on their pilot work, the investigators state: "As with other studies of pediatric trauma conducted by the Research Team, most parents were eager to talk. A number of parents recounted their stressful experiences and stated that parents of children sustaining traffic-injuries needed more resources than are currently available. " Why then is it imperative that a contractor be charged with conducting the acute setting and follow-up investigations?

The Child Behavior Checklist will be administered during interviews conducted in the acute setting and follow-up to establish a base line for behavioral and social-emotional functioning prior to injury. No psychometric properties are presented for this instrument. However, some of the questions on this instrument are deemed to be inappropriate for some of the older subjects that will participate in this investigation (e.g., bowel movements outside toilet). These data will be collected only from parents or guardians, yet many of the questions clearly focus on socialization outside the home environment.

The Family Inventory of Life Events and Changes (FILE) is a checklist of stressors and strains that may occur in the life of a family. Because stress has been defined as a contextual variable, it will only be considered as a pre-injury variable. It is not clear why this tool will not be repeated over time given that contextual dimensions of stress may contribute to a parent's ability to cope with the current situations.

It should be noted, however, that family stress and coping, as a post-hospitalization variable, is operationalized as the impact of the child's injury and course of recovery on the family. The Impact on Family Scale (IFS) will be used to assess several facets of parents' experience in the post-injury period. In addition to the IFS, parents' will be asked to respond to the Coping Health Inventory for Parents (CHIP), which yields a measure of coping strategies for parents of medically ill children. Children will be asked, using an open-ended question, about their attempts to cope with the challenges of this traumatic experience.

The remaining variables and tools that will be used to measure these variables appear to be in order.

A very impressive team of collaborators has been assembled for the proposed project. Evidence is provided demonstrating their past relationships on numerous projects. More importantly, this multidisciplinary team also reflects individual accomplishments.

All of the investigators have noted that they would "re-evaluate the effort needed to perform each project to ensure commitment is not more than 100%." However, one cannot assume that the reduction in their efforts will not come from the proposed project, which reflects an ambitious undertaking and commitment of time from several of the co-investigators.

Among the tasks assumed by the subcontractor is instrument finalization and pre-testing. According to the investigators, personnel at Response Analysis Corporation will: "(1) address issues related to the overall structure and format of the parent checklists, and (2) the overall structure and flow of the parent and child interviews." Herein lies one of the concerns that I have with this procedure. It appears from this brief it is possible that RAC will, in collaboration with CHOP research team, alter some of the questions on standardized scales without considering possible violations to the validity of these scales. Perhaps such an assumption is erroneous, but nonetheless, it appears that RAC will assume the responsibility for recommending the elimination or reordering of questions based on their perceptions of question flow.

This preliminary stage of work also includes the development of a contact information form (which will seek to obtain information of extended family who, with their permission, may be contacted to follow-up with hard-to-find families, and an advance letter to be used for contacting respondents prior to the four-month-follow-up interview. It is unclear why the latter is being subcontracted when essentially, this might be a task that the principle investigator can assume with relatively little or no additional cost.

A pretest will be conducted by Response Analysis to pilot the testing procedure, and to evaluate the format and overall structure of each survey instrument. Children in three different age groups (5-8, 9-12, and 13-18) will be recruited with the assistance of CHOP to participate in the pilot. The acute pretest interviews will be conducted in the hospital and follow-up interviews at 4 months will also be conducted at the respondents' homes. The number of children and families participating in this pilot, however, remains unclear. Moreover, it is not clear how these protocols will be evaluated.

Quality control insurances related to the data that will be collected have been implemented throughout the study. These control mechanisms appear to be adequate for checklists and other quantitative data that will be collected. However, other than the initial two interviews that are directly observed and monitored by the research staff, it does not appear that any other precautions of data collection will be introduced. Given that Response Analysis will be employed and entails the collection of over 300 interviews, only the initial interviews will be part of a systematic review to insure that the protocol operates in the planned manner.



Poverty and the Ecology of African-American Children

Grantee

Johns Hopkins University

Investigator

Patricia J. O'Campo, Ph.D.
 School of Hygiene & Public Health
 624 North Wolfe Street
 Baltimore, MD 21205
 (410) 550-5448
 (410) 955-2303 fax
 pocampo@phnet.sph.jhu.edu

Project Number MCJ-240731

Project Period 10/1/1996-9/30/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	160,853	109,380	270,233
Year 2	202,272	137,545	339,817
Year 3	133,137	90,533	223,670
Year 4			
Year 5			

Summary

Statement of the Problem

Children who are raised in poverty are at increased risk for poor developmental outcome, and African-American children are more likely to live in poverty and to experience persistent poverty more often than other children. As the result of the overrepresentation of African-Americans among the socioeconomically disadvantaged, the research literature on the socioeconomic differences in child-rearing and parenting behavior and the effects of these differences on child development is often interpreted as being descriptive of normative patterns of parenting and child development in African-American populations.

Research Questions or Hypotheses

The goal of the project is to contribute to the developmental literature by examining the ecological, situational, and cultural factors that shape behavior and set African-American children on certain developmental trajectories.

Study Design and Methods

Year 2000 Objectives

6.3, 6.14, 22.4

Study Design

Observational

Time Design

Cross-sectional

Care Emphasis

Noninterventive

Population Focus

Preschool-Age Children,
 Parents/Families/Mothers/Fathers (Adolescent
 Parents)

Race/Ethnic Focus

African-American

Data characterizing the physical and social characteristics of 16 study neighborhoods will be gathered from routine data sets, drive-through observational protocol, and social network and cultural norms data collected from the 400 study participants. Family assessment data to be collected include measures of family demographics, parenting style, parenting goals, parenting behavior, racial identity, experiences of racism, and social networks.

Population and Sampling Plan

Data will be collected from 400 African-American children (ages 3–4-1/2) and their families in study neighborhoods in Baltimore stratified by socioeconomic status and racial composition.

Analysis Plan

Multilevel modeling will be used to examine how the physical and social characteristics of neighborhoods directly and indirectly (via parenting) affect development and how these factors contribute to the increased risk or resilience of African-American children. The findings of this study will have implications for the design of intervention programs for minority groups living in poverty.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

The research described in this application is designed to increase understanding of the direct and indirect influences of living environments (specifically, neighborhoods) on the development of African-American children. In general, current knowledge about the contributions of neighborhoods to the development of children is quite limited. Most past research has focused on individual- or family-level developmental influences; effects of the larger environment have seldom been studied. Yet developmental and ecological theories would suggest that the context in which parenting and child development occur is potentially very influential. Therefore, this research is potentially very important.

Regional and National Significance

This application argues that children raised in poverty are at increased risk for poor developmental outcomes. More African-American children experience persistent poverty than do children of other racial and ethnic backgrounds. The proposed research will assist the MCH community in better understanding the ecological, situational, and cultural factors that shape behavior and set African-American children on certain developmental trajectories. Therefore, the project has regional and national significance.

Scientific and Technical Merit

This application was previously reviewed and disapproved. The previous review noted that the proposed research contained numerous creative and innovative elements. Although the review was quite positive about the importance of the research and about the overall quality of the research project, the review noted specific conceptual and methodological limitations in the project. Most of these concerns have been successfully addressed in the current application.

One of the most important issues raised by the previous review was the failure of the researchers to justify why a sample of white families was needed to address the study's questions. Justification for including this sample of 200 families was judged to be weak. In the revised application, this group has been deleted and the size of the sample of African-American families has been doubled, from 200 to 400. The previous review questioned the plan to contact those families who do not have phones by letter. The researchers argue that they have been successful in using this approach to recruit low-income families to participate in other research projects.

The previous review expressed several concerns about the qualitative data collected on parenting styles and how it will be used in the quantitative analysis. The investigator has done a good job of responding to some of these concerns and has added a nationally recognized coinvestigator with experience in ethnic development and research.

The principal investigator has more fully explained the details of the "consensus" analysis that will be performed on the pile-sorting and ranking data. However, making it clearer what this analysis does has not allayed concerns that

individual-level data are being aggregated to produce neighborhood-level indicators.

A previous concern was that the sampling plan was not well-articulated. The revised proposal is clearer in this regard. Sixteen different "neighborhoods" will be sampled, with between one and three census blocks nested within each neighborhood. These neighborhoods contain a mixture of incomes (four levels) and races and ethnicities (predominantly African American or ethnically mixed). It should be noted that the analyses nest individuals within neighborhoods, yet subjects are actually nested within census blocks of a neighborhood, a fact not taken into account in the analysis plan. As in the previous proposal, hierarchical linear modeling (HLM) will be used to estimate the direct and indirect effects of the neighborhood on child outcomes. The basics of HLM are clearly presented, and its use is one of the major strengths of the proposed study.

The principal investigator still has not demonstrated how data from individual interviews will produce neighborhood-level variables that will not be biased in favor of the hypothesis. For example, the list of variables shows that the pile-sort data will be used to generate both neighborhood-level indicators of parenting goals and priorities and individual-level indicators of parenting style and priorities.

Given the prominent place of "Social Norms and Culture" as a neighborhood-level construct in the conceptual model, it is troubling that all of the variables measuring this construct come from individual interviews of the study participants. This concern still has not been addressed.

The timeline suggests that only 1 year is allotted for conducting the scheduled 800 home visits. This may be too short a timeframe, given that only two home visitors are to be recruited. Each visitor will need to conduct approximately two visits a day, 5 days a week for this plan to work. Perhaps another home visitor should be hired.

The proposal has also been submitted to the National Institute of Child Health and Human Development (NICHD). It has received local internal review board (IRB) approval, and there appear to be no human-subject concerns.

The principal investigator has published in a number of peer-reviewed journals. Although none of her work has been on the development of African-American children, she appears to be qualified to conduct the proposed research. Other members of the team also appear to be well-qualified.

The budget has increased since the previous submission. Although the research protocol did increase from one to two home visits per family, the increase in budget does not seem proportional to this change. It is not clear that all of the budget increase is warranted.

The investigator has been responsive to the concerns raised in the previous review. The research is well-designed and sophisticated in its approaches. It has many creative features that add to the potential contribution of the findings. The recommendation is for approval with the condition that the investigator address the following concerns:

1. Given past work suggesting that parenting style is not a mediator of contextual effects on child behavior, why does parenting style continue to be given this status in the conceptual model?
2. Given past work on the cultural-ecological model, why are the primary outcomes in the present proposal the K-ABC and the Vineland?
3. Given that the pile-sort and ranking data will be used to generate both neighborhood-level and individual-level variables, why are the results not biased in favor of finding a relation between social norms of the neighborhood and parenting style?
4. The income criteria for defining neighborhoods needs to be specified, as does the likelihood of filling all cells in the design.

If the principal investigator decides to revise the conceptual model based on these concerns, the new model should be detailed, along with a new table of variables for the neighborhood and individual levels.



Predicting African American Children's School Compliance

Grantee

University of North Carolina at Chapel Hill

Investigator

Joanne E. Roberts, Ph.D.
Child Development/Behavioral Science
150 Smith Level Road, CB#8180
Chapel Hill, NC 27599-8180
(919) 966-7164
(919) 966-7532 fax
joanne_roberts@unc.edu

Project Number R40MC00145-01

Project Period 8/1/1999-7/31/2003

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	165,830	73,794	239,624
Year 2	203,931	86,744	290,675
Year 3	209,154	76,668	285,822
Year 4	197,099	72,250	269,349
Year 5			

Summary

Statement of the Problem

African American children are much more likely to be poor than are white children (40% versus 16%), are more likely to experience gaps in achievement in school, and are over-represented among students enrolled in special education classes compared to other students. Determining whether risk and buffering/protective factors during early childhood affect African American children's school functioning, and which different factors become important as children enter middle childhood, is critical for understanding children's functioning in the later elementary school grades and is only possible with longitudinal study designs. Further, the lack of literature on African American children's development leads to the dire need for research that will increase our understanding of the factors that promote and inhibit the development of African American children. Consistent with an ecological model of development, we are studying the child, family, school, and neighborhood factors that influence children's competence in school in the later elementary school years.

We are studying the role of peer adjustment (e.g., friendships, acceptance) and children's coping skills in school success, and how constructs relevant to populations of color, and specifically to African American children, (e.g., ethnic identity and socialization, children's use of African American Vernacular English) affect children's school competence, and how

Year 2000 Objectives

No Stated Healthy People Objectives

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

School-Aged Children,
Parents/Families/Mothers/Fathers (Adolescent
Parents)

Race/Ethnic Focus

African-American

environments (home, school, and neighborhood) inhibit or promote these constructs.

This project builds on earlier work which examined children's health, development, family environment, and child care experiences during infancy and the preschool years and the roles of early and concurrent measures of the child, family, and school on children's development during the first three years of elementary school.

Research Questions or Hypotheses

This project examines the role of child, family, school, and neighborhood factors in predicting African American children's school competence during the later elementary school years.

The aims of the study are to: 1) describe the developmental trajectories of African American children's language skills, social skills, and school competence from infancy through middle childhood; 2) determine the multiple predictors of school competence including academic achievement and school adjustment of African American children in middle childhood within an ecological model of child development; and 3) identify the extent to which children's social knowledge and behavior, language, peer adjustment, and the match between Afrocultural beliefs and practices at home and school mediate the relationships between child, family, school, and neighborhood background factors and school competence.

Study Design and Methods

Measures of child, family, school, and community are being examined for 75 African American children when children are in third, fourth, and fifth grades. Child measures are assessing children's language (e.g., African American Vernacular English), coping skills (e.g., race specific coping strategies), Afrocultural beliefs and practices (e.g., movement expression), social behavior (e.g., cooperation), peer adjustment (e.g., friendship), and school competence (e.g., achievement in reading). Family measures examine family characteristics (e.g., maternal education), Afrocultural beliefs and practices (e.g., communalism), and parenting beliefs (e.g., parental perceptions of discrimination). School measures assess factors such as classroom quality, Afrocultural beliefs and practices, teachers' perceptions of relationships with students, and classroom demographics. Neighborhood measures include factors such as parents' perceptions of the neighborhood and demographic characteristics of the neighborhood.

Population and Sampling Plan

Seventy-five African American children and their families who have been followed since early infancy are included in the study. Children in the study were recruited from 9 center-based child care programs before the age of 1 year. All were apparently normally developing when entering the study. The sample consists of 41 girls and 34 boys. At entry to kindergarten, 60.3% of children lived below the federal poverty level (185% of poverty), 40% of caregivers were unmarried, and 17.8% had less than a high school education.

Analysis Plan

Two types of longitudinal analyses will be used. First, using hierarchical linear models, we will examine the longitudinal patterns of change in the child's academic competence and social adjustment and relate those patterns to the types and changes in social risk factors, parenting beliefs, and neighborhood characteristics. These analyses involve testing whether characteristics, such as the child's language skills, social skills school adjustment, coping strategies, racial identity, and peer adjustment, serve to mediate associations between child outcomes and social risk and protective factors. Second, we will identify various developmental pathways or prototypic patterns of development and determine which child, family, and neighborhood characteristics distinguish children displaying different patterns of growth. Emphasis will be placed on identifying factors that mediate or moderate observed relations between child, family, school, and neighborhood factors and child competence in school. Study findings should have important implications for the sociocultural factors that affect the school success of African American children.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

Pre-award evaluation outstanding from MCHB. Submitted second request 10/26/00, JMB.



Predicting the Need for Hospitalization in Childhood Asthma

Grantee

University of Pennsylvania

Investigator

Marc Gorelick, M.D.
A.I. duPont Hospital for Children
1600 Rockland Road
Wilmington, DE 19899
(302) 651-5889
(302) 651-4227 fax
mgorelic@nemours.org

Project Number MCJ-420832

Project Period 10/1/1997-3/29/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	186,516	107,269	293,785
Year 2	178,083	105,959	284,042
Year 3			
Year 4			
Year 5			

Year 2000 Objectives

11.1, 17.2, 17.4

Study Design

Observational

Time Design

Mixed

Care Emphasis

Noninterventional

Population Focus

Preschool-Age Children, School-Age Children, Adolescents

Race/Ethnic Focus

African-American

Summary

Statement of the Problem

Substantial health resources in the United States are devoted to hospitalization of children with acute exacerbation of asthma. There is evidence that a substantial proportion of these admissions are unnecessary and avoidable. However, clinical criteria discriminating those children needing hospitalization from those who can be safely discharged from an emergency department have not been defined.

The creation of a new tool to improve accuracy of prediction of short-term outcomes in acute childhood asthma will reduce both inappropriate admission and discharge, with enormous potential for reducing both economic costs and morbidity.

Research Questions or Hypotheses

This project aims to: 1) identify those signs and symptoms which are associated with the need for admission in acute asthma and 2) develop and validate a clinical prediction rule to differentiate those children requiring admission from those capable of discharge.

Four hypotheses are proposed: 1) a set of variables measuring the past history of the patient will predict the three outcome

variables; 2) a set of variables measuring the physical status of the child at preliminary treatment will predict the three outcome measures; 3) an actuarial rule combining historical and physiological markers will accurately predict the three outcome measures; and 4) the actuarial rule will be validated when applied to a separate sample of children from another hospital.

Study Design and Methods

Patients will be treated according to nationally recommended guidelines. A standardized assessment will be performed by trained personnel to evaluate potential predictors, including historical information and clinical information. This assessment will be obtained from the parents in roughly five domains: demographic data; precipitating history of the current asthmatic episode; past asthma history; asthma medication use; and information about access to medical care. Short-term outcomes of this prospective study will be assessed by telephone interview or in person visits to all subjects. Those patients requiring admission will be defined as those actually admitted who continue to have wheezing or oxygen saturation less than 95% 12 or 24 hours after presentation, as well as those discharged from the emergency department who subsequently require admission within seven days of the initial visit.

Population and Sampling Plan

Approximately 768, mostly African-American children, ages two years old and older treated in the emergency department of the Children's Hospital of Philadelphia for acute asthma will comprise the sample for this study.

All parents of patients initially discharged will be interviewed by phone on days 1 and 7 after initial presentation to assess relapse.

A random sample of 20% of initially discharged patients will be asked to return to the ED after presentation for clinical assessment. Parents will be provided free treatment, transportation, and meal vouchers to maximize compliance.

Analysis Plan

The clinic findings in those patients needing hospitalization and those capable of discharge will be compared. Data analysis includes: assessment of interobserver reliability; 2) univariate analysis to assess for association between individual predictors and outcomes using t-tests, chi-square tests, and tests for linear trends in ordinal data; 3) multivariate stepwise logistic regression with correction for over-dispersion to develop an actuarial rule; and 4) recursive partitioning to develop rules based on the dichotomization of predictors.



Prenatal Antecedents of Infant Outcome

Grantee

The Johns Hopkins University

Investigator

Janet A. DiPietro, Ph.D.
School of Public Health
Department of Maternal and Child Health
624 North Broadway
Baltimore, MD 21205
(410) 955-8536
(410) 955-2303 fax
jdipietro@jhsph.edu

Project Number R40MC00136-01

Project Period 3/1/1999-2/28/2003

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	58,820	18,822	77,642
Year 2	72,165	23,092	95,257
Year 3	81,618	26,118	107,736
Year 4	86,135	27,563	113,698
Year 5			

Summary***Statement of the Problem***

The period before birth has long been recognized as the progenitor of postnatal development. Recent models of the potential for antenatal programming of adult diseases and conditions have contributed to a resurgence in interest in the fetal period in the biomedical community. In addition, the focus of inquiry into the origins of severe neurologic deficits, such as cerebral palsy, has shifted in the last few years from the intrapartum to the antenatal period. Yet relatively little is known about what constitutes normal development prior to birth, whether prenatal development can be successfully measured, and whether predictive validity to later developmental outcomes can be established from the fetal period. Ultimately, documentation of normal fetal ontogeny, and the factors which influence it, will allow detection of atypical antenatal development in fetuses at-risk for postnatal developmental morbidity.

Research Questions or Hypotheses

The broad conceptual orientation of this research is that fetal neurobehavioral development reflects maturation of the central

Year 2000 Objectives

No Stated Healthy People Objectives

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventive

Population Focus

Infants, Pregnant Women

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

nervous system during gestation and establishes origins of individual differences in autonomic functioning. Constraints on development may be provided by fetal factors, such as fetal sex, and maternal factors, including psychologic distress, which affect the intrauterine milieu. This project is oriented toward answering the two following research questions:

1. What is the validity of measures of fetal neurobehavioral development in predicting postnatal development and behavior through the first 2 years of life? We predict that individual differences in the rate of development, behavior, and temperament are established prior to birth and that there will be continuity in prenatal to postnatal function.
2. What are the effects of maternal stress on infant development? We predict that maternal stress will be associated with reductions in cognitive and motor development, and impairment of regulatory processes, including attention, as a result of disruption to the homeostasis of the developing hypothalamic-pituitary axis.

Study Design and Methods

This project includes only the infant follow-up portion of a larger study in which pregnant women are assessed at six gestational ages: 20, 24, 28, 32, 36, and 38 weeks, and their infants receive a standard neurobehavioral assessment at 6 weeks postpartum. During each antenatal visit, measures of fetal function (e.g., heart rate, motor activity, and their interrelation) and maternal physiology (e.g., heart rate, skin conductance response and level, and respiration) are collected. Maternal-fetal data are digitized using a computerized system during undisturbed baseline conditions as well as periods of induced maternal arousal (i.e., cognitive and emotional challenges). During each visit, women complete a battery of self-reported questionnaires regarding their levels of anxiety, mood, depression, and perceived stress. The MCHB-funded project begins with an infant follow-up assessment at 16 months based on a maternal telephone interview. The interview includes: 1) the Sleep Habits Inventory for Toddlers; 2) the Infant/Toddler Symptom Checklist designed to ascertain symptoms of regulatory difficulties; 3) a motor milestone scale; and 4) a physical activity scale.

Data collection at two years of age involves a laboratory visit. Toddler heart rate patterns, including vagal tone, are measured from ECG monitoring. The Bayley Scales of Infant Development II are administered (MDI, PDI, and Infant Behavior Record). Attention, behavioral regulation, and maternal-child interaction are assessed during two observational situations: a shape sorting task and joint book reading. The entire session is videotaped for behavioral coding. Mothers also complete a series of psychosocial questionnaires.

Population and Sampling Plan

The sample for this study is 120, stratified by parity (nulliparous vs multiparous) and fetal sex. During pregnancy, participants are volunteers recruited from the local community. Subject participation is restricted to non-smoking women with singleton, uncomplicated pregnancies who are at least 20 years of age. Given the gestational age-based nature of the study, accurate ascertainment of fetal gestational age is imperative. Exclusion criteria, determined through self-report and review of prenatal and intrapartum medical records, include maternal medical (e.g., hypertension) or behavioral (e.g., documented substance use) risk factors and fetal conditions which are known to affect fetal development and outcome. In general, the sample includes well-educated, employed women; approximately 20% are racial/ethnic minorities.

Analysis Plan

This project generates complex data which requires a series of analytic approaches tailored to the specific hypothesis being tested. The hypotheses can be broadly categorized into the following two categories: Fetus-Infant and Mother, Fetus-Infant. Four statistical techniques will be utilized: 1) exploratory and bivariate analysis to describe the simple relationships; 2) simple and multiple linear regression, in order to predict to the 16 and 2 year outcomes from single and multiple fetal and maternal measures; 3) individual growth curve modeling, to determine whether the rate and patterning of prenatal development predicts outcomes independently from level, and 4) structural equations modeling (SEM), to model fetal neural integrity, the underlying latent variable of interest. With respect to the first question, both within domain (e.g., activity level during the fetal period to activity level during infancy) and cross-domain (e.g., fetal behavioral state to infant attentional performance) predictive relations will be analyzed. With respect to the second, it is predicted that the physiologic data collected from pregnant women during both undisturbed and evoked conditions will be more potent predictors to infant outcome than paper and pencil reports of psychological stress.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

No statement of originality and importance.

Regional and National Significance

No statement of regional and national significance.

Scientific and Technical Merit

Hypotheses are fully developed and tied to the complex processes of the conceptual model provided in the proposal. Developmental assessments of the infants include an array of factors that reflect broader developmental notions of influence related to fetal neurobehavioral function, and the data analytic scheme is tied directly to the hypothesized relations that are discussed.

It is interesting from a basic science perspective to link fetal neurobehavioral functioning with later infant developmental functioning. The notion of continuity from fetal status through later childhood is entirely sensible. Given the constructs that are to be assessed in the proposal, most of which address attributes with strong biological components (e.g. regulatory behavior, motor development), it would be more surprising to find a lack of continuity than continuity between fetal neurobehavioral functioning and subsequent infant regulatory behavior. It would be helpful to know whether there is meaningful application of the ability to characterize fetal neurobehavioral status. The basic science aspects are clear, but the concepts of the applied aspects are not developed within the proposal.

One strength of this application is that a large portion of the overall project, the antenatal assessment and the six week post-birth assessment, are all funded by an NIH grant. Therefore, the current proposal only seeks support for the 12-month maternal report and an 18-month infant mother lab session. The cohort 2 study of 40 to 50 infant home assessments is also included. Whether or not this merits four years of support will be addressed later, but it seems a lengthy period.

Another conceptual issue involves the choice of the 12 and 18-month measurement periods. There is not developmental argument provided for the choice of these periods and the information that is collected within them. Why are regulatory, developmental, and interaction indices collected in depth at 18 months, and maternal report data on child behavioral symptoms, sleep habits, and motor milestones collected at 12 months. Infant regulatory abilities are well developed by age 12 months, and can be easily measured by methods similar. The choice to use 18 months may be sensible, but there is a long latency between observational assessments (6 weeks to 18 months) which is not optimal in longitudinal assessments of early developmental continuities. Some developmental rationale for these choices would have been helpful.

The inclusion of a data collection for cohort 2, entirely separate from that occurring with the cohort 1 data, presents questions. Cohort 2 is first, a small sample (and there may well not be sufficient power to demonstrate predictions despite the power analysis offered), but more importantly does include the same measurements protocols available in cohort 1. The fetal assessments are fewer and from somewhat different periods, and there are no assessments of the mediators collected in cohort 1 that form the basis of the full developmental model being investigated. In fact, it is quite simply the combination of the fetal neurobehavioral data and the developmental-contextual mediators together predicting links to children's later functioning that provide the strength of this proposal. The cohort 2 assessment cannot duplicate this wealth, and will be of limited value comparatively.

In regard to the observational measurements, there is a lack of detail that is unfortunate when these measurements are critical to the assessment plan at 18 months. For example, are the interval data to be collected scored as frequencies within the interval or simply as present or not? Is there any indication of the "degree" to which these behaviors occur (e.g. negative affect can vary widely; what qualifies as negative affect?). Are there child behaviors scored outside the attention scoring? None are listed in the maternal-child interaction description. The power analysis provided makes its assumptions on the basis of 5 variable inclusions in the regressions. Given the wealth of data that may be involved to address the complex

mediational and/or maturational aspects of the proposal, 5 variables seems rather optimistic.

The principle investigator has a strong scholarly record in the area of the proposed work, and is very well qualified to conduct the proposed research.

The sample acquisition process, and the complexity and frequency of the fetal assessments require that adequate time be given to acquire a sample so there are not too many data collections ongoing at any one time. However, the timeline provided suggests that data collection is complete by the end of the third month in Year 4. That leaves only data analysis (slated for 4 months) and report preparation (slated for 5 months). Yet, the year 4 budget is nearly \$5k greater than any other budget. This is not sensible.

Evaluator 2

Originality and Importance

The present project's goal to link in-utero behavior to later developmental outcomes is a problem worthy of pursuit. So much of antenatal development may be predicated upon in-utero development such that potential developmental problems during infancy and childhood may be addressed before birth. While such knowledge has the potential for misuse, it may also provide the information needed to create early interventions geared towards addressing in-utero problems immediately after birth.

Regional and National Significance

The proposal is well written and well conceived. There is a rich fetal data set and the initial findings appear to support many of the hypotheses posed. The literature reviewed is broad and makes some interesting assumptions about how fetal movement may be indicative of neurological development. It is still yet to be seen if these links are born out by the data, but the questions posed in the proposal go beyond what is known at present. The outcomes of such a study would be a major contribution to the field.

Scientific and Technical Merit

A major question has to do with the logic between the fetal data and some of the cognitive outcomes posed. It seems reasonable to suggest that changes in fetal movement patterns over the course of gestation may be indicative of increasing neural integration. Therefore, it also seems reasonable to predict that such patterns should relate to measures taken between 6 weeks and 18 months, especially since all of these measures are motor dependent. That is, the early cognitive measures, like the motor milestone measures, assess motor behavior and coordination. Since similar factors are being linked between the fetal and the infancy data, one would expect to see a relationship if one existed. Such a relationship is harder to justify in the 5 year old data, specifically the cognitive assessment to be made. At 5 years old, the intelligence instruments move from being motor-based to being verbally based. From my reading of the literature, the relationship between infant measures and verbal measures is not that strong. Indeed, so many other environmental factors come to be better predictors of performance on such tests than earlier mental performance. Just look at how the gap between Blacks and Whites on intelligence tests begin to diverge once the measures change from motor to verbal. The possibility that fetal behaviors relating to such culturally latent measures at age 5 seems questionable to me. Using the HOME is good given its relationship with verbal IQ measure. However, one questions the validity of the hypothesized link in this particular instance.



Preventing Mental Health Problems in Ill Children

Grantee

The Johns Hopkins University

Investigator

Henry T. Ireys, Ph.D.
Department of Population and Family Health Sciences
Hampton House, 624 North Broadway, Room 247
Baltimore, MD 21205
(410) 550-5442
(410) 955-2303 fax
hireys@jhsph.edu

Project Number MCJ-240804

Project Period 10/1/1995-7/31/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	177,223	120,512	297,735
Year 2	233,469	158,759	392,228
Year 3	224,952	143,688	368,640
Year 4	177,621	110,125	287,746
Year 5			

Summary

Statement of the Problem

More than two decades of epidemiological and clinic-based studies indicate that children with disabilities and chronic illnesses and their mothers are at high risk for secondary mental health problems. Despite this extensive body of work, few community-based interventions have been developed to reduce the risk of poor mental health outcomes, and few have been evaluated comprehensively.

Research Questions or Hypotheses

The goal of this study is to implement and evaluate a 15-month parent-professional intervention designed to reduce the risk of poor mental health outcomes for children with chronic illnesses and their parents. This study aims to (1) assess the intervention's success in reaching specific objectives, (2) assess the intervention's impact on participants' mental health, and (3) document which children and parents benefit most from the intervention.

Study Design and Methods

Year 2000 Objectives

6.3, 17.14, 17.20

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

School-Age Children,
Parents/Families/Mothers/Fathers (Adolescent
Parents)

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

The intervention is being evaluated with a longitudinal, repeated measures, randomized, controlled trial design. Participants are randomized to either a comprehensive intervention group or a low-dose control group. The intervention is delivered through a structured protocol by a team consisting of a child-life professional and a "veteran parent" (a parent who has raised a child with chronic illness).

The specific objectives of the intervention are to (1) strengthen children's self-esteem and (2) enhance maternal social support and parenting confidence. The child-life professionals work with enrolled children; veteran parents work with the children's mothers.

Data are collected via interviews with children and parents at the time of enrollment (T1), 12 months (T2, just prior to the end of intervention), and 20 months (T3). Interviews involve scales to measure key constructs, including maternal and child mental health, social support, self-esteem, and self-efficacy. Through brief telephone calls every 4 months, contact is maintained with the participants and data are gathered on health and mental health service use. Data are also gathered from teachers and specialty care providers.

Population and Sampling Plan

A sample of 200 families with children from ages 7 to 10 has been recruited for this study. Children have one of four chronic illnesses: Diabetes, sickle cell anemia, cystic fibrosis, and moderate to severe asthma. The study does not specifically address gender or ethnic issues, but these issues could be explored in secondary analyses.

Analysis Plan

We will address the question of whether the intervention was implemented as planned by conducting an administrative discrepancy analysis in which intentions are compared with actual events in four key areas: Program staffing, frequency of contacts between the intervention team and the program participants (i.e., "the delivered dose"), content of these contacts, and quality of relationships between the team and the participants.

These areas were chosen because they relate to three key threats to implementation: (1) Threats to fidelity (Was the intervention faithful to the underlying conceptual model?), (2) threats to potency (Was the program delivered with the intended power?), and (3) threats to administrative integrity (Did the administration of the program support its objectives?).

The first aim of the study is to assess the intervention's success in reaching its specific objective—to enhance psychological and social resources for the participants. We will compare the experimental and control groups for each resource variable at each time point. Means will be compared by using *t*-tests. In addition, we will compare the experimental and control groups by using resource measures collected at T2, controlling for baseline independent variables (e.g., condition-related variables). Multivariate analyses of covariance (MANCOVAs) will be completed. The independent variables will include a variable that indicates the group (experimental or control) and covariants measured at baseline. These covariants will include T1 scores, diagnostic subsample, context factors (e.g., family composition), and condition-related variables (e.g., severity of illness), depending on results of bivariate analysis. Separate analyses will be run for children and mothers.

The second aim of the study is to evaluate the intervention's effect on short-term and longer term mental health. We will undertake analyses similar to those described above. Analyses focused on child mental health will include baseline indices of maternal mental health, and vice versa. Concordance between different data sources (e.g., teacher versus parent) will be determined by using paired *t*-tests. If concordance is small, separate analyses will be run by using data from the different sources (e.g., teacher versus parent responses for the Child Behavior Checklist). The study's conceptual framework suggests that the intervention will have its effects by increasing psychological and social resources. Therefore, if the intervention is found to have effects, we will conduct additional analyses to examine whether the intervention's effects occurred via the postulated route.

The third aim of the study is to document which children and parents benefit most from the intervention in terms of enhancing psychological resources. A series of exploratory analyses will be conducted separately for mothers and children. These analyses will focus only on data from participants assigned to the experimental group. Differential effects will be analyzed by using change scores in resource variables from T1 to T2. Depending on the number of variables and interactions that are significantly related to outcomes, analyses of variance (ANOVAs) or multiple regression analyses will be used to examine different effects of the intervention.



Prospective Investigation of Twin Gestation

Grantee

University of Minnesota

Investigator

Judith E. Brown, M.P.H., Ph.D.
Division of Epidemiology, School of Public Health
1300 South Second Street
Suite 300
Minneapolis, MN 55454
(612) 626-7934
(612) 624-0315 fax
EPIVAX.EPI.UMN.EDU

Project Number MCJ-270756

Project Period 10/1/1996-9/30/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	124,921	58,713	183,634
Year 2	182,196	85,632	267,828
Year 3	185,398	87,137	272,535
Year 4			
Year 5			

Summary***Statement of the Problem***

A high incidence of poor outcomes of twin pregnancies and a lack of knowledge about how to prevent such outcomes concern the maternal and child health community. Research is needed to explore risk reduction by identifying dietary characteristics and weight changes in women with twin gestation and by examining relationships between maternal diet and the outcome of twin gestation.

Research Questions or Hypotheses

This research will focus on answering the following questions:

1. What are the dietary characteristics of women bearing twins?
2. Are caloric balance and/or nutrient density of maternal diets predictive of the birthweight or proportionate growth of twins?
3. Is timing of weight gain or total weight gain in twin gestations related to birthweight, low birthweight, or

Year 2000 Objectives

2.8, 14.5, 14.6, 14.14

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

Neonates, Pregnant Women

Race/Ethnic Focus

No Stated Racial/Ethnic Focus

proportionate growth?

4. Does the gestational age of twins vary by maternal caloric balance or nutrient density of the diet?

Study Design and Methods

The hypotheses will be addressed in a cohort study with both descriptive and comparative designs. The descriptive component consists of delineating caloric balance, nutrient density, supplement use, and weight gain characteristics of 300 twin gestations < 24 weeks. The contribution of maternal nutritional intake to predicting birthweight, proportionate growth, and gestational age in twin gestations will be determined.

Population and Sampling Plan

Participants will be recruited from *Twins Magazine* subscribers who are pregnant with twins. A total of 400 women with a twin gestation will be enrolled prior to 24 weeks' gestation, with an estimated 300 women completing the study.

Analysis Plan

Comparisons will be made between the outcomes of twin gestations and the outcomes of previously reported studies on singleton gestations to determine whether outcomes differ by nutritional intake levels in the two groups. All information will be gathered with standardized, self-administered questionnaires and medical record abstraction.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

The proposed research seeks to answer specific questions about the characteristics of diet and weight gain in twin pregnancies and test several hypotheses related to maternal nutrition and twin outcomes. Data gathered from women with twin pregnancies will be compared with other data on singleton pregnancies, and current weight gain and dietary recommendations will be analyzed.

Regional and National Significance

Higher levels of energy and nutrients are required in twin versus singleton pregnancies for normal maternal physiological adjustment and normal fetal growth. This study has the potential to provide important information about twin gestation and therefore is of regional and national significance.

Scientific and Technical Merit

This twice-revised application is well-written and addresses many of the concerns raised in earlier reviews. A power analysis is now included. It shows that a sample of 300 women should be more than adequate to test the hypotheses presented, given the expected variability of dietary intake, weight gain, and caloric balance during pregnancy. Between the first and second submission, the recruitment scheme for twins has apparently changed from recruitment with postcards to recruitment by local OB/GYNs to the current scheme to recruit via *Twins Magazine*. The previous critique suggested combining the first two approaches to enhance recruitment, shorten recruitment time, increase the efficiency of the proposal, and possibly decrease study costs. In response to this, the investigator has included more preliminary data from a previous study recruited through *Twins Magazine* only. It is now estimated that 20 women will be enrolled per month, with a 25 percent dropout rate. This will require 20 months of recruitment rather than the previously proposed 30 months. The investigator estimates that this will reduce the budget through decreased personnel costs in year 4. However, the funding period has not decreased; the investigator maintains that the team will still need 4 years to complete the project. This does not seem realistic, since the entire last year is allotted for literature reviews, data analysis, publications, and presentations. Only the first 5 months include medical record abstractions, cleaning of data files, and subfile development. A second concern raised in the previous review had to do with additional budget reductions. The investigator has deleted the travel budget from the first 2 years of the project. However, funds for secretarial and accounting support are still being requested; the investigator maintains that these services are of essential importance to the completion of the study and are not

covered by other funds. The requests for personnel time and funding still seem excessive. Another concern raised in a prior review was that the nationally based sample of twins may be more biased than a sample drawn from regional OB/GYN offices. The investigators point out that the national sample from Twins Magazine will likely be more racially diverse than a sample obtained solely from Minnesota. The investigators admit that the sample will continue to be biased in certain ways but that these will not influence the biological relationships of interest. Finally, a previous concern had to do with the failure to distinguish between low birthweight (less than 2,500 grams) and prematurity. In the new proposal, the outcomes of primary interest have been expanded to include measures of relative proportional growth. Preterm delivery was deleted as an outcome variable, but gestational age is now examined as a continuous outcome variable, and the effects of gestational age will be controlled in the analysis of predictors of the other outcomes.

A concern that was not addressed in the current revision is that of zygosity determination. This determination will be made based on placental and other characteristics, which are not defined. The assumption that the investigator makes—that all pregnancies resulting from assisted reproductive technologies are dizygotic—is not true. There is an increased incidence of monozygotic twinning after assisted reproductive techniques. The presence or absence of genetic or congenital defects apparently will be collected, but the data forms for this activity are not included.

The principal investigator is well-qualified to guide the study and has experience in assessing nutrition and reproductive outcomes. She is currently the principal investigator of a major epidemiological study of reproductive outcomes sponsored by the National Institutes of Health (NIH). Other professional and nonprofessional staff are also well-qualified.

This revised application is well-written and has been responsive to many prior concerns. The recommendation is for approval with three conditions:

1. Shorten the timeline to 3 years;
2. Decrease the budget; and
3. Address the issue of zygosity.



Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two

Grantee

Case Western Reserve University

Investigator

Lynn Singer, Ph.D.
Rainbow Babies and Childrens Hospital
11100 Euclid Avenue
Cleveland, OH 44106
(216) 844-6212
(216) 844-6233 fax

Project Number MCJ-390715

Project Period 1/1/1997-12/31/2000

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	236,109	112,141	348,250
Year 2	227,125	116,060	343,185
Year 3	236,948	120,563	357,511
Year 4	196,186	32,250	228,436
Year 5			

Summary

Statement of the Problem

Bronchopulmonary dysplasia (BPD), a chronic lung disease of prematurity, currently occurs in 25 to 40 percent of very-low-birthweight (VLBW) infants and has been found to be significantly related to poorer developmental outcome in VLBW cohorts. The first waves of postsurfactant survivors are now approaching school age, with little known about their long-term pulmonary outcomes, growth, or functional abilities. Further, there is little available data on the behavioral, psychosocial, and family outcomes of VLBW cohorts in general, and no data in which prospectively recruited cohorts of VLBW and term comparison groups have been longitudinally assessed to identify the processes by which outcomes might be affected.

Delineating the specific relationships between early medical conditions (such as BPD) and (1) other complications of preterm birth and (2) child outcomes may lead to early identification of those VLBW children at highest risk for learning and behavior problems; it may also elucidate biological and psychological mechanisms related to the negative sequelae of VLBW birth.

Research Questions or Hypotheses

Year 2000 Objectives

6.3, 6.5, 6.13, 6.14, 17.2, 17.15, 22.4

Study Design

Quasi Experimental

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

School-Aged Children,
Parents/Families/Mothers/Fathers (Adolescent
Parents)

Race/Ethnic Focus

African-American

Four study hypotheses are posed:

1. At 7 1/2 years of age, children with a history of BPD and VLBW are expected to continue to exhibit impaired functioning, compared with VLBW children without BPD and term children of similar age, race, sex, and socioeconomic status (SES), when assessed on measures of physical health and growth, lung function, cognition, school achievement, language, behavior, and specific neuropsychological abilities.
2. Parents of children age 7 1/2 who had BPD are expected to experience more symptoms of psychological distress and more stress, and to have less optimal interactions than parents of children without BPD and parents of term children.
3. After other neurological, medical, and SES risk factors have been taken into consideration, BPD is expected to account for independent variance in overall cognitive, motor, and neuropsychological outcomes in children.
4. BPD and VLBW are expected to have direct effects on children's school achievement, and indirect effects through their impact on both earlier and concurrent maternal distress and mother-child interactions.

The proposed research will investigate school-age functional abilities, with a particular focus on the influence of BPD (relative to other risk factors) on pulmonary, cognitive, language, neuropsychological, and behavioral/emotional outcomes.

Study Design and Methods

Standardized measures of child outcomes will be administered, teacher and parental report of child behaviors will be obtained, and parental self-report of psychological and parenting distress, coping mechanisms, and social supports will be provided. Videotaped observations of maternal-child interactions will also be made.

Study measures to be collected include a medical history focusing on lung, cardiac, kidney, and neurological problems; vision examination; physical assessment; hearing screening; conversational language sample; and measurements of weight, height, and lung function. The Wechsler Intelligence Scale for Children (WISC III), Woodcock-Johnson Tests of Achievement, Continuous Performance Test of Attentional Processes, Bruininks-Oseretsky Test of Motor Proficiency, Clinical Evaluation of Language Fundamentals, and the Children's Pictorial Depression Scale will be used.

Teachers of study children will be asked to complete the Adaptive Language Inventory and the Connors Teacher Rating Scale. Parents will be asked to complete the Child Behavior Checklist, the Parenting Stress Index, COPE, the Brief Symptom Inventory, the Multidimensional Scale of Perceived Social Support, and the Family Inventory of Life Events and Changes.

Population and Sampling Plan

The study sample will comprise 302 white and African-American children ages 7 1/2 who were followed prospectively from birth to age 3 in two separately funded longitudinal studies of the medical and psychosocial correlates of BPD and VLBW. Of the 302 children, 110 were VLBW at birth with subsequent BPD, 80 were VLBW at birth without BPD, and 112 were healthy term infants. The groups do not differ in age, race, sex, SES, or parental education/marital status.

Ninety children will be assessed each year for the first 3 years of the study, and 32 children will be assessed during year 4.

Analysis Plan

Descriptive statistics, multiple analysis of variance (MANOVA) and multiple analysis of covariance (MANCOVA), and hierarchical multiple regression will be used to assess group differences and the relative effects of BPD, VLBW, and other risk factors on outcome. To assess change over time and predictive models of infant risk, data sets from the two prior longitudinal studies will be merged with the outcome data from this study, and hierarchical linear or structural equation models will be applied.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This is the second phase of a continuation study of bronchopulmonary dysplasia (BPD), a chronic lung disease affecting an estimated 7,000 infants each year. Very low birthweight (VLBW) infants with BPD constitute approximately 25 to 40

percent of VLBW survivors, so this is an important group to study longitudinally. The continuation phase of this study provides the opportunity to follow a group of BPD and VLBW infants into the early years of school. Following VLBW infants through the early elementary school years should provide information that will increase our understanding of the developmental outcomes of VLBW children, including those with BPD.

Regional and National Significance

This important study has both regional and national significance. The research to date has been competently executed and has resulted in numerous quality publications.

Scientific and Technical Merit

This application is a revision of a proposal initially reviewed in June 1996. Although the previous review panel pointed out the application's numerous strengths, several important weaknesses were also noted. The researchers have revised the proposal to address each concern raised by the review panel. In general, the investigators have been very responsive to comments in the initial review. Concern was expressed that the small number of cocaine-exposed infants in the sample would preclude meaningful analyses. This group was dropped from the revised application.

The investigators argue that long-term developmental outcomes for this group are largely unknown. They hypothesize that children who had BPD in infancy will exhibit, by the time they reach school age, a lag in cognitive and behavioral competence relative to their VLBW and term peers. Understanding the long-term outcomes of infants with BPD may partially explain the heterogeneous outcomes of VLBW infants.

All parents whose children were enrolled in the prior studies in 1989–91 (except for the small group of cocaine-exposed infants) would be recontacted and asked to make a followup visit to the researchers' laboratory. To date, study data have been collected on the infants at 1, 8, 12, 24, and 36 months of age. The infants who participated in the first phase of the study became eligible for the 7.5 year followup beginning in January 1997.

The review panel noted that clear information on past and anticipated attrition was not presented in the original application.

The revision contains more detailed information on attrition. Power analyses including attrition estimates were provided, creating confidence that a sufficient sample of children will remain for the 7.5 year followup to support the desired data analyses. As requested, the researchers also provided a definition for the classification of children as having mental retardation. In addition, issues relating to subject replacement have been clarified (i.e., no subjects are to be replaced).

One of the review panel's more substantial concerns relates to whether the amount of variance in BPD-related child outcomes is sufficient to warrant continuation of the longitudinal data collection. Reviewers also noted that many of the differences between BPD and VLBW infants in the initial study disappeared after socioeconomic status, parenting, and neonatal risk factors were controlled. To address these concerns, the investigators argued that their results to date are clinically significant and thus important, regardless of the amount of variance accounted for by BPD. After other factors are accounted for, BPD was found to be responsible for a 10-point decrement in the third year's Psychomotor Development Index on the Bayley Motor Development Scale. This is a .5 standard deviation on this measure, and the investigators argue that this is clinically significant. By 3 years of age, the effects of BPD on cognitive development had disappeared, but the investigators have indicated their interest in looking for " sleeper " effects in cognitive development, which may emerge as the children progress in school.

The review panel requested additional information on the meaning of study findings concerning lower performance by BPD infants at 3 years on receptive, but not on expressive, language skills. In the revised application, the investigators speculated that the receptive language deficit may be due to undetected hearing impairments in the BPD infants. A hearing screening was not included in the initial data collection protocol. Other possible explanations presented by the investigators include poor attending to the receptive test and the possible presence of actual receptive-expressive language differences resulting from neuropsychological problems.

As requested by the review panel, the investigators provided additional information in the revised application concerning factors they believe will mediate and moderate the effects of BPD on children. They provide examples of how these processes may operate, along with preliminary STM analyses. The researchers also cite recent papers that have addressed these issues.

The former review team noted that the data protocol was extremely extensive; the approach seemed to be one of trying to measure as many things as possible, to " cast a wide net " in order to detect possible group differences. This approach lacked focus and made the research extremely expensive. The panel suggested streamlining the data collection protocol substantially, focusing on those outcomes considered critical in the researchers' previous work. The researchers have been only partially successful in this regard. Several measures have been dropped, including the Tactual Performance Test, the

Marching Test, the Category Test, the Narrative Skills Task Skillbook, the Goldman-Fristoe Test of Articulation, and the Oral and Speech Motor Control Protocol. Even so, the data to be collected are still very extensive, without a compelling rationale for including or excluding measures. Although the budget has been reduced, the data collection remains an extremely expensive effort, in part because of the large number of measures to be collected. The study includes two primary racial/ethnic groups, Euro-Americans and African-Americans. Concern was expressed during the past review that study measures were not selected based on their appropriateness for these groups of families. In the revision, each measure has been justified (to the extent possible), based on its use with African-American children and families. In addition, preliminary data analyses have been conducted, examining racial/ethnic differences in the processes underlying study outcomes. In summary, the investigators and supporting staff are well qualified and have sufficient experience to conduct the proposed study. The proposal has been approved by the Institutional Review Board. Human subjects protections appear to be adequate. Continuation of the research is recommended, with a reduction in the budget.



Puerto Rican Young Fathers' Involvement with Their Children

Grantee

Wellesley College

Investigator

Sumru Erkut, Ph.D.
Center for Research on Women
106 Central Street
Wellesley, MA 02481
(781) 283-2533
(781) 283-2504 fax
serkut@wellesley.edu

Project Number R40MC00161-01

Project Period 8/1/1999-7/31/2002

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	215,667	67,521	283,188
Year 2	252,562	78,635	331,197
Year 3	200,562	73,635	274,197
Year 4			
Year 5			

Summary

Statement of the Problem

The specific aim of the research is to answer what predisposes Puerto Rican young men to become the kind of fathers that they are by testing a random sample of Puerto Rican young men living in two Northeastern states. Our theoretical model posits relationships between social stratification derivatives (family of origin, social and economic context, and the young father's demographic characteristics) and father involvement outcomes moderated by individual risk and protective factors and mediated by normative definitions of fatherhood and life priorities. Additionally, father involvement is influenced by proximal factors, which are social support, perceived competence as a father, the quality of the relationship with the mother, and the child's characteristics.

Father involvement has direct and indirect implications for child health, and encompasses (1) the promotion of healthy development, (2) prevention of unhealthy development, and (3) intervention in cases of failure to attain developmental milestones and of illnesses through seeking appropriate health care.

Research Questions or Hypotheses

Year 2000 Objectives

No Stated Healthy People Objectives

Study Design

Observational

Time Design

Cross Sectional

Care Emphasis

Noninterventional

Population Focus

Parents/Families/Mothers/Fathers (Adolescent Parents)

Race/Ethnic Focus

Puerto Rican

Hypothesis 1: Social stratification derivatives that are associated with the family of origin, social and economic context of the residential community, and the young father's demographic characteristics will predict normative definitions of fatherhood timing and life priorities.

Hypothesis 2: A set of variables that can operate as risk or protective factors (perception of racism, alienation, machismo, risky behaviors, and acculturation) will moderate the relationship between social stratification derivatives and normative definitions of fatherhood and life priorities.

Hypothesis 3: Normative definitions of fatherhood timing and sequence and life priorities will predict father involvement outcomes. Here, following the logic of the integrative model of minority youth development, we examine culturally based cognitive beliefs regarding what is fatherhood, when is it best to become a father, and a young man's life priorities.

Hypothesis 4: Men who receive social support for fathering from their extended family, peers and, social institutions with which they are involved (such as the work-place) and who see themselves as competent fathers are likely to be involved with their children if they have a positive relationship with the child's mother and have a first-born, easy, male child.

Hypothesis 5: The nature of the normative definition of fatherhood will covary with acculturation.

Study Design and Methods

The proposed research is a theory-driven, multi-method, cross-sectional study of 300 Puerto Rican young fathers' involvement with their children.

While the young men will be the unit of analysis, their self-reports of father involvement, child characteristics, and relationship with the mother will be augmented by independent interviews with the mother/s of their child/ren; quantitative and qualitative information will be collected from both father and mother through face-to-face interviews.

Data on social and economic characteristics of the municipalities in which the father resides will be obtained from on-line data sources.

Population and Sampling Plan

The population being studied is Puerto Rican young fathers aged 18–26, living in the greater Boston and greater Providence areas who have experienced the birth of a child in the past year.

The sampling plan includes two subsamples. One will be 150 married Puerto Rican young fathers recruited from the birth records of babies born in the greater Boston area, the other will be 150 married and unmarried Puerto Rican young fathers from Rhode Island.

Analysis Plan

Piloting of survey instruments - We will field test all measurement instruments in order to establish their psychometric properties with this population. In order to establish each instruments' reliability, we will conduct item-by-item analyses of all scaled measures (test-retest where appropriate), and estimate an internal consistency coefficient (Cronbach's alpha) for each scale. We will examine each instrument's validity by estimating inter-correlations among the constructs to ascertain whether they are mutually distinct and correlated in appropriate directions.

We will code the data regarding educational and occupational aspirations and expectations to form a rating list of life priorities. We will code the definitions of fatherhood and its perceived ideal timing to form closed-ended questions to be scaled. The final forms of the interview instruments will be determined from the results of these analyses.

Data Analysis - The first step will be data reduction through the construction of the proposed scaled indices among our predictor variables. A scale will be constructed using confirmatory factor analysis to arrive at a unidimensional scale. If the item analysis suggests the presence of more than one underlying factor, the scale will have more than one subscale. If necessary, we will correct the nonnormality or excessive kurtosis by either power transformations of the observed variables or dichotomizing prior to fitting the linear models to test our hypotheses. We will assess the internal consistency of each scale (Cronbach's alpha) and will estimate inter-correlations among the various scales to ascertain whether they are mutually distinct (divergent validity). This is especially important as not all of the proposed measures have undergone psychometric analyses for use with minority populations (e.g., the scales for family and peer support for fathering).

The second step will be the construction of our outcome variable: Puerto Rican father involvement. We propose four inter-related dimensions: disciplinarian, provider, nurturer and maternal support to measure father involvement. We will fit a covariance structure model (CSM) using LISREL in order to determine whether 1) the items in each of the four scales are

reliable; 2) each scale is internally consistent; 3) the four scales represent four mutually distinct constructs and 4) these four factors might be related to a single construct of Father Involvement. The advantages of fitting a CSM for our outcome variable lie in the explicit acknowledgment of measurement error and the definition of latent constructs by covariances among multiple indicators of a construct. These analyses will determine whether we will be able to use a single continuous variable for Father Involvement in our hypothesis testing or whether each model will be fit separately for each the disciplinarian, provider, nurturer and maternal support dimensions of father involvement.

The third step will be to complete descriptive analyses of the data collected from the subjects concatenated with the municipal level statistics because systematic descriptions of the multiple contexts of Puerto Rican young men's lives is lacking in the literature.

The fourth step will be to fit the appropriate models to test each of our hypotheses. The relationships among all of our variables will be examined using linear modeling techniques (e.g., correlational analyses, multiple regression, logistic regression and ordinary least square-moderated multiple regression) as determined by the level of measurement of each outcome.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

The investigators use their reading of earlier research (including their own work) to make a strong argument for the need to address the central concerns of the study. They point out that some common assumptions about teen fathers (depression, limited earning capacity etc.) hold true when one looks at the profile of Euro-Americans but not at other minorities. Since common assumptions do not necessarily hold, they can make a good case for research to look at some fundamental questions regarding fathering outcomes of mainland Puerto Rican young men.

Regional and National Significance

No statement of regional and national significance.

Scientific and Technical Merit

For the most part, the investigators spell out very clearly the tasks they will be conducting and why. The research team is very sophisticated and productive. Several members of the team have worked together for quite some time. Their extensive research and scholarly work, both individually and collectively, is evident in the writing of the proposal, as well as being documented in their biographical sketches.

They are concerned to draw from and develop a theory-driven study. A great deal of their theoretical foundation derives from the work of one of the investigators, Garcia Col., who has proposed an "integrative model of development."

Major constructs are clearly stated in operational terms. The hypotheses are equally clear. The central hypothesis is that the four variables they call "stratification derivatives" (education, employment, income and family of origin) have a causal influence on fatherhood outcomes as moderated or mediated by a set of other variables they define as "personal characteristics," (sex-role ideology, acculturation, alienation and risky behavior syndrome).

The team proposes collecting multiple sources of data on the same construct in order to determine "convergent validity." This is a real strength of this proposal since self-reports alone can be notoriously unreliable and the researchers carefully note that it is important in cases where the relationship between mother and father of the child is not intact.

The team is multilingual and interviewers will be multilingual and bicultural. The investigative team has extensive experience within the Puerto Rican community in this area.

While in the redesign of their earlier study the investigators attempt to address many of the sampling questions raised by the last MCHB review and members of the site team. They have opted to modify their earlier proposal by recruiting an entirely new sample (and increasing the upper age range to more easily meet their sampling needs). While this addresses sampling

concerns, it raises some new difficulties.

The investigators are concerned to probe in a culturally sensitive and culturally reliable way a number of quite sensitive issues. They make a compelling case for the need to be keenly aware that even within a Latino community, sub-cultures are significantly distinct and may have very different responses to fathering. Since the great majority of Latinos in the U.S. are Mexican, it is essential, they argue, to devise instruments that are specifically targeted to the Puerto Rican mainland community. If this level of attention should be paid to the development of culturally appropriate instruments (as I can well believe it should), what about the whole process of conducting interviews and administering tests? In many cultural communities, a stranger asking questions of the sort these tests and questionnaires are designed to elicit, would not be welcome.

This research intends to elicit data that is potentially highly sensitive. Informants may not be inclined to be forthcoming about their attitudes and behaviors regarding fathering and their own sexual behavior.

While the investigators plan to try to address this problem through independent interviews with mothers, it is not clear that this will be enough in assuring that reliable data is gathered. What if the women give information about the behavior of the fathers that is very different from that which emerges in interviews with the young men? Does this mean that the women are to be believed?

What if the father and mother are both present at the time the interviewer comes to visit. Will the interviewer try to reschedule with one and interview the other?

While an interview about this topic in the home might seem like the most comfortable place for the interviewee, the opposite may be the case. Even if teenage pregnancy does not carry the stigma that is often associated with such a situation in white middle class families (as the researchers suggest) the question of stigma and shame will surely vary by family. Presumably, many of these young mothers will be living at home with their own parents and siblings. How will the interview handle the potential discomfort of discussing the child in the home?

In some families and in some cultures, other members of the family will often try to "speak for" the person who is identified to be interviewed. This results in a kind of "group interview" or an interview in which a dominant spokesperson for the family, perhaps a grandmother, offers answers to questions. (This is so common in many cultural situations that anthropologists often speak of co-narration as a standard part of the interviewing process. See, for example, Byron and Mary-Jo Good, on interview attempts to elicit illness narratives in Turkey, or Catherine Reissman on eliciting data on child infertility among South Indian women).

The research design now depends upon data collected from a single interview (with earlier phone or letter contact). Can the investigators really count on the forthrightness and honesty of their informants based on such brief contact? While they intend to ask for the most sensitive material through written answers, will the mothers feel they can answer such questions confidentially if other family members are present in the interview situation? What about the literacy issues for the written material?

Although these are smaller issues (because presumably they will not be difficult for the researchers to address), some new concerns arise regarding the recruitment of potential subjects given the new study design. This may not be a problem, but two worries come to mind. One is that names of potential subjects must be gained through access to confidential vital records for the underage single mothers. These will be available after IRB review by the state's Bureau of Health Statistics. The investigators have begun the application process. How difficult is it to obtain permission for this access?

One of the advantages of the proposal is that it proposes to build upon a longitudinal study, following the male half of the cohort into late adolescence and young adulthood to study transitions into the world of fatherhood. The researchers were already well placed, so that subject recruitment would not be a major issue. And they already had a great deal of information about these subjects.

Finally, regarding the hypotheses. Many of these do not seem very startling. From an anthropological perspective, at least,

they represent mainstream common sense. That is, we would expect, for example, that social, economic and cultural factors would shape beliefs about such important matters such as fathering. We also expect that these factors will be mediated by the kinds of risk and protective factors that the investigators point toward.

It might also be expected that normative beliefs would significantly influence behavior—though this latter connection is always interesting to explore and it is interesting to discover when and under what circumstances there is a gap between espoused beliefs and behavior.

Given the common sense nature of many of these hypotheses, will this study yield new culturally specific insights that the researchers have so skillfully maintained are necessary regarding the issue of young fathering in the Puerto Rican mainland community?

Evaluator 2

Originality and Importance

The proposed investigation addresses MCHB's Research Agenda. In particular, this proposal relates to the study of social context as a source of variation. Secondly, it addresses investigations of the community context, and studies of the influence of the timing of fatherhood in men's lives and in the context of their own roles.

Regional and National Significance

The proposed study is grounded in an integrative model of minority youth development anchored on social stratification theory. This theory is significant to the proposed investigation in two ways. First, the authors argue that Puerto Rican young men may be significantly affected by their minority position in the social hierarchy of their communities. Moreover, the impact of this social position is mediated by alienation resulting from racism and prejudice. They argue that adaptation to these inhibiting environment exigencies is moderated by resources available to these young persons, their level of acculturation, and current contextual demands and opportunities. Thus they argue that father involvement will be a product of many influences inclusive of those internal to the individual, relationship with partner, extended family, peer group, neighborhood/community and institutional forces. This is a very comprehensive and compelling argument that is worthy of exploration.

Scientific and Technical Merit

There is one curious oversight that is not addressed, and, that is: Are there cross cultural differences in perceptions of fathering and paternal responsibilities? That is a very good possibility. The investigators point to the work of Garcia Col, one of the co-investigators, who has found that adolescent childbearing among Puerto Ricans on the mainland is a normative life event. They also cite earlier work published by Garcia Coll and Vasquez Garcia reinforcing that "in spite of the possibility that adolescent parenting may be viewed as normative among Puerto Ricans on the mainland, external stresses created by migration and becoming a minority in the majority Anglo society may render young parents (both men and women) susceptible to negative consequences of early parenthood." Hence, it seems critical that the investigators might want to focus some attention on the cross-cultural conflicts and their consequences.

Several research questions will be examined within this investigation. A central question that is proposed explores two theories of contextual developmental perspectives with the four-factor model of father involvement. Unlike previous investigations, the integration of these theories permit the investigators to examine father involvement from the perspective of potential positive involvement. Four factors that will be examined within this investigation are the perception of the father's sense of self-competence as a father, the nature of the paternal and maternal relationship as well as the paternal and child relationship, the child's characteristics, and the support received for fathering from extended family. This model represents a departure from previous research and by the same token a culturally relevant approach in that the extended family is viewed as potentially impacting the contribution of young fathers. Unfortunately, it is not clear if the investigators believe

that circular migration, and the involvement with the extended family in proximity versus at a distance, will make a significant impact.

A second research question is proposed to examine the impact of social stratification derivatives (e.g., family of origin, social and economic context, demographic characteristics) and the affect that these have on father involvement through their influence on young fathers' definitions of fatherhood and its timing and his life priorities. A concern with this question, albeit minor, is related to the stress that may occur from the complex interaction of individual self-perceptions and desires with familial, cultural, and/or contextual issues. In other words, the question is important, but does it really provide us with the insight that the investigators claim can be addressed through the use of the integrated model of development?

A third question that will be examined is whether a set of individual characteristics, defined either as risk or protective factors, can moderate the relationship between social stratification derivatives and normal definitions of fathers and life priorities. While this focus on both risk and protective factors is critical, one would recommend that the investigators focus more effort on the protective factors for two reasons. First, as the authors note, this investigation is an effort to examine the unique dimensions of normative development among young Puerto Rican males. I fear that the focus on risk factors will simply parallel previous research which provides insight into what is wrong as opposed to what can be done to enhance and/or minimize the negative consequences of circumstances that surround young fatherhood.

An exhaustive set of measures has been proposed. Psychometric properties for these are reported. Substantial effort will focus upon the translation of instruments if not available. Using the dual-focus approach that has been developed by the investigators, careful attention will be devoted to the cultural sensitivity of questions and their related psychometric properties. This effort in and of itself is a worthy contribution, and as such, the investigators should be commended for their careful attention to culturally relevant scientific procedures.

The target population is young Puerto Rican fathers (up to age 26) living in the greater Boston and greater Providence areas who have experienced the birth of a child within a one-year period. A multi-method, cross-sectional study will allow the investigators to interview mothers in the language of their choice. Approximately one year will be allocated to the interviews and collection of data.

Of minor concern is the sampling methodology that will be utilized. Although the investigators recognize that the recruitment of fathers from birth records will not permit immediate access to father after the birth of their child, they argue that it will provide them with a more accurate sampling frame of births than from other methods. It can only be assumed that careful attention will be devoted to recruiting Puerto Rican fathers and Puerto Rican mothers. If this is not the intent, then the meaning of the aforementioned statement is unclear. In other words, it is assumed that inter-ethnic relationships may violate the model that has been presented for this investigation. Specific dimensions of the sampling frame should be clarified with related justification.

One final comment on the sampling frame. These collaborators are highly skilled and have previously effectively engaged in, and are currently involved in other research projects. The projects that they have engaged in have resulted in a high level of public trust and participation in their investigations. Given their previous successes, it is somewhat unclear why the choice has been made to use a more restrictive sampling frame.

Adequate statistical power can be derived from the target sample.

The time frame for this study seems more than adequate. Ample time for the analysis of the psychometric properties and need to translate any additional instruments, using the methodology that they have developed in previous projects, will be employed. Data collection is anticipated to take approximately 12 months, which may be somewhat optimistic. The third and final year will be devoted to data reduction, analysis, and generating manuscripts

Based on their previous track records,, this is a highly compatible group that appears to work well together. The research team includes expertise in several pedagogical areas, with a mixture of junior and senior researchers. More important, their previous efforts have provided them with community recognition and support for their research.

Evaluator 3

Originality Importance

No statement of originality and importance.

Regional and National Significance

No statement of regional and national significance.

Scientific and Technical Merit

The study focuses on predicting fathering with emphasis on an appropriate new and different sampling plan. Variables to be measured are based on validated measures or previous surveys. Recruitment of young Puerto Rican fathers will be accomplished by searching vital records for father's ethnic status. The investigators must deal with the fact that records of underage mothers are not public record and that they must obtain access through an IRB review. They have already begun this process. One problem with this form of recruitment is the accuracy of the vital records with respect to Puerto Rican ethnicity. The other issue is that the mother may not be of Puerto Rican descent but father may be and father may not be acknowledged on the birth certificate. The investigators have provided information on the extent to which this might affect the sampling. They estimate that only about 10% of fathers remain unidentified in birth records. On the whole the investigators did a good job of getting this component of the proposal together.

Sample size estimates seem to be appropriate. Methods for data collection appear appropriate. Methods of analysis are carefully laid out with the hypotheses to be tested, the variables to be used and the method of analysis. Missing data issues will be addressed through the IvfIX program. Dr Ronald Seifer will be the consultant senior statistician.

This team of researchers did an excellent job of getting this proposal organized. It clearly demonstrates their ability to work as a team and dedication to their subject matter. They are quite capable of conducting this research.

The direct cost per interview is $\$743,362/300 = \$1,445$ per interview. This is quite pricey for an interview study. Some of this is appropriate because the individuals have to be tracked down. However, there is no doubt that the investigators have been generous with their time on the budget. It is rather heavy on principle investigator/Co-principle investigator FTEs.



Reducing Preterm Birth by Bacterial Vaginosis Screening

Grantee

The Johns Hopkins University

Investigator

David Paige, M.D.
 School of Hygiene and Public Health
 Department of Maternal and Child Health
 624 North Broadway
 Baltimore, MD 21205
 (410) 955-3804
 (410) 955-2303 fax

Project Number MCJ-24C701

Project Period 10/1/1997-9/30/2001

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	225,015	40,503	265,518
Year 2	225,672	40,467	266,293
Year 3	222,826	40,109	262,935
Year 4	212,774	38,299	251,073
Year 5			

Summary

Statement of the Problem

Despite the dramatic decrease in the infant mortality rate over the past several years, preterm and low weight births remain an intractable problem within the MCH community and contribute to high rates of neonatal morbidity and mortality. The problem is most acute among African-American women who have almost double the number of preterm live births and more than double the percentage of low birthweight newborns than do white women. Despite advances in the science of obstetrics, understanding the basic causes of preterm labor, low birthweight, and intrauterine growth retardation is limited. It is known that the determinants of low birthweight, including genetic, social, environmental, and behavioral factors, as well as underlying medical or biological conditions. In many cases of premature birth, however, no association with a pathologic factor can be identified. Newly published experimental data suggests infections of the genital tract double the number of preterm births, contributing up to 40% of preterm births. Bacterial vaginosis (BV), the term applied to an overgrowth of bacteria resulting in vaginal infection, is the most prevalent cause of vaginitis found in childbearing women today. BV doubles the risk of spontaneous preterm delivery and has been experimentally associated with a number of other adverse birth outcomes. Pregnant African-American women have nearly three times the level of BV as pregnant white women. Half the population of pregnant African-American women with BV are asymptomatic. Current prenatal care in the

Year 2000 Objectives

14.1, 14.5, 14.14, 5.11, 18.13, 19.11, 19.13, 22.4

Study Design

Quasi Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates, Pregnant Women

Race/Ethnic Focus

African-American

community has not integrated BV screening as part of overall prenatal care. In the absence of a screening and treatment program for asymptomatic BV, these pregnant high-risk women are unidentified and untreated during their pregnancy. The integration of a community-based program to identify and treat BV asymptomatic women can contribute to a significant reduction in the high rates of preterm birth and low birthweight among pregnant African-American women.

Research Questions or Hypotheses

This community-based intervention study is designed to determine the effect of a screening/treatment program for bacterial vaginosis (BV) which will be integrated into existing prenatal services. The program will identify and treat asymptomatic and symptomatic pregnant African-American women with BV in order to reduce preterm and low birthweight births.

Study Design and Methods

This study applies a previously experimental model to a new population and will generate knowledge as to the efficacy of the model and the ability to integrate it into existing systems of community based prenatal care, while sustaining the nature and effectiveness of the prototype.

This study will screen all participants presenting at the clinics for BV on initial prenatal examination. Patients confirmed to have BV will be treated with 250 mg of metronidazole three times a day for seven days or .75% metronidazole vaginal cream twice a day for five days. These patients will have a test of cure when they return following their therapy, and if they have not been cured, will be retreated.

The design of the study is a five-period cross-over design of over 30 months in which each clinic will alternate six-month periods in which they enroll patients in either the treatment or control arms of the study. Outcome variables include the incidence of preterm births, number of low birthweight babies born to mothers in the study, and the incidence of newborns who exhibit intrauterine growth retardation. Potential confounding variables to be assessed and statistically controlled for include: cigarette, alcohol, and drug abuse; gestational weight gain; infant sex; maternal age; parity; prior incidence of low birthweight or prematurity; and socioeconomic status.

Population and Sampling Plan

The sample is expected to consist of 2500 pregnant African-American women from 4 east Baltimore community clinics. About 750 of these women are expected to be symptomatic and will be treated as usual. Of the remaining 1750 asymptomatic women, half will be screened for BV in the treatment arm at some point prior to 33 weeks. Those who test positive in the treatment arm will receive immediate treatment as well as follow-up treatment as needed. Partners of asymptomatic women in the treatment arm will also be assessed and treated whenever possible.

Analysis Plan

Data analysis consist primarily of exploratory data analysis and logistic regression.



Responsiveness of CHIP to Children With Special Health Care Needs

Grantee

George Washington University Medical Center

Investigator

Sara Rosenbaum, J.D.
Ross Hall, Suite 712
2300 Eye Street, N.W.
Washington, DC 20037
(202) 530-2343
(202) 296-0025 fax
resaxb@gwumc.edu

Year 2000 Objectives

Study Design

Time Design

Care Emphasis

Population Focus

Race/Ethnic Focus

Project Number R40MC00165-01

Project Period 8/1/1999-7/31/2002

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	201,493	51,250	252,743
Year 2	288,364	59,942	348,306
Year 3	306,564	44,075	350,639
Year 4			
Year 5			

Summary

Pre-Award Evaluation

Evaluator 1

Originality and Importance

The proposed study is designed to test two general hypotheses related to state CHIP programs. The first, that states that elect to establish a freestanding Child Health Insurance Program (CHIP) use the flexibility available under the statute to depart from Medicaid principles in a range of ways and reflect high variability in program design, will be tested using data collected in the project. The second hypothesis will be tested using national databases. It states that variability in coverage and benefits, such as found in freestanding CHIP programs, influence access to and utilization of health care by children, both for children generally and more specifically for children with chronic conditions and special health care needs. These two hypotheses form the basis for Parts I and 2, respectively, of the proposed study.

Part 1 is a descriptive study with three components. The first component is an in-depth study of eligibility criteria under freestanding CHIP programs using key Medicaid eligibility criteria under state plans as a benchmark. Twenty-five states that as of April 6, 1999 had approval from HCFA to establish a freestanding CHIP program for some or all children will be studied. An instrument will be developed to abstract data from basic legal documents that all states must maintain as a condition for participating in CHIP, including published, written eligibility criteria and the content of state plans.

The second component is a comparative study of the benefits coverage and managed care design features under freestanding CHIP programs compared with Medicaid expansion programs. It will involve an analysis of contracts between state CHIP agencies and managed care organizations (MCOs) and state Medicaid managed care contracts and related primary sources. Data for the state Medicaid contracts come from an ongoing study of publicly supported state MCO arrangements for low-income children.

The third component is a case study of up to six states with variation in their freestanding CHIP programs. It will involve key informant interviews with a number of key stakeholders, including directors of state CHIP and Medicaid programs, legislators, members of the Governor's staff on children, representative members of health plans, consumer and advocacy groups, safety net provider groups, and CHIP enrollees with special health care needs.

In Part 2 of the proposed project, an analysis will be undertaken using national databases, specifically the National Health Interview Survey (NHIS), Medical Expenditures Panel Survey (MEPS), and Area Resources File (ARF). The purpose of this part is "to develop a rapid understanding of the probable effects of state decisions about the CHIP program to depart from the structure of Medicaid." It will include simulated modeling of the variations in benefits coverage and eligibility criteria of freestanding CHIP programs and their effects on access and utilization of care.

This well-written proposal has several major strengths. First, it focuses on the fundamental choice of states to use CHIP to extend the Medicaid program, or to develop an alternative, non-entitlement, freestanding program that may use different eligibility criteria and whose benefits and insurance structures may more closely resemble those found in traditional commercial insurance plans. Second, the investigators provide an excellent discussion of the key differences between the requirements of Medicaid and the options available to states for freestanding CHIP programs. These differences are important to document because of the constraints that Medicaid places on the design of programs and the preferences of families for non-Medicaid coverage.

A third major strength of the proposed study is the ability to piggyback the current annual ongoing point in time study of Medicaid managed care contracts that is conducted by the Center for Health Services Research and Policy (CHSRP) with data collected about the features of freestanding CHIP programs. This ongoing study has not only given CHSRP researchers experience in abstracting contract documents, but it also insight regarding the departures of the typical Medicaid managed care contracts from the requirements of Medicaid. It also points to the approach that many states use in dealing with MCOs to supplement their plans with additional services and benefits, particularly wraparound services traditionally available from health departments. The investigators use their experience from this study to indicate the types of information they plan to abstract about eligibility from the legal documents of states.

Despite these major strengths, there are also some important weaknesses of the proposed study. The first is the lack of details about some aspects of Part I of the proposed project, particularly with regard to the actual states that will be surveyed, the specific data collection instruments, issues related to confidentiality of human subjects, and the plan of analysis for the descriptive studies. While, in general, it is likely that the investigators will do an excellent job with filling in details as the project is developed, their omission is important, particularly with regard to the analysis of data.

The major weaknesses of the proposed study involve Part 2 of the proposed project. These weaknesses relate to the many implicit assumptions inherent in this part of the study. The most important is the investigators' inability to directly assess the impact of CHIP in states with freestanding programs and the presumption that data will be obtained in Part 1 which will actually inform the analysis of the national databases. It is not evident that there will, in fact, be enough distinct features of either the eligibility criteria or the benefits structure of freestanding CHIP programs to relate them to the information in the national databases and, in turn, to look at their effects on access and utilization of care. In addition, the investigators provide

a laundry list of measures of access and utilization available from MEPS and indicate that they plan to look at all measures without prioritizing any of them. Surely, issues related to the content of services available are more important as measures of access than waiting time at the site. The investigators do the same for various measures that may define the population of children with special health needs.

Part 1 of the study is descriptive, involving three components, each of which draws on the results of the previous one. The investigators specify the eligibility criteria that will be abstracted from legal and other publicly available documents. They will develop, review, pre-test the instrument to be used to abstract these documents and will collect data using the instrument in the first project year. This time line seems somewhat ambitious given that there is no discussion of how the documents will be accessed from the states, nor whether or not states have agreed to provide the needed documents.

A major concern related to this component is that the plan for data analysis only involves detailed tables being prepared. There is no discussion of the specific aspects of eligibility that will be targeted in the analysis, nor what specific methods will be used to prepare the detailed tables. Since some of the results from this component will be used to inform the analysis of the MEPS, this information is important in evaluating the potential usefulness of data from this first component. The investigators also note that, with the appropriate data on the value of Medicaid deductions and disregards, it would be possible "to simulate the additional reach of a state's CHIP program were its gross income standard to be increased in order to offset the loss of a disregard." There is no evidence in the proposal that the data that will be obtained in component one, as it is currently described, will yield this type of information, particularly because there is no mention of the population data needed for such a simulation.

Component two addresses an important aspect of the freestanding CHIP programs, their benefits structure, and the investigators do a good job of pointing out the potentially important effects of variations in benefits coverage. This component is an extension of the data collection in component one, but deals with the benefit structure of the CHIP program rather than eligibility criteria, and draws upon data from their ongoing annual survey of Medicaid managed care. This ongoing study will be expanded in 1999 to include contracts between state CHIP agencies and MCOs from states with freestanding, non-Medicaid CHIP programs. Although not explicitly stated and, accordingly somewhat confusing to the reader, it appears that this data collection effort will provide data for both components one and two. The investigators indicate that they will supplement the contract database with data from state statutes, regulations and program guidelines for both Medicaid and freestanding CHIP programs. They will also determine the extent of available wraparound services for families of children in CHIP and Medicaid. While this is very important information to obtain, the investigators do not discuss their strategy for obtaining it.

There is no data abstraction instrument included in the proposal for component two, despite the fact that the investigators are already conducting an ongoing study for which some instrument must be used to collect data. To the investigators credit, however, they do provide a list of specific items they plan to obtain under the categories of managed care and residual state plan coverage under freestanding CHIP programs and the conditions of participation of MCOs in freestanding programs. Within each of these categories, a number of features of CHIP freestanding programs are to be addressed.

Like component one, a major missing piece of the methods in this component is the analysis plan. This is particularly disturbing because this second component is the only one in Part I for which hypothesis testing can actually be conducted. The proposal mentions only that reports will be prepared that compare benefits and conditions of participation across freestanding CHIP programs and between CHIP and Medicaid programs. Will statistics actually be used to evaluate these comparisons. Is hypothesis testing really the focus here, or is this component, like one and three, primarily descriptive?

Component three of Part 1 of the proposed project involves case studies in up to six states with freestanding CHIP programs and in which the CHIP programs use Medicaid extension as its approach. While the investigators indicate that they are studying the 25 states with HCFA approval for freestanding CHIP programs, component three appears to broaden the number of states for which sampling will be performed to ones which use Medicaid extension in their CHIP program. If this is the case, are data being collected in the ongoing Medicaid study for these latter CHIP programs?

There are a number of other concerns about this component. First, the investigators do not provide a justification of how the information from this component adds to that obtained in the first two; their list of questions to be addressed can be asked

of all states. Secondly, while only up to six states will be studied, there are 15 criteria to be used to select these states. Some priority needs to be placed on the most important criteria. Thirdly, using only six states does not seem adequate to cover the variability across states that is likely to be seen in the freestanding CHIP programs, their current Medicaid programs, and other issues that may affect their decisions to choose various options. Consideration should be given to increasing the number of states to yield more meaningful results. This can be accomplished by reducing the number of stakeholders that will be the focus of key informant interviews. This component is likely to yield little valid information about the effects of CHIP variations. The focus of the key informant interviews would best be placed on informants with decision making power politically and who administer the programs and with providers that may be responsible for extended services for children, such as safety net providers or providers of wraparound services. Information collected from CHIP enrollees with special needs and, to a lesser extent, from consumer or advocacy groups may be unreliable, given the need to obtain a large and representative sample of enrollees to obtain meaningful data for this group.

Again, the analysis plan is a problem for this component because there is none provided. Given the number of stakeholder groups represented in the case studies and the use of semi-structured interviews, a carefully conceived analysis strategy is important here. This strategy needs to address the key domains that will be summarized across key informants as well as the use of appropriate techniques to analyze qualitative data.

As noted above, a major weakness of the proposed project is Part 2, which uses national databases to simulate the effects of the eligibility criteria and benefits structure of freestanding CHIP programs. There are also problems with inferring that the impact of CHIP features on individuals who now have insurance through CHIP would yield the same effects of the insurance features for families with children who had insurance before CHIP. Because actual data about children enrolled in CHIP will not be available, the investigators will not have information about the differences in characteristics of CHIP enrollees versus insurance recipients in MEPS to understand how they might influence the effects of eligibility or coverage. It is difficult to envision with these constraints and those noted above that there would be meaningful results from Part 2. Moreover, these analyses could lead to erroneous conclusions about the potential impact of freestanding CHIP programs.

The investigators, themselves, point out limitations of Part 2 related to the fact that the MEPS data were not fully released at the time of proposal writing and related to the need to preserve the confidentiality of human subjects with linking data from the NHIS, MEPS and ARF.

In the discussion of issues related to human subjects, the investigators do not address the procedures to be undertaken to protect the rights of the respondents in the case study. Even with semi-structured interviews which primarily address issues related to public programs, procedures still need to be used including disclosures or informed consent forms and assurance of anonymity of respondents.

The investigators appear to be highly capable of undertaking the proposed research, particularly for Part 1, based on their previous experience with similar studies and their track record of disseminating the results of their studies. The one area of deficiency is related to the lack of individuals with experience in data analysis, especially with regard to qualitative data. This expertise needs to be added to the study team.

The budget for the proposed study does not adequately cover the scope of personnel needed to complete project tasks. It includes a number of investigators with large salaries on the project for small amounts of time, but a limited number of individuals who will actually conduct the daily work, and be involved in data abstraction, data entry or data analysis. An example is the project director who will spend 35 percent of his effort on the project, but who appears to be highly overqualified to be a project director. Sara Rosenbaum, the Principal Investigator, is included in the budget for 10 percent effort in year one and 5 percent in years two and three. Is this adequate time to fulfill her role as PI? Also, who and what is the role of the person listed as TBN for \$20,000 on the personnel line in the budget?

Recommendation:

Approval with the following conditions:

- 1) The investigators eliminate Part 2 of the proposed study. The number of assumptions required in this study, and the lack

of a focused strategy for data analysis, make the potential results of this part not very meaningful.

2) The study methods for Part I be more clearly specified including the following:

- The 25 states who were approved by HCFA for freestanding CHIP programs;
- The methods that will be used to gain participation of states;
- The details related to the acquisition of contracts and other documents from states and the extent to which this is done only as a part of the ongoing study or is an additional contact and data collection effort with states;
- The data abstraction instrument that is currently used in the ongoing study and recommended modifications of or additions to it for the proposed study
- An analysis plan for components one and two that lays out the potential information that will be gleaned from the data and the specific variables that will be compared between Medicaid and free standing CHIP programs
- A reconsideration of a larger number of states to be included in the case studies and a reduction in the range of key informants to be interviewed
- An analysis plan for the third component that indicates some of the domains that might be included from the data and strategies to reduce and compile the qualitative data.

3) A revised budget that includes data analysts and other appropriate research staff to complete the scope of the work in Part 1 and eliminates the subcontract with the Children's National Medical Center (CNMC) for Part 2 without increasing the cost of the project.



Role of Early Family Supports in Adult Self-Sufficiency

Grantee

University of North Carolina at Chapel Hill

Investigator

Frances A. Campbell, Ph.D.
Frank Porter Graham Child Development Center
105 Smith Level Road
CB# 8180
Chapel Hill, NC 27599
(919) 966-4529
(919) 966-7532 fax

Project Number MCJ-370632

Project Period 6/1/1996-5/31/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	125,177	55,704	180,881
Year 2	117,000	52,065	169,065
Year 3	142,102	63,236	205,338
Year 4	132,918	59,149	192,067
Year 5			

Summary*Statement of the Problem*

This study addresses the long-term, multigenerational outcomes of the Abecedarian Project, a randomized clinical trial of early childhood development intervention. This research represents the endpoint of a 21-year longitudinal study that began in the early infancy of the study's subjects.

Research Questions or Hypotheses

The investigators will examine the effect of early child care on the levels of educational attainment, self-sufficiency, and social adjustment in young adults and their parents. Specially, the project will document whether earlier effects of care contribute to adult competence, and whether contextual and personal variables modify the effect and are also related to the trajectory of development.

*Study Design and Methods***Year 2000 Objectives**

8.2, 8.3

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Parents/Families/Mothers/Fathers (Adolescent Parents)

Race/Ethnic Focus

African-American

This is a prospective, longitudinal, randomized clinical trial. The Wechsler Adult Intelligence Scale–Revised will be used to measure general intelligence. The Woodcock-Johnson Psycho-Educational Battery–Revised will be used to measure reading and math achievement. The School Archival Records Search (SARS) will be used to abstract cumulative secondary school records. The SARS provides a framework for describing educational histories including demographics, in-school and out-of-school referrals, negative comments, and disciplinary contacts.

The Parent of a Young Adult Interview (PAI) and the Young Adult Interview (YAI) will be used to measure current educational status, attitudes toward educational experiences, living circumstances, and attitudes toward school. Complete histories of schools attended and diplomas and degrees earned will be obtained. An instrument developed specifically for this study, the Scale of Independent Living, will be used to summarize self-sufficiency in economic support, living arrangements, transportation, and medical care.

The Adult Nowicki-Strickland Internality-Externality Scale (ANS-IE) will be used to assess locus of control. The Multigroup Ethnic Identity Measure (MEIM) will be used to measure three aspects of racial identity: Positive ethnic attitudes and sense of belonging, ethnic identity achievement, and ethnic behaviors and practices.

The Taylor Life Events Inventory, an adaptation for low-income families of Saranson's Life Events Scale, will be used and modified to include events in the past year relevant to young adults.

Population and Sampling Plan

The original sample was first recruited between 1972 and 1977. All study participants had incomes within the guidelines for the Federal poverty level, and 98 percent were African American. A total of 111 children from 109 families comprised the sample for the original study. This study will follow 105 young adults from 105 families. (The remaining subjects were omitted from the current sample because of death, seizure disorder, or refusal to participate.)

Analysis Plan

The analysis will test the primary hypotheses concerning the long-term correlates of early educational intervention and will evaluate interactions among individual, family, and community-level influences on development. The findings are relevant to priority areas involving the growth and development of minority children living in poverty and will provide important answers concerning ecological, personal, and situational factors associated with different developmental trajectories.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This application presents a clearly written, thorough, and comprehensive review of the literature. The study is grounded in an ecological framework that has guided other analyses to date. As the study subjects enter adulthood, important questions emerge. For example, what are the effects of the early childhood intervention on rates of substance abuse, employment, education, and the need for public assistance? These are important social policy questions, and this study can provide the necessary data and analysis.

Regional and National Significance

This proposed study has several strengths and it addresses an important topic. Interventions that assist minority children in maximizing the benefits of education and making successful transitions to adulthood may have widespread national and regional importance.

Scientific and Technical Merit

The investigators make a clear distinction between the data that have been collected previously and the data to be collected in the proposed study. The proposal includes previously measured child and parent variables, including mother's IQ, attitudes, and locus of control, and the child's cognitive and social development in infancy and periodically thereafter. In addition, the psychometric properties of the instruments to be used are presented, as are the availability of normative data for African-American children and young adults. Another strength of the study is that data will be collected at age 21 from instruments that are comparable to those used previously in the Abecedarian study.

The researchers have been extremely successful in holding their sample over time with very low attrition. Of the 111 original subjects, the researchers hope to include 105 in the 21-year followup. This level of retention is particularly impressive since the young adults must invest up to 8 hours in providing data and information for the study.

The proposed study has a number of weaknesses. Although the investigators provide a framework for their proposed work, the conceptual link between early education and adult competence is not well-developed. The effect of the intervention on the parents of the children who received the intervention is particularly questionable.

The list of variables to be obtained for the young adults is not well-focused. There are too many instruments used in the study for the few degrees of freedom in the sample. The list of instruments is not effectively integrated into the conceptual framework, and it is at times unclear what construct the instrument is supposed to measure. The reader has to go back to the conceptual framework or analysis plan to know where the instruments fit into the conceptual model. Some of the new measures that the investigators propose to collect do not fit the conceptual model, or at least no rationale is provided as to how they fit. While there is a great deal of interest in studying racial/ethnic identification, the investigators appear to be stretching their conceptual framework. The life events scales duplicate some of the data obtained in other instruments.

Some of the study's approaches to data analysis appear to be in reverse order. The investigators plan to do the multivariate analysis first, and then conduct the univariate analysis. The univariate analysis should be done first.

Data will be obtained from the young adults and parents over a 3-year period. The costs associated with the data collection are extremely high for the proposed work. Similarly, in year 4 no data are to be collected, yet the budget is comparable to years 1–3. This is an extremely experienced research team, who are fully capable of collecting, analyzing, and interpreting their data. The requested consultants are not needed and should be deleted from the budget.

The research questions addressed by the application are extremely important. The application is well-written and technically sound. However, there are far too many variables that are not conceptually linked. Nevertheless, the recommendation is for approval, with the condition that prior to funding the investigators submit a revised plan that includes

1. A reduced set of variables that address the most important potential effects of the early childhood intervention;
2. A clear conceptual link between this set of variables and the early intervention; and
3. A reduced budget that reflects a more parsimonious set of variables and excludes all consultant costs.



Satisfaction with and Utilization of Prenatal Care

Grantee

University of Illinois

Investigator

Arden Handler, Dr.P.H., M.P.H.
School of Public Health, Prevention Research Center
850 West Jackson Boulevard, Suite 400, M/C 275
Chicago, IL 60607
(312) 966-5954
(312) 996-3551 fax
u5975@uicvm

Project Number MCJ-170835

Project Period 10/1/1997-9/30/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	131,225	79,262	210,487
Year 2	143,958	71,979	215,937
Year 3	118,169	59,085	177,254
Year 4			
Year 5			

Summary***Statement of the Problem***

Improving access to prenatal care is viewed as a key strategy for decreasing the incidence of low birthweight and infant mortality in the United States. However, a significant portion of the Nation's women, particularly low-income and minority women, still fail to obtain adequate prenatal care. In fact, approximately 32 percent of African-American women who start prenatal care by the fourth month of pregnancy receive less than adequate care.

One factor that may affect prenatal care utilization is patient satisfaction with care. Studies of prenatal care characteristics that affect women's satisfaction have had a host of methodological problems, and only two studies have considered the relationship between satisfaction and prenatal care utilization. The information gained from this study can be used in the design of interventions or in the development of policy changes to increase the use of prenatal care by pregnant women, particularly African-American women.

Research Questions or Hypotheses

The following hypotheses will be tested:

Year 2000 Objectives

14.1, 14.5, 14.11, 14.14, 14.16, 22.4

Study Design

Observational

Time Design

Mixed

Care Emphasis

Noninterventional

Population Focus

Pregnant Women

Race/Ethnic Focus

African-American

1. The characteristics of prenatal care are related to a woman's satisfaction, independent of the woman's personal characteristics.
 - a. Some care characteristics (e.g., patient-practitioner communication, waiting time at the site of care) will have a stronger relationship to satisfaction than others; and
 - b. The relationship between care characteristics and satisfaction does not differ between African-American women who receive medicaid assistance and African-American women who do not receive medicaid assistance.
2. Satisfaction with prenatal care is associated with subsequent prenatal care utilization, independent of the woman's personal characteristics (including her barriers to prenatal care).
 - a. The relationship between satisfaction and subsequent prenatal care utilization does not differ between African-American medicaid recipients and nonrecipients.

Study Design and Methods

Information on care characteristics and satisfaction will be obtained through face-to-face interviews. Information on subsequent prenatal care utilization will be obtained through retrospective medical record review. Questionnaires for the interviews will be developed specifically for the study; medical record data will be abstracted from the clinical prenatal and delivery records maintained at the health care delivery sites that will be participating in the study. During the interview, each study participant will be asked about the characteristics of her prenatal care experience and her satisfaction with that care. Following delivery, each woman's medical chart will be abstracted to obtain information on prenatal care utilization.

Population and Sampling Plan

The study sample will comprise 500 African-American women obtaining prenatal care at one of two health centers that are part of a large managed care organization. In 1994, this health plan began serving the medicaid population in addition to its traditional commercial and medicare clients. Approximately half of the sample will consist of clients receiving medicaid assistance; the other half will be clients not receiving medicaid assistance. Women will be recruited at each of the two sites on the day of their prenatal care appointment. To qualify for the study, the following criteria must be met: Women must be 18 years of age or older, length of gestation must be less than 29 weeks, and women must consent to participate. Following her prenatal care visit, each woman will complete a face-to-face interview (35–40 minutes in length) with an experienced interviewer in a private space at the health care site. To ensure that the study reflects a cross section of the experiences of African-American women who use prenatal care, the study will include women of varying gestations and with varying numbers of visits at the time of interview.

Analysis Plan

Plans for data analysis include the use of univariate, bivariate, and multivariate statistical techniques, including model fitting and determination of the validity and reliability of the study measures.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This study should contribute substantially to an understanding of the factors that lead some women to seek and sustain prenatal care. The study will seek to examine those characteristics or attributes of prenatal care that increase satisfaction and to explore the relationship between satisfaction and subsequent utilization of prenatal care. The published literature is clear about the positive effects of prenatal care on perinatal outcomes. This study will also address a major void in the literature: factors that predict sustained use of prenatal care. The answer to this question could help identify preventive strategies that might ultimately have an impact on high rates of infant mortality and low-birthweight births.

Regional and National Significance

The proposed study is an extremely important one. Issues related to satisfaction with and utilization of prenatal care are important to the Maternal and Child Health Bureau's programs, and this project has both regional and national significance.

Scientific and Technical Merit

This submission is a revision of an application reviewed during the June 1996 cycle, when it was recommended for disapproval. The revision has been judged by the reviewers to be quite responsive to the concerns raised in their prior review, with noticeable improvements in the organization and presentation of the information. A 3-year investigation is proposed.

The investigators have revised the conceptualization of the problem. The study now focuses on characteristics of care related to satisfaction with prenatal care among African-American women, the contribution of satisfaction with care to subsequent prenatal care utilization among those who initiate care, and the possible differences in these two relationships according to payer status (medicaid versus non-medicaid). This focus of the research is also described more clearly. On the basis of a pilot study funded by the Agency for Health Care Policy and Research (AHCPR), the care characteristics have been revised to retain only those expected to vary in the study sites. Generally, these are appropriate changes that address the reviewers' earlier concerns.

The original proposal for a comparison between Mexican-American women and African-American women has been replaced by a comparison of medicaid and non-medicaid participants among a sample of African-American women. This change not only addresses the issue of inadequate sample size in the Mexican-American component, but also proposes to answer an interesting question on differences in determinants and consequences of satisfaction between women who receive medicaid assistance and those who do not.

Recruitment problems have been addressed by restricting recruitment to the Humana clinic sites and to the use of research staff as recruiters. This further eliminates the problem of determining risk status as a criterion for inclusion, because Humana treats both high-risk and low-risk clients. Further, the use of research staff addresses concerns about confidentiality, namely the concern that a woman's response to questions about satisfaction with care will become known to her provider. Questions about recruitment still remain. For example, how will African-American racial status be determined? In addition, the study design calls for enrolling the "next" non-medicaid client after enrolling a medicaid client. If the selected woman declines, how will a replacement control be identified? Although the application indicates that one researcher will be able to interview both women, it is not clear that recruitment will be optimized if a 35- to 40-minute interview is needed for women scheduled essentially at the same time for appointments.

The previous reviewers raised concerns about the potential for bias, especially recall bias, given the inclusion criteria described in the application and the choice of women who had made two visits since enrollment. The revised inclusion criteria would include all African-American women who are age 18 or older at any visit before their 28th completed week of gestation. The number of visits at the interview and the length of gestation at time of interview will be considered in the analysis. Questions concerning the timing of the interview and subsequent measures of satisfaction have been addressed by more rigorous description of the interview and the medical-record abstraction protocol.

The statement of the hypotheses has been revised, and the current statement is clear and presented in terms of relationships between characteristics of prenatal care, personal characteristics of the client, and the impact of these two factors on client satisfaction with care and subsequent utilization of care. The investigators have been careful to focus on the issues of measuring satisfaction at an early point in prenatal care (less than 29 weeks) and on subsequent utilization. The power and the sample size considerations are much improved. Data from the AHCPR-funded study carried out by the investigators have contributed to estimation of correlations on which sample size is based. Refusal rates are estimated at 8–10 percent, which seems acceptable. Finally, the methods of statistical analysis have been revised in accordance with the changes in the hypotheses. The approach to analysis is sound.

The time schedule seems appropriate, and confidentiality of clients seems well considered. The investigators are capable and have the necessary experience to carry out the study.

The revised application is vastly improved and the investigators have been responsive to the concerns identified in an earlier review. The recommendation is for approval, with two conditions: the investigators need to describe in more detail how the control subjects are going to be selected, and the budget must be reduced by 15 percent.



Social Context of Puerto Rican Child Health and Growth

Grantee

Wellesley College

Investigator

Odette Alarcon, M.D.
Center for Research on Women
106 Central Street
Wellesley, MA 02481
(617) 283-2460
(617) 283-3645 fax
oalarcon@wellesley.edu

Project Number MCJ-250643

Project Period 10/1/1994-9/30/1999

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	141,819	87,928	229,747
Year 2	149,025	92,396	241,421
Year 3	168,866	77,833	246,699
Year 4	173,049	82,607	255,656
Year 5	165,644	75,798	241,442

Summary

Statement of the Problem

This study focuses on the healthy development of Puerto Rican children living on the mainland of the United States. The research is grounded in a cultural-ecological framework, which views children as embedded in their family, surrounded by an ethnic community, school, and peers, which, in turn, are embedded in a larger society. These contexts are subject to change over time and with migration to the mainland and back to the island of Puerto Rico. Moreover, as a consequence of migration, Puerto Ricans become minority group members, and this can make them vulnerable to discrimination. This research is designed to be responsive to the Maternal and Child Health Bureau's priorities for studying the healthy growth of minority children, and the research agenda set forth in the Surgeon General's National Hispanic/Latino Health Initiative, by employing culturally appropriate theories, models, and methodologies involving Hispanic researchers at all levels of research activities and by using a multidisciplinary approach.

Research Questions or Hypotheses

The specific aims of this study are to: (1) Describe the life patterns of children of Puerto Rican origin living on the U.S.

Year 2000 Objectives

22.4

Study Design

Quasi Experimental

Time Design

Mixed

Care Emphasis

Noninterventional

Population Focus

School-Age Children,
Parents/Families/Mothers/Fathers (Adolescent
Parents)

Race/Ethnic Focus

Puerto Rican

mainland, taking into consideration variations in socioeconomic status (SES), gender, and color; (2) describe Puerto Rican children's experiences with migration and the impact of migration on the interconnected contexts of their family, peer groups, school, neighborhood, and ethnic community, as well as the majority culture; and (3) examine the relationships between migration, social contexts, and Puerto Rican children's development, both cross-sectionally and longitudinally. Specifically, the following hypotheses will be tested:

1. Other things being equal, healthy child outcomes are positively related to the resources available to the family and the child.
2. To the extent that migration and racism diminish these resources, children's healthy development will be jeopardized.
3. Families and external institutions can moderate the impact of migration and racism on children's healthy development.

Study Design and Methods

This is a prospective, longitudinal study led by a multidisciplinary team of researchers. The project is designed to be a 5-year study of 125 boys and 125 girls (grades 1–3 at the beginning of the study) and their primary caregivers from two socioeconomic strata (working class and welfare recipients). Data will be gathered yearly through face-to-face interviews with the children and their primary caregivers, ethnographic studies of their communities, and survey and archival research on demographic and economic conditions of their residential neighborhoods and the larger metropolitan area. Components of healthy development to be examined include physical health, self-esteem, school performance, behavioral adjustment, and ethnic identity.

Special emphasis will be placed on the influence of migration, racism, and prejudice on the healthy development of children. Child variables of interest are subjective perception of (skin) color, perception of social support, coping strategies, and perception of safety at school. The family variables to be examined include socioeconomic status, parent's job stress, racial identification, family structure, parental depression, acculturation, home environment, family values, sex roles, and parenting styles.

The final survey instrument will be a composite of some existing measures as well as new measures developed for this study. The existing measures include those adapted for use by the Normative Development of Puerto Rican Adolescents and The Social Ecology of After-School Care of Puerto Rican Elementary School Children (projects in which the principal investigators are involved). The measures developed for this study are "The Color of My Skin," "Self Esteem," and "Ethnic Identity," for children ages 6–8 years. The final survey instrument will be available in English and Spanish. The study will use the dual focus technique for translation.

Population and Sampling Plan

An initial sample of 300 children will be recruited, with a 5–10 percent attrition rate expected at each data collection wave. Attrition is expected to be highest for the lowest SES group; therefore, these families will be oversampled. Families will be identified through schools and community agencies, and through door-to-door methods in communities with a large Puerto Rican population. These families will be called and screened for inclusion in the study.

Analysis Plan

Cross-sectional data will be analyzed using multivariate techniques such as multiple regression and analyses of covariance. Longitudinal data will be analyzed using hierarchical linear modeling techniques to examine the impact of changes in social context on child development over time.



Three-Generation Intervention Among Adolescent Mothers

Grantee

University of Maryland School of Medicine

Investigator

Maureen M. Black, Ph.D.
Department of Pediatrics
Western Health Center
700 West Lombard Street
Baltimore, MD 21201
(410) 706-5289
(410) 706-0653 fax
mblack@umabnet.ab.umd.edu

Project Number MCJ-240301

Project Period 1/1/1996-12/31/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	122,230	52,439	174,669
Year 2	141,886	53,323	195,209
Year 3	182,589	68,620	251,209
Year 4	140,460	52,787	193,247
Year 5	116,651	43,839	160,490

Summary

Statement of the Problem

In 1990, nearly 1 of 8 live births (12.8 percent) was to an adolescent mother. Adolescent parenthood alters the developmental life course of adolescents and increases the risk of behavioral and developmental problems among their children. The adolescent tasks of emerging autonomy, career development, and formation of mutually supportive relationships are interrupted with the birth of a child and the responsibilities of parenthood. In the past, pregnant adolescents often married and lived with their husbands, but current trends indicate that adolescent mothers often remain with their families and share caregiving with the baby's grandmother. African Americans have a tradition of extended families, which may partially protect them from the negative consequences often associated with single parenting. Grandmothers are often conceptualized as providing support, nurturing, and sociological, financial, and legal stability; however, little is known about the challenges presented by multigenerational caregiving.

The previous study (MCJ-240621, Growth and Development: Longitudinal Followup, September 1, 1992–August 31, 1997) demonstrated the efficacy of home visiting in promoting parenting and early development among drug-abusing mothers and families of infants with failure to thrive. This research extends the work of that study into a three-generational

Year 2000 Objectives

2.4, 5.1, 7.4, 14.14, 14.16

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Infants, Toddlers, Adolescents (Pregnancy related), Parents/Families/Mothers/Fathers (Adolescent Parents), Other-Grandparents

Race/Ethnic Focus

African-American

project involving adolescent mothers and their infants, together with the babies' grandmothers. Despite the impact of adolescent parenthood on families, most intervention programs have been rather narrowly focused on maternal behavior such as reducing the incidence of pregnancy; few have addressed children or have been influenced by theories that examine ecological, family systems, or personal-social perspectives. Moreover, the limited information available about the relationships between grandmother coresidence, adolescent parenting, and children's development is controversial.

Research Questions or Hypotheses

This research project study seeks to study the following issues:

1. Through qualitative methods of interviews and focus groups, we can identify the ethnotheories of adolescent mothers and grandmothers regarding parenting, adolescent development, and child rearing.
 - a. This information can be used to develop an intervention guide based on ecological, family systems, and personal-social theories.
 - b. The information can also be used to produce a videocassette directed toward enhancing relationships between adolescent mothers and grandmothers.
2. Adolescent mothers and their families who receive a 1-year community-based intervention program will accomplish adolescent tasks (educational/career preparation, relationships with grandmother, and risk behavior, including contraceptive use and fertility) and parenting tasks (preventive health care, household/mealtime routine, mother-infant interaction during feeding, and child-oriented home environment). In addition, children of mothers who receive the intervention will demonstrate better growth, development, and mother-infant interactions during feeding.
 - a. When confronted with a potential conflict, mothers and grandmothers who receive the intervention will be better able than those in the control group to reach a compromise that demonstrates concern for the long-term relationship more than the immediate problem.
3. Based on Bronfenbrenner's person-process-context models, secondary hypotheses will be tested to examine the mechanisms underlying the impact of the intervention.
 - a. Consistent with the psychosocial perspective, mothers with relatively well-developed social skills who report high levels of self-esteem and family support and low levels of depressive symptoms and parenting stress and who view their child as having an easy temperament will be most likely to benefit from the intervention.
 - b. Consistent with the family systems perspective, adolescent mothers who have a supportive, open relationship with the baby's grandmother will be better able than those without such a relationship to negotiate caregiving roles with other family members to ensure that their children are adequately cared for and to develop both their adolescent and parenting roles.
 - c. Consistent with the ecological perspective, adolescent mothers who remain in school and/or access community services (e.g., family support programs) will be better able to enhance their adolescent and parenting roles and promote their child's development than will adolescent mothers who are not involved in these services.

Study Design and Methods

This research extends previous work demonstrating the efficacy of home visiting in promoting parenting and early development among drug-abusing mothers. This study encompasses a two-phase, three-generational project involving adolescent mothers, infants, and grandmothers.

Phase 1 is a qualitative examination of the ethnotheories of adolescent mothers and grandmothers regarding parenting, decision making, and social problem solving, with an emphasis on the mealtime context. This phase culminates in the development of an intervention guide to be used in the second phase and in the production of a videocassette directed toward enhancing communication and conflict resolution between adolescent mothers and grandmothers.

Phase 2 is conducted in partnership with community family support organizations and includes a three-generational developmentally oriented intervention based on three theoretical perspectives—ecological, family systems, and psychosocial. The 1-year intervention, designed to promote the developmental outcomes of adolescent mothers and their infants, consists of biweekly home visits, monthly support groups, and coordination with community services. The intervention includes the videocassette produced in the first phase and emphasizes social problem-solving skills, open and direct communication, and emotional support, using mealtimes as a primary context.

Baseline data are collected at delivery and outcome data are collected midway through the intervention, at completion of the intervention, and 1 year later. Multimethod assessment procedures are used, including observation, self-report, and

performance on standardized measures. Maternal domains include adolescent tasks (educational preparation and risk behavior) and parenting tasks (preventive health care, household/mealtime routine, and mother-infant interaction during feeding). Infant domains include growth, development, and mother-infant interaction. Grandmother domains include the relationship with the mother and infant.

Population and Sampling Plan

Phase 1: Ethnotheories. For the ethnotheory phase of the project, 20 adolescent African-American mothers of infants under 12 months of age will be recruited from two urban clinics that provide services through the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). Eligibility criteria for WIC services are based on financial resources and nutritional status. Two WIC clinics were chosen as recruitment sites to ensure representation of adolescent mothers of low-income status, including those who have not returned to school.

Phase 2: Intervention. In the second phase, 180 adolescent mothers and infants from the full-term nursery at the University of Maryland Hospital (UMH) will be recruited. UMH is a university-based teaching hospital that serves a large portion of inner-city Baltimore. African-American women under 18 years of age account for about 20 percent of the approximately 2,100 births annually at UMH. Recruitment will extend over 18 months at the rate of 10 per month.

Maternal eligibility criteria for phase 2 include the following: African-American women under age 18 who are giving birth for the first time, who have no recognized psychiatric disorders, who intend to provide primary care for their baby, and who are living with a grandmother or "grandmother-figure." The study has limited the recruitment to adolescent mothers who are living with a grandmother at the time of delivery in order to study the communication that occurs as adolescents enter parenthood. Infant eligibility criteria include full term (37 weeks), birthweight appropriate for gestational age, and absence of identified congenital or disabling conditions.

Analysis Plan

Phase 1: Ethnotheories. The qualitative data will be entered into a computer as both text and numeric files. Textual data will be analyzed using the text search and retrieval program DtSearch. Analysis of the data will involve pattern searching, content analysis, and the derivation of summarization figures on key themes, including: (1) Parenting roles for mothers; (2) meaning of parenting for mothers; (3) decision-making models regarding parenting roles; (4) local models and perceptions relating to adolescent/young adult female role development, parenting responsibilities, and child development; (5) local patterns of communication and information sharing regarding parenting; (6) influence of personal child-rearing history on decisions regarding parenting; and (7) influence of others (e.g., fathers, grandparents) on decisions regarding parenting.

Phase 2: Intervention. The initial step in the analysis will be to examine equivalence across the intervention and control groups. Because the groups are assigned using a randomization procedure, no differences are expected. However, if there are differences in demographic variables, they will be used as covariates in the analysis. Initial analyses will include correlations, means, and standard deviations for all variables.

Repeated measures multivariate analysis of covariance (RMANCOVA) will be used to assess changes in the primary adolescent and child variables that can be measured in a continuum over time (hypothesis 2). Maternal dependent measures are: Relationship with other family members, household and mealtime routines, and interactions during mealtime. Child dependent measures are: Development, interactions during mealtime, and behavior. Intervention group is the independent variable. The within-subject factor is time, and an interaction between groups (intervention vs. control) by time would indicate that the two groups responded differently over time and would suggest an effect of the intervention.

Logistic regression equations will be used to examine changes in binary outcomes over time, controlling for baseline values. Maternal categorical variables include educational achievement, risk behavior, and preventive health care. Child categorical variables include growth (adequate vs. insufficient/excess growth).

Hypothesis 2a involves the problem-solving skills of mothers. Because the scores are categorical, chi-square analysis will be used to examine problem-solving skills at each data collection point and logistic regressions will be used to examine changes in problem-solving skills over time. The independent variable will be intervention status.

Multivariate analyses of variance using intervention group as the independent variable will be used to assess the direct effects of the intervention on mother and child outcome variables (hypothesis 2) and the mechanisms underlying the impact of the intervention (hypothesis 3). The research team will regress intervention status and the intervening variables and their interactions on the outcome variable under investigation.

Structural equation modeling (SEM) also will be used to examine the theory behind hypotheses 3a, b, and c by determining

whether the intervening psychosocial, family systems, and ecological variables are related to the dependent variables of adolescent role, parenting role, and child development.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

In 1990, almost 13 percent of live births were to adolescent mothers. Many of these women and their offspring are at risk for negative life outcomes. The development of effective interventions targeting this population has major national public health implications.

Regional and National Significance

This proposal addresses a topic that is of regional and national significance.

Scientific and Technical Merit

As noted in this application, most interventions for adolescent parents have focused on the adolescent mother, ignoring the relationship between the adolescent and her own mother. Yet, maternal grandparents are often central figures, organizing the family, supporting the adolescent, and sometimes assuming the role of primary caregiver for the infant. Given that these relationships can sometimes be detrimental (rather than supportive) to the adolescent mother and her infant, it is important to understand how to assist the entire family system to move toward optimal relationships that enhance the development of the infant.

This is a well-documented and well-written proposal. Its strengths stem from the investigators' expertise in conducting home-based interventions with African-American adolescent mothers and their families. The investigators also have extensive experience with innovative methods of data collection and have the extensive community-based networks necessary to conduct the proposed study.

A major strength of the proposed research is the random assignment of adolescents to the intervention and control groups. The proposed work builds on successful intervention studies conducted by the investigators. The experience of the research team in conducting similar studies bodes well for their ability to conduct this complex intervention research. The study design is well conceptualized and the research measures are state-of-the-art and appropriate for the study questions. Study hypotheses are conceptually driven and clearly stated. The application is comprehensive, clear, and easy to read. Although this is an excellent proposal, a few issues need to be addressed before the study is implemented. Investigators discuss numerous strategies to minimize threats to the research design, including examiner bias, comparison group adequacy (i.e., validation of receipt of intervention), chronology bias (age of mother), adequacy of timing of observations, continuity of measurement (measures that may become outdated because of developmental changes in the child), and attrition. Although this list suggests that the investigators have thought through many potential problems, can the planned home-based assessments of controls threaten the validity of the design? In other words, the intensive nature of the proposed home assessments may actually operate as a modified intervention for controls. This may be particularly problematic since the single most important independent variable is intervention status.

The investigators plan to study African-American families. The application states that studying children within one cultural context minimizes the need for controls for processes that vary across different environmental/cultural contexts. The application also notes the rich history of African-American parenting and child-rearing values/traditions that may be somewhat distinct from those of the majority culture. This perspective is a potential strength of the proposed research, but, unfortunately, culturally relevant aspects of the conceptual framework are not developed in the application. In addition, the literature on African-American families is not reviewed.

The qualitative examination of ethnotheories provides a strong mechanism for tapping culturally based parenting and problem-solving strategies. However, a more elaborated discussion of the cultural aspects of the proposed intervention is needed. In addition, a clear statement is needed concerning the group of families for whom the intervention is appropriate. It is assumed that the intervention will be specific to African-American families, with no generalization to families from other cultural groups.

Although the list of intervening variables for maternal psychosocial characteristics is quite comprehensive, it appears that similar information about the grandmother will not be collected. This is surprising, given this study's emphasis on family systems and the discussion regarding the idea that adolescent pregnancy is viewed as an "off time" occurrence for both

adolescents and their parents. Variations in grandmothers' abilities to cope with the adolescent mother and the grandchild suggest important individual differences. Thus, the assessment of variables, such as depressive symptoms, self-esteem, social skills, social support, etc., could add important insights into the relational strengths and impasses experienced between the adolescent mothers and the grandmothers.

The complexity and variety of roles that grandmothers assume in families of adolescent mothers is not adequately reflected in the proposed intervention. The range of caregiver roles of the grandparents is not clearly defined or addressed. Would the intervention strategies be the same across differing family constellations? For example, would the desired intervention be identical in families in which (1) the grandparent, rather than the adolescent mother, is the primary caregiver; (2) the adolescent takes primary responsibility for the infant, and the grandparent provides support when needed; or (3) a father figure is prominent in the adolescent's life? Would the desired intervention outcomes be the same for families with different distributions of child care roles and responsibilities?

There is also some question as to whether an intervention focusing on problem-solving is really powerful enough to intervene in the relationship between the adolescent and her mother. What if this relationship is highly conflictual or otherwise troubled? How will the investigators make sure that, by intervening in the family system, they are not causing harm, upsetting the balance of the system without providing a sufficiently intensive intervention to assist the family in dealing with the emotional issues generated by the intervention? How will home visitors be trained to make sure they can competently address hostile or seriously conflicted family situations that may emerge from being exposed to certain aspects of the intervention? These issues needed to be addressed in the application.

Although the longitudinal data analysis plan is well delineated, it is not entirely clear how the data collected from the 100 interviews from the first phase of the study will be coded and interpreted. Given the research team's extensive amount of experience with this population, it would be helpful to propose some preliminary themes for exploration.

This is a very strong, clearly written application that addresses an extremely important research topic. It uses a randomized design to study the effectiveness of a potentially important intervention. The recommendation is for approval with the following conditions: 1. Clarify the extent to which the proposed study sample of adolescent mothers overlaps with those participating in the other studies being conducted by the investigator.; 2. Elaborate on the cultural framework focusing on African-American families with a clear statement of the group targeted by the intervention. For what groups of families will the intervention be appropriate/generalizable?; 3. Address issues of complex, varying roles of grandparents in the families, and the ramifications of these roles for the proposed intervention.; 4. Address issues relating to home visitor competence in dealing with conflicted or troubled family situations.



Welfare Reform and the Perinatal Health of Immigrants

Grantee

SUNY Downstate Medical Center

Investigator

Howard Minkoff, M.D.
450 Clarkson Avenue, Box 1240
Brooklyn, NY 11203
(718) 283-7048
(718) 283-8468 fax
hminkoff@maimonidesmed.org

Project Number MCJ-360836

Project Period 4/1/1998-3/31/2002

Costs	Direct Costs	Indirect Costs	Total
	Awarded	Awarded	
Year 1	217,353	89,891	307,244
Year 2	326,605	100,080	426,685
Year 3	366,332	118,176	484,508
Year 4	278,176	128,506	406,682
Year 5			

Year 2000 Objectives

14.14, 14.16

Study Design

Quasi Experimental

Time Design

Mixed

Care Emphasis

Noninterventional

Population Focus

Infants, Pregnant Women

Race/Ethnic Focus

Hispanic (Hispanic overall)

Summary

Statement of the Problem

America's new immigrants may be the first to experience the public health effects of recent welfare reform through the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. While that legislation ended the guarantee of cash welfare assistance to all income-eligible families, the changes it mandated in the medicaid program disproportionately affect immigrants. The consequences of this new law for maternal and infant health may be dramatic, especially in urban areas where large proportions of new mothers are immigrants. Subsequent legislation may also influence the perinatal outcomes of these families. For example, the State Children's Health Insurance Program (SCHIP), enacted as part of the 1997 Balanced Budget Act, may improve infant health through expanded health coverage—but the extent remains to be seen. Within the framework provided by the 1996 and 1997 legislation, each State's legislature has significant leeway in shaping the health policy that will affect its residents. The consequences of welfare reform for immigrants, therefore, may vary considerably from one State to another. To discern the effects of legislation on the maternal-child health of immigrants, over a 4-year period we will track the implementation of these laws and the perinatal health outcomes for immigrants in four States with large immigrant populations—California, Texas, Florida, and New York. Investigators from the disciplines of obstetrics and gynecology, pediatrics, public policy, and health economics will utilize three approaches to study the effects of legislative changes: (1) Analyzing each State's policy environment, (2) compiling vital data sets in four States from time

intervals before and after the new law's implementation, and (3) interviewing service recipients in three of these States. In the 30 years following the passage of the Nation's first medicaid bill in 1965, perinatal and maternal mortality rates dropped dramatically. Although many have assumed that the two events were linked, a conflicting body of research has failed to clarify the relationship between medicaid expansions and perinatal health. To date, most studies of this relationship have not included information regarding postpartum or infant care. Many such studies relied on aggregate vital data and thus failed to link prenatal care patterns with adverse outcomes (such as infant mortality). Most importantly, these studies lacked adequate control populations, and researchers were, therefore, unable to isolate their observations from time-varying factors such as the crack cocaine epidemic or advances in neonatology.

Two elements of our study design promise more reliable conclusions. Current changes in medicaid most directly affect immigrants; therefore, our study will use American-born women of similar ancestry as a control group. By comparing outcomes for immigrant women before and after welfare reform to outcomes for indigent American-born women during the same time intervals, we will be better able to isolate any changes caused by the new legislation from time-dependent factors affecting all poor women. Client-level data from interviews with women will provide information on the interaction between entitlement status; patterns of prenatal, postpartum and infant care; and infant health outcomes.

In addressing the legislative policies that affect immigrant women's perinatal health, welfare reform legislation will be analyzed simultaneously with SCHIP, which is a Federal Block Grant available to States to provide medical assistance to children who are not eligible for any other insurance coverage, including medicaid. The manner in which each State will utilize SCHIP dollars may influence the degree to which other legislatively mandated programs affect immigrant women. In order to gather data on legislative mandates and programs that have not been fully implemented, several strategies will be utilized.

Research Questions or Hypotheses

The hypotheses and specific aims of the study are as follows:

1. The welfare reform act will affect the health of immigrant women and their newborns.
 - a. Describe changes in the categorical and income guidelines for medicaid eligibility associated with welfare reform and subsequent legislation such as SCHIP;
 - b. Determine rates of preterm birth, low birthweight, intrauterine growth restriction (IUGR), low Apgar scores, and congenital infections among women whose medicaid status is altered by welfare reform;
 - c. Determine the change in the adequacy of prenatal care use by immigrant women as related to medicaid access;
 - d. Determine the change in the number and timing of postpartum visits, well-baby checkups, and immunizations as related to medicaid access;
 - e. Describe through case studies whether resources that are available for the care of all pregnant women and newborns are affected by any financial encumbrance experienced by States and municipalities as they seek to replace Federal funds.
2. Maternal-newborn outcomes will vary according to the medicaid policies of the State in which women reside.
 - a. Among recent immigrant women whose medicaid status is altered by the bill, determine how rates of preterm birth, low birthweight, IUGR, low Apgar scores, and congenital infections vary between States;
 - b. Determine if there are differences by State in the adequacy of prenatal care use by immigrant women as related to medicaid access; and
 - c. Determine if there are differences by State in the frequency of well-baby checkups and vaccinations as related to medicaid access or to related programs such as SCHIP.

Study Design and Methods

The research design involves a three-tiered strategy for the collection of data. First, we will conduct interviews with health officials and administrators to examine new regulations and State policies as they are implemented in four States. Second, we will analyze vital data sets in two of these States through a series of cross sections of birth certificate data before and after the implementation of welfare reform policies. Third, we will interview postpartum women in sentinel hospitals in New York, Florida, and California and interview them again after 5 to 7 months to determine if postpartum and newborn care has occurred.

Population and Sampling Plan

The study will focus on Latina immigrant women, primarily women from Mexico, Central and South America, and the Caribbean. In 1994, infants of foreign-born women constituted 18.5 percent of the 3.95 million births in the United States, with 70 percent of births to women of Hispanic origin occurring in California, Florida, and New York.

The commissioner of health and social services of each State, the CEO of sentinel hospitals (i.e., hospitals with high percentages of immigrant and indigent women), and chairs of obstetrics in each State will be interviewed by a single investigator. A uniform instrument was designed for these contacts. Case studies developed from the data gathered in these interviews will illustrate the unique approaches designed in a given State or municipal setting.

A series of cross sections of birth certificate data before and after policies that are related to welfare reform go into effect will be analyzed to assess whether broader patterns of change in perinatal care and outcomes among immigrants can be detected. These data have provided much of the currently available information regarding the impact of entitlements on health outcomes. Although these sources may not have the requisite specificity to sustain detailed analysis, they can be used to measure changes in utilization of prenatal services and perinatal outcomes by immigrant and indigent populations.

In the analysis of the interview data, medicaid eligibility will serve as the exposure variable, and adequacy of prenatal care, birthweight, Apgar score, and postpartum maternal and infant care are examples of measurable outcomes. Based on power estimates for possible differences in such outcomes among U.S.-born eligible and ineligible immigrant women, we have planned a sample size of 2,400 women from each of the three States for a total of 7,200 women. Completed interview forms will be sent to the data center (SUNY-Downstate) where they will be reviewed for completeness, accuracy, and consistency. Standardization of data gathering will be achieved by using uniform data-gathering instruments and procedures. Interviewers will be trained by the data center staff and will be observed conducting interviews to ensure adherence to study protocol. Confidentiality of the participating study subjects will be ensured through multiple protocols for storing documents, using unique identifiers, and maintaining separate storing spaces for contact data and medical/interview data.

Analysis Plan

The manner in which these three sets of data will be used to reach our goals is illustrated below:

I. Client Data Collection for Hypothesis I: PRWORA will affect the health of immigrant women and their newborns.

Predictor Factors: Medicaid and benefits status

Source of data: Patient interview/patient eligibility

Co-variate Factors: Drug use, smoking, cultural factors, etc.

Source of data: Preterm birth; IUGR; adequacy of prenatal, postpartum, or newborn care; etc.

Outcome Factors: Patient interview/patient eligibility Interview/chart review

Source of data: Chart review Patient follow-up

II. Client Data Collection for Hypothesis II: Maternal-newborn outcomes will vary according to the medicaid policies of the State in which women reside.

Predictor Factors: State medicaid regulations

Source of data: Medicaid official interview to determine eligibility criteria

Co-variate Factors: Drug use, cultural factors, smoking etc.

Source of data: Interview/chart review

Outcome Factors: Preterm birth; IUGR; adequacy of prenatal, postpartum, or newborn care; etc.

Source of data: Chart review

III. State Vital Data Sets Review for Hypothesis II: Maternal-Newborn Outcomes Will Vary According to the Medicaid

Policies of the State in Which Women Reside

Predictor Definition: Locale

Source of data: Birth certificates

Intermediate Variable Definition: Birthplace (country)

Source of data: Birth certificates

Outcome Definition: Change in payment source of outcomes

Source of data: Birth certificates

Data gathered from the client interviews will be analyzed according to general linear models (for continuous variables), logistic regression models (for discrete variables), or multinomial logit models (for discrete outcomes with more than two levels). Based on court orders in each State and current iteration of State policy priorities, it is likely that pregnant women in California and New York will remain eligible for State-only or federally matched medicaid in each State regardless of their immigration status. Florida will provide medicaid coverage to pregnant immigrants to the extent permitted by Federal law, with newly ineligible populations potentially eligible for State-funded programs. A direct comparison of the perinatal outcomes for immigrants in California, Florida, and New York, however, would not account for local trends that might confound the data. Low-income, U.S.-born women (whose eligibility for medicaid is unlikely to change in either State as a result of the 1996 welfare reform legislation) will serve as an effective control group for poor immigrant women who may lose their health benefits. The existence of this control group will help account for local trends that may affect birth outcomes in each of the three States. We will, therefore, use a differences-in-differences estimate. This method will allow us to relate the change over time of the treatment group (immigrants) to that of the control group (U.S.-born women) in each of the study States and then to compare those differences to assess the effects of the 1996 and 1997 legislation.

Pre-Award Evaluation

Evaluator 1

Originality and Importance

This application proposes an investigation of the impact of welfare reform on the perinatal health of immigrants in four locations: Brooklyn, NY; Houston, TX; Miami, FL; and San Francisco, CA. The focus of the study is on changes in the health of immigrants who may be denied Medicaid. The application addresses an issue of high scientific, medical, political, and ethical importance.

Regional and National Significance

There is little doubt that welfare reform will drastically change the political landscape of the United States. It is also likely that such reform will result in increased adverse perinatal outcomes. If such is the case, the results could not only be disastrous for the infants involved, but for many health care institutions in urban areas likely to bear the brunt of any adverse financial consequences. Documentation of such changes in outcomes would be of major scientific and of practical importance for the Maternal and Child Health Bureau and other Federal agencies. In general, the study will provide information that has the potential to impact policy related to Medicaid and financing of antenatal care.

Scientific and Technical Merit

This application has many strengths. The investigators (PIs) are extremely qualified and experienced at conducting research of this type. The proposal is well written and presents clearly the problem and the potential policy implications of the research they propose. The literature review is extensive including presentation of data that indicate that immigrants often have better outcomes in the face of less prenatal care.

The logistics of conducting the study and data to be collected have been well thought out and draw on experiences in

conducting similar types of studies. Hypotheses are clearly stated and concepts well defined. The principle investigator presents proposed tests and measures as well as data gathering procedures. Preliminary data intake forms are also included. Representative plans for data analysis is clearly presented.

Weaknesses are present. The investigation intends to look at a lot of things. Although there is some evidence that prenatal care is associated with better perinatal outcomes, this link is not as firm as these investigators postulate. Moreover, even assuming such a link exists, it is not clear that all potential outcomes to be measured can in fact be linked in some way to welfare reform. At the same time, noticeably absent from the list are some important perinatal outcomes that could be readily obtainable from local databases at the sentinel hospitals- the 5 most important such outcomes are: 1) admission to an intensive care setting (for mother or child); 2) assisted ventilation; 3) intra-ventricular hemorrhage; 4) major congenitally acquired infection (e.g., HIV, syphilis); and 5) fetal and neonatal deaths. Why not get an electronic download from local NICU databases? Similarly, some of the other outcome variables (e.g., immunization rates) need to be defined in time (e.g., vaccines by age 12 months).

A related issue is that the investigators will be looking at such outcomes on a "micro" level ("high grain" with N: 9600) as well as on a "macro level" ("low grain", using vital statistics data sets). The relationships between these two analytic strategies need to be made more explicit. The investigators also need to address the issue of how they intend to handle those situations where the results of the "micro and macro" analyses are in conflict.

With respect to Study II, the investigators intend to ask various officials for information regarding how their entities will cope with welfare reform. Some of the information regarding how they plan to request is likely to be considered privileged because it relates to how a given entity games the system in order to survive. Moreover, given the tremendous weight these investigators place on this part of the project, it is of concern that there are no letters of commitment from the relevant administrators. The fact that chairs of obstetrics departments have endorsed the project does not necessarily mean that these other informants will necessarily collaborate.

Letters of support from the participating institutions are included. There will be two hospital sites in each of the four cities. The second hospital in each of the four participating cities has not yet been determined, however.

The investigators propose to use US-born women receiving Medicaid (who will not lose their benefits as a result of the welfare reform legislation) as the control group of foreign born women. While the use of these women as a control group is the best one can do, in interpreting and reporting data it will be important to keep in mind that it is not perfect and some secular trends could occur differentially in the US- and foreign--born women.

Could the change result in changes in care patterns? Could some hospitals (especially referral centers) see a change in the baseline risk of adverse outcomes among their patients that could influence comparisons?

The investigators propose to compare changes in outcome in states where undocumented immigrants continue to receive Medicaid with states where such coverage is denied. They indicate that it is likely that pregnant women in New York will remain Medicaid eligible and that the "status quo is likely to remain unchanged for at least several months." What would be the impact on the study analyses if women in all states (including New York) became ineligible during the study period?

Given personnel, there are limitations on the number of interviews that can be performed on a given day or in a given week. How will the investigators select women to be interviewed if there are too many patients available?

A limitation of the study is the lack of detailed information related to Medicaid in Florida and Texas vital statistics. The investigators have dealt with this by using women equal to or more than 20 years of age without a high school diploma as a proxy. These analyses will result in less precise evaluations. The investigators are aware of the limitations.

All senior investigators listed for the project are highly qualified and have exemplary track records as clinicians, multi-center project coordinators, and researchers. Resources and facilities are adequate.

The budget includes \$25,700 for office furniture (\$14,700 in main budget and \$11,000 in subcontracts) that should be

excluded. In year 2, the NBER has included additional money for office furniture (amount not specified) that should be deleted. The request for \$7500 to recruit personnel at the New York site (main budget) seems high. The need for seven additional phone lines at the New York site completely paid by the grant does not seem justified. Overall, the budget could stand reductions of 15 to 25 percent.

Issues related to human subjects have been carefully considered. The investigators are aware of the importance of confidentiality in performing the study.

SUBJECT INDEX





Subject Index

- Access to Health Care** Satisfaction with and Utilization of Prenatal Care
Use of Child Health Services by Hispanic Families
Welfare Reform and the Perinatal Health of Immigrants
- Adolescent Nutrition** Factors Associated with Nutritional Intake in Adolescents
- Adolescent Parents** Behavior Problems in School-Aged Children of Teen Mothers
Three-Generation Intervention Among Adolescent Mothers
- Adolescent Pregnancy Prevention** Adolescent Attitudes About Pregnancy
- Adolescents** Adolescent Attitudes About Pregnancy
Behavior Problems in School-Aged Children of Teen Mothers
Choices of Life for Adolescence Success
EICS Phase IV: Adolescence
Factors Associated with Nutritional Intake in Adolescents
Health Care Utilization: Pediatric Organ Transplantation
Home Nursing to Avoid Pediatric Hospitalization
Interparental Conflict and Adolescent Violence
Neighborhood and Family Effects on Adolescent Health Behaviors
Predicting the Need for Hospitalization in Childhood Asthma
- African Americans** African-American Children's Transition to School
Alternatives for Developmental Screening in Primary Care
Choices of Life for Adolescence Success
Crossing Cultural Boundaries: An Ethnographic Study
Factors Associated with Nutritional Intake in Adolescents
Poverty and the Ecology of African-American Children
Predicting African American Children's School Compliance
Predicting the Need for Hospitalization in Childhood Asthma
Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two
Reducing Preterm Birth by Bacterial Vaginosis Screening
Satisfaction with and Utilization of Prenatal Care
Three-Generation Intervention Among Adolescent Mothers
- AIDS Prevention** Comprehensive Elementary School AIDS Education
- Asians** Factors Associated with Nutritional Intake in Adolescents
- Asthma** Predicting the Need for Hospitalization in Childhood Asthma
- Behavior Disorders** Behavior Problems in School-Aged Children of Teen Mothers
Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two
- Body Composition** Factors Associated with Nutritional Intake in Adolescents
Maternal Health and Pregnancy Outcomes Among Hispanics
- Breastfeeding** Effect on Breastfeeding of Pacifiers and Bottle Feeding
- Case Management** Predicting the Need for Hospitalization in Childhood Asthma
- Child Abuse** Evaluation of Hawaii's Healthy Start Program - Phase Two

Child Care	Early Child Care Study of Children with Special Health Needs Role of Early Family Supports in Adult Self-Sufficiency
Child Care Centers	Predicting African American Children's School Compliance
Child Neglect	Evaluation of Hawaii's Healthy Start Program - Phase Two
Children with Special Health Needs	Adolescent Health Care: A Comparison of Five Risk Adjustment Systems Alternatives for Developmental Screening in Primary Care Crossing Cultural Boundaries: An Ethnographic Study Early Child Care Study of Children with Special Health Needs EICS Phase IV: Adolescence Health Care Utilization: Pediatric Organ Transplantation Predicting the Need for Hospitalization in Childhood Asthma Preventing Mental Health Problems in Ill Children Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two
Chronic Illnesses and Disabilities	EICS Phase IV: Adolescence Health Care Utilization: Pediatric Organ Transplantation Predicting the Need for Hospitalization in Childhood Asthma Preventing Mental Health Problems in Ill Children Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two
Clinics	Adolescent Attitudes About Pregnancy Maternal PKU Resource Mothers Program: A Clinical Trial Reducing Preterm Birth by Bacterial Vaginosis Screening
Community Based Health Services	Home Nursing to Avoid Pediatric Hospitalization Reducing Preterm Birth by Bacterial Vaginosis Screening
Community Integrated Service System	Improving Health/Development of Low Income Pregnant Women
Community Participation	American Indian Fatherhood in Two Oklahoma Communities
Compliance	Health Care Utilization: Pediatric Organ Transplantation Predicting African American Children's School Compliance
Cost Effectiveness	Home Nursing to Avoid Pediatric Hospitalization Predicting the Need for Hospitalization in Childhood Asthma
Counseling	Infant ETS Exposure: Clinic-Based Maternal Counseling
County Health Agencies	Home Nursing to Avoid Pediatric Hospitalization
Cultural Diversity	Assessment of Enhanced Prenatal Care by Ethnically Diverse Women Predicting African American Children's School Compliance
Cultural Sensitivity	American Indian Fatherhood in Two Oklahoma Communities Choices of Life for Adolescence Success Crossing Cultural Boundaries: An Ethnographic Study Infant Temperament: Neonatal-5 years in Rural Appalachia Poverty and the Ecology of African-American Children Puerto Rican Young Fathers' Involvement with Their Children Use of Child Health Services by Hispanic Families
Data Analysis	Early Child Care Study of Children with Special Health Needs Evaluation of Hawaii's Healthy Start Program

Data Collection	Early Child Care Study of Children with Special Health Needs Evaluation of Hawaii's Healthy Start Program Social Context of Puerto Rican Child Health and Growth
Decision Making Skills	Choices of Life for Adolescence Success
Delayed Development	Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two
Developmental Disabilities	Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two
Developmental Evaluation	Alternatives for Developmental Screening in Primary Care Prenatal Antecedents of Infant Outcome Role of Early Family Supports in Adult Self-Sufficiency
Developmental Screening	Alternatives for Developmental Screening in Primary Care Does Lead Burden Alter Neuropsychological Development?
Dissemination	Crossing Cultural Boundaries: An Ethnographic Study
Early Childhood Development	Alternatives for Developmental Screening in Primary Care American Indian Fatherhood in Two Oklahoma Communities EICS Phase IV: Adolescence Evaluation of Hawaii's Healthy Start Program - Phase Two Predicting African American Children's School Compliance Prenatal Antecedents of Infant Outcome Role of Early Family Supports in Adult Self-Sufficiency
Early Intervention	Alternatives for Developmental Screening in Primary Care Early Child Care Study of Children with Special Health Needs EICS Phase IV: Adolescence
Families	Crossing Cultural Boundaries: An Ethnographic Study Evaluation of Hawaii's Healthy Start Program - Phase Two Three-Generation Intervention Among Adolescent Mothers
Family Centered Health Care	Crossing Cultural Boundaries: An Ethnographic Study
Family Centered Health Education	Increasing Safety Seat Use Among Preschoolers
Family Characteristics	African-American Children's Transition to School American Indian Fatherhood in Two Oklahoma Communities An Intervention for the Transition to Fatherhood Early Child Care Study of Children with Special Health Needs Neighborhood and Family Effects on Adolescent Health Behaviors Predicting African American Children's School Compliance Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two Puerto Rican Young Fathers' Involvement with Their Children
Family Environment	Evaluation of Hawaii's Healthy Start Program - Phase Two Infant ETS Exposure: Clinic-Based Maternal Counseling Interparental Conflict and Adolescent Violence Poverty and the Ecology of African-American Children Predicting African American Children's School Compliance
Family Support Programs	Health Care Utilization: Pediatric Organ Transplantation Three-Generation Intervention Among Adolescent Mothers

Fathers	American Indian Fatherhood in Two Oklahoma Communities An Intervention for the Transition to Fatherhood EICS Phase IV: Adolescence Puerto Rican Young Fathers' Involvement with Their Children
Fragile X Syndrome	Improved Prenatal Detection of the Fragile X Mutation
Gestational Weight Gain	Prospective Investigation of Twin Gestation
Health Care Financing	Adolescent Health Care: A Comparison of Five Risk Adjustment Systems
Health Education	Improving Health/Development of Low Income Pregnant Women
Health Insurance	Adolescent Health Care: A Comparison of Five Risk Adjustment Systems Responsiveness of CHIP to Children With Special Health Care Needs
Health Professionals	Crossing Cultural Boundaries: An Ethnographic Study
Health Promotion	Office Systems to Improve Preventive Care for Children
Hispanics	Alternatives for Developmental Screening in Primary Care Factors Associated with Nutritional Intake in Adolescents Infant ETS Exposure: Clinic-Based Maternal Counseling Interparental Conflict and Adolescent Violence Maternal Health and Pregnancy Outcomes Among Hispanics Use of Child Health Services by Hispanic Families Welfare Reform and the Perinatal Health of Immigrants
Home Visiting Programs	Welfare Reform and the Perinatal Health of Immigrants Evaluation of Hawaii's Healthy Start Program Home Nursing to Avoid Pediatric Hospitalization Home Versus Group Visits After Early Postpartum Discharge Maternal PKU Resource Mothers Program: A Clinical Trial
Home Visiting Services	Evaluation of Hawaii's Healthy Start Program - Phase Two Home Nursing to Avoid Pediatric Hospitalization Home Versus Group Visits After Early Postpartum Discharge
Immigrants	Welfare Reform and the Perinatal Health of Immigrants
Infant Health Care	Home Versus Group Visits After Early Postpartum Discharge
Infant Morbidity	Home Versus Group Visits After Early Postpartum Discharge Infant ETS Exposure: Clinic-Based Maternal Counseling Maternal PKU Resource Mothers Program: A Clinical Trial Prenatal Antecedents of Infant Outcome Reducing Preterm Birth by Bacterial Vaginosis Screening
Infant Mortality	Reducing Preterm Birth by Bacterial Vaginosis Screening
Infant Temperament	Infant Temperament: Neonatal-5 years in Rural Appalachia
Infants	Alternatives for Developmental Screening in Primary Care Crossing Cultural Boundaries: An Ethnographic Study Effect on Breastfeeding of Pacifiers and Bottle Feeding Evaluation of Hawaii's Healthy Start Program - Phase Two Home Nursing to Avoid Pediatric Hospitalization Home Versus Group Visits After Early Postpartum Discharge Infant ETS Exposure: Clinic-Based Maternal Counseling Maternal PKU Resource Mothers Program: A Clinical Trial Prenatal Antecedents of Infant Outcome Welfare Reform and the Perinatal Health of Immigrants

Injuries	Post-Traumatic Stress Disorder After Pediatric Traffic-Related Injury
Injury Prevention	Increasing Safety Seat Use Among Preschoolers
Lead Poisoning	Does Lead Burden Alter Neuropsychological Development?
Lead Poisoning Prevention	Does Education Limit Lead Burden?
Lead Poisoning Screening	Does Education Limit Lead Burden?
Learning Disabilities	Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two
Low Birthweight	Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two Reducing Preterm Birth by Bacterial Vaginosis Screening
Low Income Population	Adolescent Attitudes About Pregnancy African-American Children's Transition to School Alternatives for Developmental Screening in Primary Care Poverty and the Ecology of African-American Children Role of Early Family Supports in Adult Self-Sufficiency
Marital Conflict	Interparental Conflict and Adolescent Violence
Maternal Nutrition	Prospective Investigation of Twin Gestation

MCH Research	<ul style="list-style-type: none"> Adolescent Attitudes About Pregnancy Adolescent Health Care: A Comparison of Five Risk Adjustment Systems African-American Children's Transition to School Alternatives for Developmental Screening in Primary Care American Indian Fatherhood in Two Oklahoma Communities An Intervention for the Transition to Fatherhood Assessment of Enhanced Prenatal Care by Ethnically Diverse Women Behavior Problems in School-Aged Children of Teen Mothers Biomarkers of Infection and Risk of Preterm Delivery Choices of Life for Adolescence Success Comprehensive Elementary School AIDS Education Crossing Cultural Boundaries: An Ethnographic Study Does Education Limit Lead Burden? Early Child Care Study of Children with Special Health Needs Effect on Breastfeeding of Pacifiers and Bottle Feeding EICS Phase IV: Adolescence Evaluation of Hawaii's Healthy Start Program - Phase Two Evaluation of Hawaii's Healthy Start Program Factors Associated with Nutritional Intake in Adolescents Health Care Utilization: Pediatric Organ Transplantation Home Nursing to Avoid Pediatric Hospitalization Home Versus Group Visits After Early Postpartum Discharge Improved Prenatal Detection of the Fragile X Mutation Improving Health/Development of Low Income Pregnant Women Increasing Safety Seat Use Among Preschoolers Infant ETS Exposure: Clinic-Based Maternal Counseling Infant Temperament: Neonatal-5 years in Rural Appalachia Interparental Conflict and Adolescent Violence Life Around Newborn Discharge (LAND) Maternal Health and Pregnancy Outcomes Among Hispanics Maternal PKU Resource Mothers Program: A Clinical Trial National Practice-Based Network to Improve Children's Health Care Neighborhood and Family Effects on Adolescent Health Behaviors Office Systems to Improve Preventive Care for Children Post-Traumatic Stress Disorder After Pediatric Traffic-Related Injury Poverty and the Ecology of African-American Children Predicting African American Children's School Compliance Predicting the Need for Hospitalization in Childhood Asthma Prenatal Antecedents of Infant Outcome Preventing Mental Health Problems in Ill Children Prospective Investigation of Twin Gestation Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two Puerto Rican Young Fathers' Involvement with Their Children Reducing Preterm Birth by Bacterial Vaginosis Screening Responsiveness of CHIP to Children With Special Health Care Needs Role of Early Family Supports in Adult Self-Sufficiency Satisfaction with and Utilization of Prenatal Care Social Context of Puerto Rican Child Health and Growth Three-Generation Intervention Among Adolescent Mothers Use of Child Health Services by Hispanic Families Welfare Reform and the Perinatal Health of Immigrants
Medicaid	Satisfaction with and Utilization of Prenatal Care
Medicaid Managed Care	<ul style="list-style-type: none"> Assessment of Enhanced Prenatal Care by Ethnically Diverse Women Satisfaction with and Utilization of Prenatal Care
Mental Health	Preventing Mental Health Problems in Ill Children
Mental Retardation	Improved Prenatal Detection of the Fragile X Mutation
Metabolic Disorders	Maternal Health and Pregnancy Outcomes Among Hispanics

Mexicans	Health Care Utilization: Pediatric Organ Transplantation Interparental Conflict and Adolescent Violence Maternal Health and Pregnancy Outcomes Among Hispanics
Minority Groups	Social Context of Puerto Rican Child Health and Growth
Multiple Births	Prospective Investigation of Twin Gestation
Native Americans	American Indian Fatherhood in Two Oklahoma Communities Factors Associated with Nutritional Intake in Adolescents
Neonatal Mortality	Reducing Preterm Birth by Bacterial Vaginosis Screening
Neonates	Effect on Breastfeeding of Pacifiers and Bottle Feeding Home Versus Group Visits After Early Postpartum Discharge Life Around Newborn Discharge (LAND) Reducing Preterm Birth by Bacterial Vaginosis Screening
Newborn Screening	Life Around Newborn Discharge (LAND)
Nutrition	Factors Associatead with Nutritional Intake in Adolescents Life Around Newborn Discharge (LAND)
Outreach	Evaluation of Hawaii's Healthy Start Program - Phase Two Evaluation of Hawaii's Healthy Start Program
Pacific Islanders	Factors Associatead with Nutritional Intake in Adolescents
Parent Education	An Intervention for the Transition to Fatherhood Does Education Limit Lead Burden?
Parent Support Services	Preventing Mental Health Problems in Ill Children
Parenting Skills	Behavior Problems in School-Aged Children of Teen Mothers
Parents	An Intervention for the Transition to Fatherhood EICS Phase IV: Adolescence Health Care Utilization: Pediatric Organ Transplantation Interparental Conflict and Adolescent Violence Neighborhood and Family Effects on Adolescent Health Behaviors Preventing Mental Health Problems in Ill Children Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two
Patient Education	Office Systems to Improve Preventive Care for Children
Pediatricians	National Practice-Based Network to Improve Children's Health Care
Peer Counseling	Does Education Limit Lead Burden?
Peer Support Programs	Improving Health/Development of Low Income Pregnant Women
Perinatal Health	Home Versus Group Visits After Early Postpartum Discharge Reducing Preterm Birth by Bacterial Vaginosis Screening Welfare Reform and the Perinatal Health of Immigrants
Phenylketonuria	Maternal PKU Resource Mothers Program: A Clinical Trial

Pregnant Women	An Intervention for the Transition to Fatherhood Assessment of Enhanced Prenatal Care by Ethnically Diverse Women Biomarkers of Infection and Risk of Preterm Delivery Improved Prenatal Detection of the Fragile X Mutation Improving Health/Development of Low Income Pregnant Women Maternal PKU Resource Mothers Program: A Clinical Trial Prenatal Antecedents of Infant Outcome Reducing Preterm Birth by Bacterial Vaginosis Screening Satisfaction with and Utilization of Prenatal Care Welfare Reform and the Perinatal Health of Immigrants
Prenatal Care	Assessment of Enhanced Prenatal Care by Ethnically Diverse Women Prospective Investigation of Twin Gestation Reducing Preterm Birth by Bacterial Vaginosis Screening Satisfaction with and Utilization of Prenatal Care Welfare Reform and the Perinatal Health of Immigrants
Prenatal Diagnosis	Improved Prenatal Detection of the Fragile X Mutation Prenatal Antecedents of Infant Outcome
Prenatal Screening	Factors Associatead with Nutritional Intake in Adolescents Prenatal Antecedents of Infant Outcome Reducing Preterm Birth by Bacterial Vaginosis Screening
Preschool Children	Alternatives for Developmental Screening in Primary Care Crossing Cultural Boundaries: An Ethnographic Study Home Nursing to Avoid Pediatric Hospitalization Increasing Safety Seat Use Among Preschoolers Infant Temperament: Neonatal-5 years in Rural Appalachia Predicting the Need for Hospitalization in Childhood Asthma
Preterm Birth	Biomarkers of Infection and Risk of Preterm Delivery Reducing Preterm Birth by Bacterial Vaginosis Screening
Preventive Health Care	Office Systems to Improve Preventive Care for Children Post-Traumatic Stress Disorder After Pediatric Traffic-Related Injury
Preventive Health Care Education	Maternal PKU Resource Mothers Program: A Clinical Trial
Primary Care	Adolescent Attitudes About Pregnancy Alternatives for Developmental Screening in Primary Care Home Nursing to Avoid Pediatric Hospitalization National Practice-Based Network to Improve Children's Health Care
Professional Education in Adolescent Health	Adolescent Attitudes About Pregnancy
Psychological Evaluation	Does Lead Burden Alter Neuropsychological Development? Post-Traumatic Stress Disorder After Pediatric Traffic-Related Injury
Psychological Problems	Health Care Utilization: Pediatric Organ Transplantation Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two
Psychosocial Services	Health Care Utilization: Pediatric Organ Transplantation
Public Policy	Maternal Health and Pregnancy Outcomes Among Hispanics
Puerto Ricans	Puerto Rican Young Fathers' Involvement with Their Children Social Context of Puerto Rican Child Health and Growth Use of Child Health Services by Hispanic Families

Pulmonary Disease	Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two
Quality Assurance	Assessment of Enhanced Prenatal Care by Ethnically Diverse Women Home Nursing to Avoid Pediatric Hospitalization
Research	Adolescent Attitudes About Pregnancy Adolescent Health Care: A Comparison of Five Risk Adjustment Systems African-American Children's Transition to School Alternatives for Developmental Screening in Primary Care American Indian Fatherhood in Two Oklahoma Communities An Intervention for the Transition to Fatherhood Assessment of Enhanced Prenatal Care by Ethnically Diverse Women Behavior Problems in School-Aged Children of Teen Mothers Biomarkers of Infection and Risk of Preterm Delivery Choices of Life for Adolescence Success Comprehensive Elementary School AIDS Education Crossing Cultural Boundaries: An Ethnographic Study Does Education Limit Lead Burden? Does Lead Burden Alter Neuropsychological Development? Early Child Care Study of Children with Special Health Needs Effect on Breastfeeding of Pacifiers and Bottle Feeding EICS Phase IV: Adolescence Evaluation of Hawaii's Healthy Start Program - Phase Two Evaluation of Hawaii's Healthy Start Program Factors Associatead with Nutritional Intake in Adolescents Health Care Utilization: Pediatric Organ Transplantation Home Nursing to Avoid Pediatric Hospitalization Home Versus Group Visits After Early Postpartum Discharge Improved Prenatal Detection of the Fragile X Mutation Improving Health/Development of Low Income Pregnant Women Increasing Safety Seat Use Among Preschoolers Infant ETS Exposure: Clinic-Based Maternal Counseling Interparental Conflict and Adolescent Violence Life Around Newborn Discharge (LAND) Maternal Health and Pregnancy Outcomes Among Hispanics Maternal PKU Resource Mothers Program: A Clinical Trial National Practice-Based Network to Improve Children's Health Care Neighborhood and Family Effects on Adolescent Health Behaviors Office Systems to Improve Preventive Care for Children Post-Traumatic Stress Disorder After Pediatric Traffic-Related Injury Poverty and the Ecology of African-American Children Predicting African American Children's School Compliance Prenatal Antecedents of Infant Outcome Preventing Mental Health Problems in Ill Children Prospective Investigation of Twin Gestation Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two Puerto Rican Young Fathers' Involvement with Their Children Reducing Preterm Birth by Bacterial Vaginosis Screening Responsiveness of CHIP to Children With Special Health Care Needs Role of Early Family Supports in Adult Self-Sufficiency Satisfaction with and Utilization of Prenatal Care Social Context of Puerto Rican Child Health and Growth Three-Generation Intervention Among Adolescent Mothers Use of Child Health Services by Hispanic Families Welfare Reform and the Perinatal Health of Immigrants
Rural Population	Infant Temperament: Neonatal-5 years in Rural Appalachia
Safety Seats	Increasing Safety Seat Use Among Preschoolers

School Age Children	African-American Children's Transition to School Behavior Problems in School-Aged Children of Teen Mothers Crossing Cultural Boundaries: An Ethnographic Study Home Nursing to Avoid Pediatric Hospitalization Post-Traumatic Stress Disorder After Pediatric Traffic-Related Injury Predicting African American Children's School Compliance Predicting the Need for Hospitalization in Childhood Asthma Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two
School Dropouts	Choices of Life for Adolescence Success
School Health Programs	Comprehensive Elementary School AIDS Education Increasing Safety Seat Use Among Preschoolers
Schools	African-American Children's Transition to School Predicting African American Children's School Compliance
Screening	Adolescent Attitudes About Pregnancy Post-Traumatic Stress Disorder After Pediatric Traffic-Related Injury
Self Esteem	Preventing Mental Health Problems in Ill Children
Sexual Behavior	Adolescent Attitudes About Pregnancy Comprehensive Elementary School AIDS Education Interparental Conflict and Adolescent Violence Neighborhood and Family Effects on Adolescent Health Behaviors
Smoking During Pregnancy	Infant ETS Exposure: Clinic-Based Maternal Counseling
Specialized Care	Health Care Utilization: Pediatric Organ Transplantation
Standards of Care	Home Versus Group Visits After Early Postpartum Discharge National Practice-Based Network to Improve Children's Health Care Predicting the Need for Hospitalization in Childhood Asthma
State Programs	Alternatives for Developmental Screening in Primary Care
Stress	Post-Traumatic Stress Disorder After Pediatric Traffic-Related Injury Prenatal Antecedents of Infant Outcome
Support Groups	Improving Health/Development of Low Income Pregnant Women
Surveys	Factors Associatead with Nutritional Intake in Adolescents
Toddlers	Alternatives for Developmental Screening in Primary Care Crossing Cultural Boundaries: An Ethnographic Study Home Nursing to Avoid Pediatric Hospitalization
Trauma	Post-Traumatic Stress Disorder After Pediatric Traffic-Related Injury
Twins	Prospective Investigation of Twin Gestation
Urban Population	Adolescent Attitudes About Pregnancy Crossing Cultural Boundaries: An Ethnographic Study Neighborhood and Family Effects on Adolescent Health Behaviors
Violence	Interparental Conflict and Adolescent Violence
Violence Prevention	Interparental Conflict and Adolescent Violence

Attachment Behavior	Behavior Problems in School-Aged Children of Teen Mothers Infant Temperament: Neonatal-5 years in Rural Appalachia
Family Relations	An Intervention for the Transition to Fatherhood Behavior Problems in School-Aged Children of Teen Mothers EICS Phase IV: Adolescence
Attachment	Behavior Problems in School-Aged Children of Teen Mothers
Health Care Utilization	Adolescent Health Care: A Comparison of Five Risk Adjustment Systems Health Care Utilization: Pediatric Organ Transplantation Home Nursing to Avoid Pediatric Hospitalization Life Around Newborn Discharge (LAND) Predicting the Need for Hospitalization in Childhood Asthma Satisfaction with and Utilization of Prenatal Care Welfare Reform and the Perinatal Health of Immigrants
Psychosocial Factors	Three-Generation Intervention Among Adolescent Mothers
Child Abuse Prevention	Evaluation of Hawaii's Healthy Start Program
Paraprofessional Personnel	Evaluation of Hawai's Healthy Start Program - Phase Two Improving Health/Development of Low Income Pregnant Women
Community Health Aides	Improving Health/Development of Low Income Pregnant Women
Domestic Violence	Interparental Conflict and Adolescent Violence
Premature Labor	Reducing Preterm Birth by Bacterial Vaginosis Screening
Postpartum Women	Effect on Breastfeeding of Pacifiers and Bottle Feeding Home Versus Group Visits After Early Postpartum Discharge Life Around Newborn Discharge (LAND) Welfare Reform and the Perinatal Health of Immigrants

