

Active Projects

FY 1996
AND
FY 1997

Maternal and Child Health RESEARCH PROGRAM

Maternal and Child Health **RESEARCH PROGRAM**

Active Projects FY 1996 and FY 1997



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, Virginia

Cite as

National Center for Education in Maternal and Child Health. 1998. *Maternal and Child Health Research Program: Active Projects FY 1996 and FY 1997*. Arlington, VA: National Center for Education in Maternal and Child Health.

Maternal and Child Health Research Program: Active Projects FY 1996 and FY 1997 is not copyrighted. Readers are free to duplicate and use all or part of the information 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 98-68259
ISBN 1-57285-054-X

Published by:

National Center for Education in Maternal and Child Health
2000 15th Street, North, Suite 701
Arlington, VA 22201-2617
(703) 524-7802
(703) 524-9335 fax
Internet: info@ncemch.org
World Wide Web: 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 22182-2536
(703) 356-1964
(703) 821-2098 fax

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.

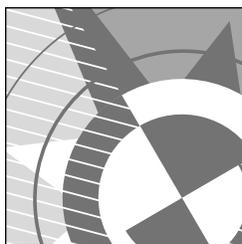


Table of Contents

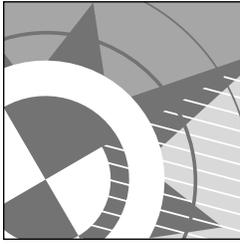
Preface	vii
An Analysis of Selected Performance Indicators for the Maternal and Child Health Bureau Research Program: FY 1996 and FY 1997	ix
Maternal and Child Health Bureau Research Grants Review Committee Roster of Members, FY 1996 and FY 1997	xix
Project Classification Guide	xxi
New Grants Awarded	
Infant ETS Exposure: Clinic-Based Maternal Counseling	3
<i>Melbourne F. Hovell, Ph.D.</i> San Diego State University	
Interparental Conflict and Adolescent Violence	7
<i>Jeanne Marie Tschann, Ph.D.</i> University of California	
Crossing Cultural Boundaries: An Ethnographic Study	11
<i>Cheryl Mattingly, Ph.D.</i> University of Southern California	
Home Versus Group Visits After Early Postpartum Discharge	15
<i>Tracy Lieu, M.D.</i> Kaiser Permanente	
Health Care Utilization: Pediatric Organ Transplantation	18
<i>Margaret Stuber, M.D.</i> University of California, Los Angeles	
Satisfaction with and Utilization of Prenatal Care	22
<i>Arden Handler, Dr.P.H., M.P.H.</i> University of Illinois	
Poverty and the Ecology of African-American Children	26
<i>Patricia J. O'Campo, Ph.D.</i> Johns Hopkins University	
Reducing Preterm Birth by Bacterial Vaginosis	30
<i>David Paige, M.D.</i> The Johns Hopkins University	
Improving Health/Development of Low Income Pregnant Women	35
<i>Lee Anne Roman, Ph.D., R.N.</i> Butterworth Health System	
Prospective Investigation of Twin Gestation	40
<i>Judith E. Brown, M.P.H., Ph.D.</i> University of Minnesota	

Factors Associated with Nutritional Intake in Adolescents	43
<i>Dianne Neumark-Sztainer, Ph.D., M.P.H., R.D.</i>	
University of Minnesota	
Choices of Life for Adolescence Success	47
<i>Larry E. Davis, Ph.D.</i>	
Washington University	
Effect on Breastfeeding of Pacifiers and Bottle Feeding	50
<i>Cynthia R. Howard, M.D.</i>	
University of Rochester	
Alternatives for Developmental Screening in Primary Care	54
<i>Harris Huberman, M.D.</i>	
Medical and Health Research Association of New York City, Inc.	
Home Nursing to Avoid Pediatric Hospitalization	58
<i>Kenneth McConnochie, M.D.</i>	
University of Rochester	
Role of Early Family Supports in Adult Self-Sufficiency	62
<i>Frances A. Campbell, Ph.D.</i>	
University of North Carolina at Chapel Hill	
Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two	66
<i>Lynn Singer, Ph.D.</i>	
Case Western Reserve University	
Early Cortisol Replacement to Prevent BPD: Pilot Study	70
<i>Kristi L. Watterberg, M.D.</i>	
Pennsylvania State University	
Predicting the Need for Hospitalization in Childhood Asthma	74
<i>Marc Gorelick, M.D.</i>	
University of Pennsylvania	
San Antonio Triethnic Children's Blood Pressure Study	78
<i>Shirley W. Menard, Ph.D., R.N.</i>	
University of Texas	
Maternal Birthweight and Reproductive Outcomes-Phase 2	81
<i>Irvin Emanuel, M.D.</i>	
University of Washington	
Infant Temperament: Neonatal to 5 Years in Rural Appalachia	84
<i>Margaret Fish, M.S., Ph.D.</i>	
Marshall University	
Office Systems to Improve Preventive Care for Children	88
<i>Peter Margolis, M.D., Ph.D.</i>	
University of North Carolina	

Continuation Grants

Indicators of Maternity Care in Medicaid Managed Care	95
<i>Carol Korenbrot, Ph.D.</i>	
The Regents of the University of California	
Watchful Waiting Versus Antibiotics As Soon As Possible	97
<i>Gabriel J. Escobar, M.D.</i>	
Kaiser Permanente	
Use of Child Health Services by Hispanic Families	99
<i>Sharon Telleen, Ph.D.</i>	
University of Illinois at Chicago	
Adverse Effects of Cow Milk in Infants	101
<i>Ekhard E. Ziegler, M.D.</i>	
University of Iowa Hospitals and Clinics	
Free β and HCG in Screening for Down Syndrome	103
<i>George J. Knight, Ph.D.</i>	
Foundation for Blood Research	
Three-generation Intervention Among Adolescent Mothers	105
<i>Maureen M. Black, Ph.D.</i>	
University of Maryland School of Medicine	
Growth and Development: Longitudinal Followup	109
<i>Maureen M. Black, Ph.D.</i>	
University of Maryland Medical School	
Regulatory Disorders and Developmental Outcomes	111
<i>Stephen W. Porges, Ph.D.</i>	
University of Maryland at College Park	
Evaluation of Hawaii's Healthy Start Program	113
<i>Anne K. Duggan, Sc.D.</i>	
Johns Hopkins University	
Injury Prevention in an Urban Pediatric Clinic	118
<i>Andrea C. Gielen, Sc.D.</i>	
Johns Hopkins University	
Development of Monitoring Methods for Perinatal Outcomes	121
<i>Patricia O'Campo, Ph.D.</i>	
Johns Hopkins University	
Preventing Mental Health Problems in Ill Children	123
<i>Henry T. Ireys, Ph.D.</i>	
The Johns Hopkins University	
Social Context of Puerto Rican Child Health and Growth	126
<i>Odette Alarcon, M.D.</i>	
Wellesley College	
Early Intervention Collaborative Study: Age 10 Follow-up	129
<i>Jack P. Shonkoff, M.D.</i>	
Brandeis University	

Homeless Mothers and Children: A Longitudinal Study	131
<i>Ellen Bassuk, M.D.</i>	
Harvard University Medical School	
Does Lead Burden Alter Neuropsychological Development?	133
<i>Elsa G. Shapiro, Ph.D.</i>	
University of Minnesota School of Medicine	
Does Education Limit Lead Burden?	135
<i>Amos S. Deinard, M.D., M.P.H.</i>	
University of Minnesota School of Medicine	
Mom/Kid Trial: A Multicomponent Abuse Prevention Program	137
<i>Lizette Peterson-Homer, Ph.D.</i>	
University of Missouri	
Improved Prenatal Detection of the Fragile X Mutation	140
<i>Edmund C. Jenkins, Ph.D.</i>	
Research Foundation for Mental Hygiene, Inc.	
Antenatal Formula Distribution: Effect on Breastfeeding	143
<i>Cynthia R. Howard, M.D.</i>	
University of Rochester School of Medicine	
Diarrheal Illness Surveillance in Child Day Care	146
<i>Kristen Weigle, M.D.</i>	
University of North Carolina	
African American Children's Transition to School	148
<i>Joanne Erwick Roberts, Ph.D.</i>	
University of North Carolina	
Pediatric Health Supervision to Promote Literacy	150
<i>Robert D. Needlman, M.D.</i>	
Case Western Reserve University	
Cost-Effective Emergency Department Screening for UTI Febrile Children	153
<i>Kathy Shaw, M.D.</i>	
Children's Hospital of Philadelphia	
Behavior Problems in School-age Children of Teen Mothers	155
<i>Robert J. McMahon, Ph.D.</i>	
University of Washington	
Early Child Care Study of Children with Special Needs	158
<i>Cathryn L. Booth, Ph.D.</i>	
University of Washington	
Maternal Birthweight and Reproductive Outcomes	161
<i>Irvin Emanuel, M.D., M.S.</i>	
University of Washington	
Clinician Help for Mothers of Infants with Lung Disease	164
<i>Karen F. Pridham, Ph.D.</i>	
University of Wisconsin School of Nursing	
Healthy People 2000 Objectives	167
Project Index	175
Subject Index	177



Preface

This publication presents information for each of the 51 research projects active under the support of the Maternal and Child Bureau (MCHB) Research Program in FY 1996 and FY 1997. The information is presented in summary form similar to that used for a companion publication reporting on research completed in 1994–1996. 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.

This publication is broadly divided into two sections—new and continuation projects. Within each of these sections, projects are ordered according to grant number. The first two digits of the grant number represent the State where the grantee institution is located (i.e., MCJ-01 = Alabama). Thus, new and continuation projects are also arranged alphabetically according to State.

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. The projects are indexed by title and by subject at the back of this publication.

Except for the information in the pre-award evaluations (new projects only), the content of the abstracts in the two sections 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.

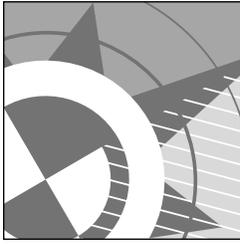
The information in the pre-award evaluation contains a synthesis of the written comments of the assigned reviewers as well as notes taken during the discussion that precedes the collective recommendation of the MCHB Research Grants Review Committee. This information is made available for several reasons. 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 1998



An Analysis of Selected Performance Indicators for the Maternal and Child Health Bureau Research Program: FY 1996 and FY 1997

I. Introduction

Supporting an applied research program is one of the many ways that MCHB meets its national responsibility to promote and improve the health of all mothers, children, and families. The MCHB Research Program, which has supported researchers since 1964, is administered by the Division of Systems, Education and Analysis, MCHB, Health Resources and Services Administration (HRSA). HRSA is an agency of the Public Health Service, which is part of the U.S. Department of Health and Human Services (DHHS).

The research supported by MCHB Research Program has traditionally been guided by a research agenda developed by a consensus of national experts. The research agenda, which was updated at a conference held in 1994, was first published as chapter 3 in the *Proceedings of the Fourth National Title V Maternal and Child Health Research Priorities Conference* (1996).¹ The research agenda, along with a subject index, is also part of the guidance materials sent to perspective applicants to the program. The guidance materials can also be accessed via the World Wide Web at www.os.dhhs.gov/hrsa/mchb. Since many of the investigators included in this publication had already begun or were just beginning their projects when the new research priorities agenda was released, a discussion of how these projects address the research priorities identified and published in 1996 will not be included in this publication. Future editions of this publication will contain a discussion of the research priorities being addressed by each of the projects.

Research projects are selected for support by the MCHB Research Program through the use of a peer review system similar to but independent of the National Institutes of Health (NIH) review system. This review group, or study section, called the Maternal and Child Health Bureau Research Grants Review Committee, is composed of non-government experts appointed by the Secretary of DHHS, plus an ex officio member from the National Institute of Child Health and Human Development (NICHD). The committee members are nationally recognized research scientists who are also experienced and knowledgeable in maternal and child health programs. Members are

¹For a copy of the *Proceedings*, contact the National Maternal and Child Health Clearinghouse, (703) 356-1964.

selected from the fields of biostatistics, developmental psychology, epidemiology, medical anthropology, nursing, nutrition, child development, obstetrics, pediatrics, sociology, social work, and public health. Special and collateral reviewers are sometimes used to supplement the Review Committee's expertise, when required by the volume and/or content of the applications received.

II. Applications Reviewed and Approved

A total of 201 applications were reviewed by the Research Program during the FY 1996 and FY 1997 review cycles. Fifty-seven (28.4 percent) of these applications were classified as noncompeting (i.e., continuations), and the remaining 144 (71.6 percent) as competing (see table 1).

Of the 144 competing applications reviewed in FY 1996 and FY 1997, 137 were new and 7 were competing extensions. The overall category of new applications comprises four subcategories: (1) new applications submitted to the MCHB Research Program for the first time; (2) new applications from the previous cycle, for which the review committee deferred recommendation for action; (3) revisions of previously disapproved new applications; and (4) revisions of previously approved applications that had remained unfunded because of an insufficient priority score. Competing extension applications are requests for additional funds to extend the project period of an ongoing project.

The rate of approval for all new applications combined was 16.8 percent. The approval rate was lowest for applications submitted for the first time (7.1 percent) and highest for competing extension applications (42.9 percent). The approval rate of 41.0 percent for the resubmission of previously disapproved applications reflects the conscious efforts of the Review Committee to be constructive in their reviews as well as the willingness of disapproved applicants to profit from the criticisms and suggestions for improvement made by reviewers. In general, the "gross" approval rate of 16.8 percent (the number of new applications recommended for approval by the committee, divided by the total number of new applications reviewed) is relatively low when compared to other Federal research programs such as those of NIH. The "net" approval rate (the number of new applications actually funded, divided by the total number of new applications reviewed) compares quite well with other Federal research programs, including those of NIH.

Of all new applications accepted for review during FY 1996 and FY 1997, 4 (12.1 percent) addressed medical concerns; 7 (16.7 percent) addressed behavioral health concerns; 8 (19.5 percent) addressed health services organization, use, and delivery; and 4 (19.0 percent) addressed epidemiological issues (see table 2). This distribution mirrors the MCHB's programmatic emphases on prevention, treatment, remediation,

TABLE 1				
<i>Number and Percentage of Applications Reviewed, by Type and Committee Recommendation: FY 1996 and FY 1997</i>				
Type of Application	Approved, No. (%)	Disapproved, No. (%)	Deferred, No. (%)	Total No.
All Types	83 (41.3)	108 (53.7)	10 (5.0)	201
New	23 (16.8)	105 (76.6)	9 (6.6)	137
New	7 (7.1)	86 (87.8)	5 (5.1)	98
Revised	16 (41.0)	19 (48.7)	4 (10.3)	39
Competing Extension	3 (42.9)	3 (42.9)	1 (14.3)	7
Continuation	57 (100)	0 (0.0)	0 (0.0)	57

program evaluation, and problem definition.

Unless there has been a significant departure from the originally approved project plan, a request for increased funding, and/or evidence that the project is experiencing difficulties in execution, continuing applications are ordinarily reviewed by program staff and, for the most part, are assured of continuing support for the duration of the originally approved project plan.

Approval rates by type of research ranged from a low of 12.1 percent to a high of 19.5 percent. Applications addressing health services had the highest approval rate (19.5 percent), followed by epidemiological (19.0 percent), behavioral (16.7 percent), and medical concerns (12.1 percent). Overall, the amount of variation in rates of approval by type of research is sizable but not necessarily suggestive of bias in the review process. The variation is likely to represent differences in research experience and capability in conducting research among those who apply. For example, applications addressing epidemiological and health services may come from service organizations with a lower level of documented experience and capacity in conducting research.

TABLE 2			
<i>Number and Percentage of New Applications, by Type of Research and Committee Recommendation: FY 1996 and FY 1997</i>			
Type of Research	Approved, No. (%)	Disapproved or Deferred, No. (%)	Total No.
All Types	23 (16.8)	114 (83.2)	137
Medical	4 (12.1)	29 (87.9)	33
Behavioral Health	7 (16.7)	35 (83.3)	42
Health Services	8 (19.5)	33 (80.5)	41
Epidemiological	4 (19.0)	17 (81.0)	21

III. Active Projects

Table 3 describes the active projects according to type of grantee. As expected, the grantees represented are those defined as eligible by the Research Program's authorizing legislation. Recipients of MCHB research grants are predominantly institutions of higher learning (70.6 percent), compared with children's hospitals and other research hospitals (13.7 percent) and other grantees (15.7 percent). Within institutions of higher learning, the schools of public health received the largest number of grants (25.4 percent). Schools of medicine and other subdivisions within institutions constitute 19.6 percent of the research grantees.

During FY 1996 and FY 1997, no State, county, or city health department received a grant through the MCHB Research Program, reflecting the small number of research applications submitted annually by these government entities. It is clear that much needs to be done to increase the level of participation by State, county, and city health departments in the MCHB Research Program.

The geographic distribution of the funded applicants favors Federal Regions in the Atlantic, Pacific, and Midwest (as shown in table 4). During FY 1996 and FY 1997, as in FY 1994 and FY 1995, only one grant was awarded to an institution in Region VI, and no grants were awarded to institutions in Region VIII. The factors that create unbalanced award distributions according to geographic region are difficult to pinpoint. However, geographic distribution is highly related to concentrations in population and wealth, which in turn are related to corresponding concentrations of institutions of higher learning as well as research and development centers.

During FY 1996 and FY 1997, approximately 53.2 percent of the principal investigators funded through the MCHB Research Grant Program are Ph.D.s and 38.3 percent are M.D.s (table 5). One investigator earned a joint M.D./Ph.D. degree. The M.D./Ph.D. disparity is typical of Federal extramural research programs in biomedical and health services. The traditional public health degrees, Sc.D. and Dr.P.H., are represented by about 6 percent of the principal investigators. The low percentage of degrees in the public health category is due, in part, to the relatively small

TABLE 3		
<i>Number and Percentage of New Applications, by Type of Grantee: FY 1996 and FY 1997</i>		
Type of Grantee	Number	Percentage
All Types—Total	51	100.0
Research Hospitals	7	13.7
Institutions of Higher Learning	36	70.6
Schools of Medicine	10	19.6
Schools of Public Health	13	25.4
Schools of Nursing	2	3.9
Other Subdivisions	11	21.5
All Other Grantees	8	15.7

TABLE 4		
<i>Active Projects by Federal Region: FY 1996 and FY 1997</i>		
Federal Region	Number	Percentage
All Regions	51	100.0
Region I	4	7.7
Region II	5	11.5
Region III	13	25.0
Region IV	4	7.7
Region V	10	19.2
Region VI	1	1.9
Region VII	3	5.8
Region VIII	0	0.0
Region IX	7	13.5
Region X	4	7.7

FY 1995, 28 percent of the projects used an experimental study design, and 24 percent used a quasi-experimental design. The remaining 48 percent employed an observational study design. These percentages indicate a high degree of scientific rigor for the research supported by the MCHB Research Program.

A high degree of scientific rigor is also reflected when the time dimension of the study design is taken into consideration. As figure 2 indicates, the majority (78.9 percent) of the projects

number of such degrees awarded nationally. In total, 47 principal investigators have undertaken the research described in the 51 projects presented in this book. More women (61.7 percent) than men (38.3 percent) received MCHB research grants in FY 1996 and FY 1997.

Figure 1 presents the 51 active projects according to three study design characteristics: Experimental, quasi-experimental, and observational. The experimental category includes randomized clinical control trials; the quasi-experimental category includes case/matched control, case/unmatched control, case/historical control, and interrupted time-series studies. Observational design studies are purely descriptive or correlational. Slightly more than half (51 percent) of the active projects employ either an experimental or quasi-experimental study design; the remaining 49 percent are observational. During the previous cycle in FY 1994 and

TABLE 5		
<i>Academic Degrees of Principal Investigators: FY 1996 and FY 1997</i>		
Types of Degree	Number	Percent
All Degrees	47	100.0
Ph.D.	25	53.2
M.D.	18	38.3
M.D./Ph.D.	1	2.1
Sc.D./Dr.P.H.	3	6.4

currently funded by the MCHB Research Program are longitudinal. These include short-term as well as long-term longitudinal studies and reflect the nature of the research supported by the program. This research, for the most part, is concerned with characterizing, defining, and measuring risk factors for unwelcome outcomes. This type of research requires that the agent or exposure thought to define risk precede the outcome of concern. During the FY 1994 and FY 1995 cycles, 76 percent of the projects were longitudinal, and 9 percent were cross-sectional, mirroring the distribution among the FY 1996 and FY 1997 projects.

Figure 3 shows the 51 active projects according to care emphasis. The care emphasis distinguishes projects that are interventional from those that are noninterventional in nature. In medicine and public health, intervention is used for a variety of activities designed to prevent, limit, or improve conditions in order to enhance the health of individuals and groups. As a group, intervention studies address a variety of maternal and child health problems and represent an inadequately tapped resource of tested approaches to solving maternal and child health problems at the State and community levels. In the FY 1996 and FY 1997 cycles, slightly less than half (46.2 percent) of the projects are interventional in nature, compared with 33 percent during the FY 1994 and FY 1995 cycles. The majority of the interventional studies presented in this publication are preventive rather than remedial or curative in intention; most of these projects use experimental designs with blind measurements and employ standardized protocols for delivering and mon-

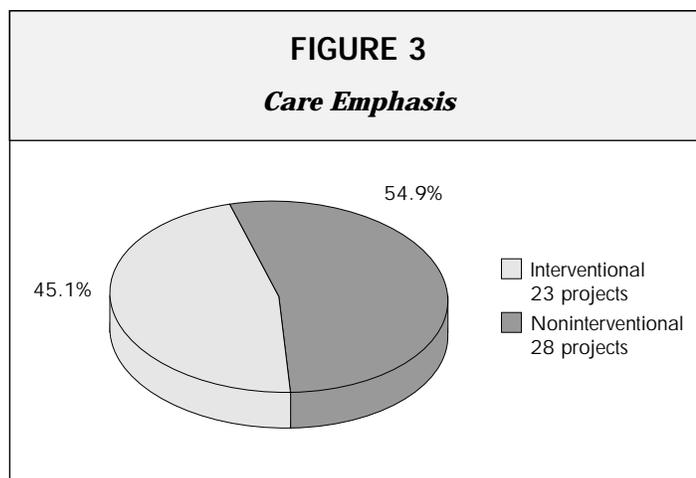
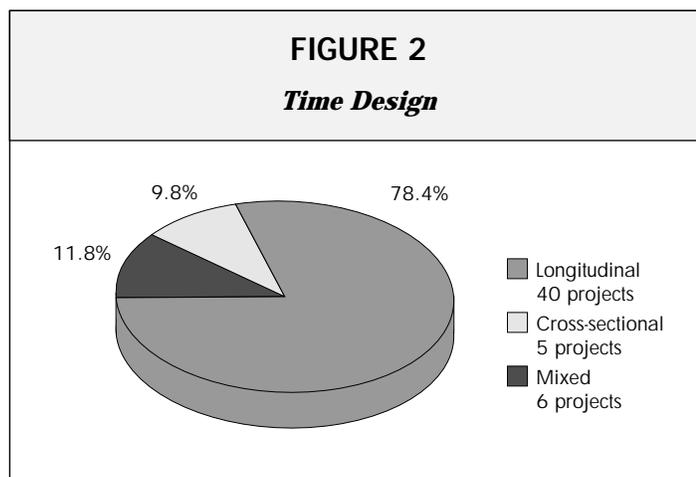
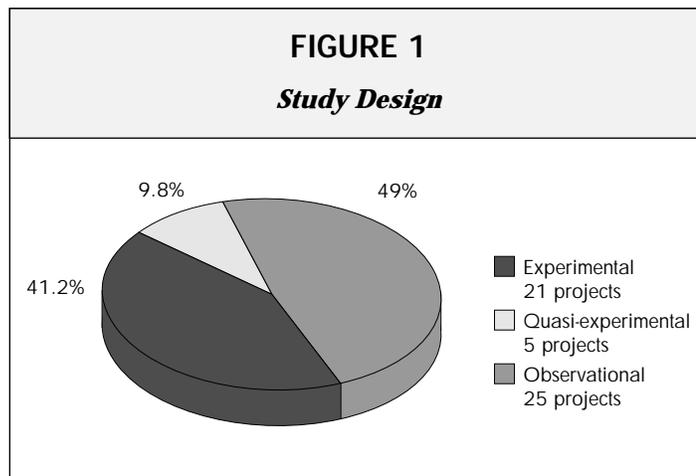


TABLE 6		
<i>Population Focus: FY 1996 and FY 1997</i>		
Population	Number of Projects	Percentage of Projects Studying Specific Populations
Neonates	16	31.4
Infants	24	47.1
Toddlers	16	31.4
Preschool Children	16	31.4
School-Age Children	16	31.4
Adolescents	8	15.7
Adolescents (Pregnancy-related)	1	2.0
Pregnant Women	11	21.6
Parents/Mothers/Fathers (Adolescent Parents)	22 1	43.1 2.0
Other		
Grandparents	1	2.0
Physicians	1	2.0
Postpartum Women	5	9.6
Young Adults (older than age 21)	1	2.0

TABLE 7		
<i>Racial and Ethnic Group Focus: FY 1996 and FY 1997</i>		
Racial/Ethnic Focus	Number of Projects	Percentage
Total	51	100.0
Racial/Ethnic Focus	29	56.9
Group-Specific	18	35.3
Between Groups	11	21.6
No Stated Racial/Ethnic Focus	22	43.1

itoring the array of services constituting the interventions.

Table 6 shows the populations being studied by the 51 projects. Many of the active projects described in this publication focused on more than one population (e.g., infants and toddlers) within the same scope of research. Of the 51 projects listed here, 24 (47.1 percent) chose infants as a population focus. Twenty-two projects (43.1 percent) studied populations of parents, mothers, and fathers. Only one project focused on pregnancy in an adolescent population.

Research grants are routinely tracked to determine whether they have a racial/ethnic focus. Projects are classified as such if the investigators have stated that they seek to elucidate some aspect of the health of minority women and children, using either a within-group or a between-group study

design. Table 7 shows the distribution of all active projects according to whether they have a stated racial/ethnic focus. Of the 51 projects, 29 (56.9 percent) have a racial/ethnic focus; this represents a 10-percent increase over the number of such studies in FY 1994 and FY 1995 (45.7 percent). Of the 29 projects having a racial/ethnic focus, 18 use a group-specific study design, and 11 use a between-group study design. Twenty-two of the projects (43.1 percent) have no stated racial or ethnic focus. However, some of these projects have sufficient numbers in

their samples to conduct minority analyses, and the principal investigators of these projects have been so informed.

As indicated in table 8, the research projects having a racial/ethnic focus are predominantly studying African-American populations. Twenty-four of the 29 projects with a racial/ethnic focus have identified African Americans as one or more of their minority study populations. Nine of the projects focus on Mexican Americans, and seven projects focus on Puerto Ricans. However, more research needs to be conducted to elucidate maternal and child health concerns among Alaskan Native, Chinese, Japanese, Pacific Islander, and Hawaiian Native populations.

Research projects are also tracked according to the specific *Healthy People 2000* objectives addressed by each study. The number of objectives addressed by the project ranged from zero to 19. (This does not imply that projects addressing fewer objectives are less rigorous or of less interest to the MCH community.) Not surprisingly, 43 of the 51 projects address *Healthy People 2000* objectives in maternal and infant health; 32 address objectives in diabetes and disabling conditions, and 25 address objectives in mental health and mental disorders. Table 9 lists the 22 topic areas addressed in *Healthy People 2000* and indicates the number of MCHB active projects conducting research in these topic areas during FY 1996 and FY 1997. (A listing of the specific *Healthy People 2000* objectives related to the current research studies can be found in the back of this publication.)

TABLE 8

***Specific Racial and Ethnic
Group Focus:
FY 1996 and FY 1997***

Racial/Ethnic Focus	Number of Projects
Total	29
African-American Only	14
Mexican-American Only	2
Puerto Rican Only	1
Mexican-American and Puerto Rican	1
African-American and Mexican-American	2
African-American and Puerto Rican	1
African-American and Hispanic (Hispanic overall)	1
African-American, Mexican-American, Puerto Rican, and Native American	1
African-American, Alaskan Native, Mexican-American, Puerto Rican, and Native American	1
Japanese, Filipino, and Hawaiian Native	1
African-American, Asian (Asian overall) Mexican-American, Puerto Rican, and Native American	1
African-American, Chinese, Filipino, and Hispanic (Hispanic overall)	1
African-American, Asian (Asian overall) Mexican-American, Puerto Rican, and Native American	1
African-American, Pacific Islander, Hispanic (Hispanic overall), and Native American	1

TABLE 9

***Healthy People 2000 Objectives
(by Topic Area and by Number of Projects
Addressing Specific Topic Area):
FY 1996 and FY 1997***

Topic Area	Number of Projects Addressing This Topic Area
1. Physical Activity and Fitness	5
2. Nutrition	16
3. Tobacco	5
4. Alcohol and Other Drugs	1
5. Family Planning	2
6. Mental Health and Mental Disorders	25
7. Violent and Abusive Behavior	13
8. Educational and Community-Based Programs	17
9. Unintentional Injuries	9
10. Occupational Safety and Health	0
11. Environmental Health	7
12. Food and Drug Safety	0
13. Oral Health	3
14. Maternal and Infant Health	43
15. Heart Disease and Stroke	4
16. Cancer	4
17. Diabetes and Chronic Disabling Conditions	32
18. HIV Infection	1
19. Sexually Transmitted Diseases	2
20. Immunization and Infectious Diseases	7
21. Clinical Preventive Services	11
22. Surveillance and Data Systems	12

IV. Summary

The distribution of active projects by geographic region and by type suggests that an initiative is needed to generate strong applications from certain regions of the country as well as from State, county, and local health departments.

Information on the study design indicates a high degree of scientific rigor in the research studies supported by the MCHB Research Program. This is corroborated by the high rate of publications per project and the quality of the peer-reviewed journals publishing findings from the research projects supported by the MCHB Research Program.² The number of intervention projects represented in this publication suggests that the MCHB Research Program is fulfilling its responsibility to develop new program components for MCHB. Efforts should be expanded to increase both the awareness and adoption of these research-tested interventions at State, county, and local levels.

Data on the racial/ethnic focus of the active projects support the conclusion that the MCHB Research Program has made progress in addressing the health of minority mothers and children, particularly among African-American populations. Although more research studies are needed to address the MCH concerns of other minority populations, this should not obscure the fact that the MCHB Research Program provides crucial support for research in minority health issues.

²See *Maternal and Child Health Research Program: Completed Projects 1994-96*.

The diversity of the populations being studied in the 51 projects indicates that the MCHB Research Program is funding a broad portfolio of research, with projects focusing on populations throughout the developmental continuum as well as on maternal and women's health issues. The number of *Healthy People 2000* objectives addressed by the current projects attests to the fact that maternal and child health is a multidisciplinary, cross-cutting field encompassing education, nutrition, mental health, chronic disabling conditions, and other areas of special interest to the MCH research community.

Gontran Lamberty, Dr.P.H.

Director, Maternal and Child Health Bureau Research Program

October 1998



Maternal and Child Health Bureau Research Grants Review Committee

Roster of Members, FY 1996 and FY 1997

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 946110-5714

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

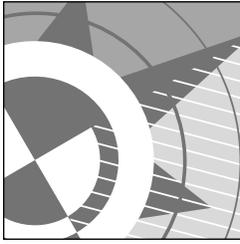
Francisco A. Villarruel, Ph.D.
Department of Family and
Child Ecology
Michigan State University
East Lansing, MI 48824-1030

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.

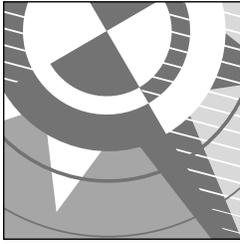
Race/Ethnic Focus

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**

New Grants Awarded





Infant ETS Exposure: Clinic-Based Maternal Counseling

Grantee

San Diego State University

Investigator

Melbourne F. Hovell, Ph.D.
Center for Behavioral Epidemiology
7051 Alvarado Road, Suite B
La Mesa, CA 91941
(619) 667-4730
(619) 667-0660 fax

Project Number MCI-060634

Project Period 6/1/96-5/31/00

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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			

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, Toddler, Parents, Mothers

Race/Ethnic Focus

None

Summary***Statement of the Problem***

Babies' exposure to environmental tobacco smoke (ETS) is a significant problem. 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

The study tests a behavioral counseling intervention designed to reduce ETS exposure in children younger than 1 year of age. Specific aims are to (1) determine the effects, as measured by mothers' reports and results of babies' urine cotinine analyses, of clinic-based behavioral counseling on ETS exposure in babies of low socioeconomic status (SES); (2) validate parent-reported ETS exposure measures with 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

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 group or the “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 Description and Sampling Plan

A total of 150 English-speaking mothers and Spanish-speaking mothers will be recruited from clients 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

Change in ETS exposure between experimental and control groups will be evaluated with 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

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 vari-

ables, 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

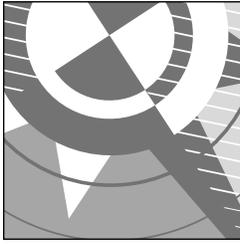
reactivity threat be handled?

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.



Interparental Conflict and Adolescent Violence

Grantee

University of California

Investigator

Jeanne Marie Tschann, Ph.D.
Department of Pediatrics
3333 California Street, Suite 11
San Francisco, CA 94143-0962
(415) 476-7761
(415) 476-7744 fax

Project Number MCJ-060702

Project Period 1/1/97–12/31/2000

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			

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

Race/Ethnic Focus

Hispanics—Mexican Americans

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 project 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

This longitudinal research study 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 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 for 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 address precisely the associations between conflict and child outcomes.

Population Description and Sampling Plan

This study sample will comprise 303 adolescents and their parents who are participating in currently funded research as study subjects. Adolescents ages 15–18 and their parents will be interviewed individually by telephone 3 times at 6-month intervals. Families will be recruited from the membership of Kaiser Permanente, a large health maintenance organization serving northern California.

Analysis Plan

Scales will be developed for this research, and 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 with latent variable structural equation modeling (SEM). The model will be tested separately for white families and for Mexican-American families. Following this, differences between Mexican Americans and whites will be assessed with 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 multigroup analysis will include only those scales common to both groups.

Pre-Award Evaluation

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 addi-

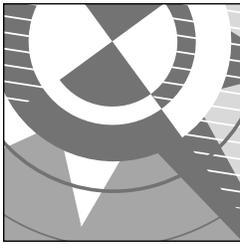
tional information. The first issue concerned the reliability and validity of data obtained through telephone interviews. The investigators provide a detailed response to this question, citing the advantages of data collection by phone rather than face-to-face interviews (namely, ease of scheduling and 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 aggres-

sion, 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.



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 MCI-060799

Project Period 12/1/96–11/30/97

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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

Noninterventional

Population Focus

Infants, Toddlers, Preschool Children, School
Age Children, Families

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

This study concerns problems 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, race/ethnicity, and community affiliation. When practitioners and family members interact, their values, assumptions, and perceptions of 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 policymakers 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 treatment decisions, 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 provide family-centered care. 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. Misunderstandings about the nature of the disability and the focus of the treatment intensify when the child is from a cultural background that differs significantly from that of the clinic culture.

Research Questions or Hypotheses

The research questions that 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. The purpose of this 3-year ethnographic study is to examine (1) how the problems of children with special health care needs are variously understood or framed by family members and health care practitioners, (2) the influence of different frames or understandings on the intervention process, (3) the process undertaken by family members and practitioners to negotiate or impose alternative views, and (4) the impact of these multiple perspectives on the effectiveness of interventions.

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 illustrate 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 and experiences in caring for 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 (i.e., African-American families from inner-city neighborhoods).

Population Description and Sampling Plan

The research team will follow 30 African-American children with special health care needs (ages newborn to 8), their families, and the health care providers that serve them. The study period will be approximately 3 years.

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 3-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. (Emic refers to the culture-specific framework for making sense of experience; etic refers to the outside researcher's perspective.) Emic categories and meaning will be derived from open-ended and narrative interviews, which allow respondents to reflect on and describe their experience in their own words. Etic categories will be derived from the theoretical literature in medical ethnography, psychological anthropology, and ethnography of organizations. Overall research direction for the analysis will be guided by

the four team members (principal and co-principal investigators and two research associates) primarily responsible for data collection. These team members will meet weekly.

Pre-Award Evaluation

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 or 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.

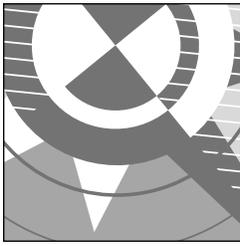
In preparation for the study's implementation, the principal investigators during recent months have (1) gained entry to the primary clinical site (CHLA); (2) identified and gained entry to a transition site (CCS); (3) established initial working relationships with key clinicians at both sites; (4) identified 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.



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 1/1/98–6/30/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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			

Year 2000 Objectives
14.14

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates, Infants, Postpartum Women

Race/Ethnic Focus

None

Summary

Statement of the Problem

Hospital discharge of mothers and newborns 48 hours or less after uncomplicated delivery is now standard practice throughout the United States. Recently enacted legislation mandates reimbursement for routine stays up to 48 hours only. However, it is essential that the newborn and the mother be examined on the third day postpartum, when jaundice peaks and lactation begins. Providers vary in how follow-up examinations are offered—as home visits, individual clinic visits, or group visits—and 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 decreased risk for adverse health outcomes if assigned to receive a home visit rather than a group clinic visit on the third day postpartum.

Study Design and Methods

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

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.



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
e-mail: mstuber@npimain.medsch.ucla.edu

Project Number MCI-060839

Project Period 12/1/97–11/30/2002

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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

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

Noninterventonal

Population Focus

School Age Children, Adolescents, Parents

Race/Ethnic Focus

Hispanics—Mexican Americans

Summary

Statement of the Problem

The use of organ transplantation has transformed a number of previously fatal childhood illnesses into chronic conditions. In exchange for survival, children must experience a lifetime of immunosuppressive medications and are 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; it is further complicated when families have tangible obstacles to care, such as restricted or insufficient health insurance coverage, lack of transportation to the transplant center, and inadequate English language skills. Families are followed by nurse coordinators and social workers as part of routine care after transplant. However, concerns about costs are increasingly limiting the availability of psychosocial assistance for children and their parents, despite evidence that psychosocial intervention can decrease the need for medical care utilization and can improve functional outcomes.

Research Questions or Hypotheses

The goal of this study is to identify psychosocial factors that can be readily assessed on an ongoing basis and that may be amenable to supportive or specific psychosocial intervention. The study also seeks to identify those psychosocial factors that are predictors of increased medical and psychosocial health care utilization or of poor functional outcome.

Study Design and Methods

This longitudinal study will assess five major predictor variables: (1) Availability of tangible resources, (2) social support, (3) socioeconomic status, (4) acculturation, and (5) medical insurance. Four outcome variables will be assessed: (1) medical utilization costs, (2) support service utilization, (3) patients' functional outcomes, and (4) parents' functional outcomes.

Use of psychosocial support services will be monitored by each pediatric transplant worker and nurse coordinator, who will maintain biweekly logs of the amount of time spent in face-to-face or telephone contact with enrolled families. Functional outcome will be assessed by self-report of the primary caregiving parents and by information obtained from the transplant recipient and teacher. Patients' dimensions to be assessed include schoolwork, behavior, pain, self-esteem, and social relationships. Parents' dimensions include financial stress, job functioning, psychological distress, and disruption of social ties.

Evaluation of cost outcome variables will be accomplished through review of billing records and reports from the transplant social workers and nurse coordinators.

Moderator variables, such as type of organ transplant, age at transplant, type of illness leading to transplant, and medical complications, will be statistically controlled for.

Population Description and Sampling Plan

In total, 150 pediatric kidney, heart, and liver transplant recipients who received their care at the University of California at Los Angeles (UCLA) Center for the Health Sciences will constitute the sample for this study. UCLA is one of the largest and most established transplant centers in the country. The study popula-

tion will include Spanish-speaking families of Mexican and Central American origin.

Families will be assessed at 24, 36, and 48 months after transplant, through 1-hour face-to-face or telephone interviews. Typically, 3–4 years after transplant, a maintenance regimen is in place, and vigilance and contact with the treatment center may decrease. This is why the study team chose to focus on the period 2–4 years after transplant, since this is the time when family psychosocial factors are likely to assume a dominant role in determining outcome.

Analysis Plan

The primary tests of significance will be multiple regression analyses in which predictor and moderator variables are included. Exploratory regressions will be conducted to investigate possible interaction effects. The study teams will demonstrate a link between psychosocial services and improved functional outcomes for children with organ transplants. By defining the predictive factors of interest, the study team seeks to develop a standardized psychosocial screening instrument to identify at-risk families, as well as supportive or compensatory psychosocial interventions.

Pre-Award Evaluation

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 bidirectional nature of support and outcomes, it seems appropriate to address this issue as part of the over-

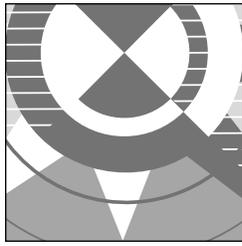
all scope of the project. Exploring causal relationships more precisely seems especially important because this study is intended to provide the groundwork for future psychosocial interventions.

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.



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

Project Number MCJ-170835

Project Period 10/1/97-9/30/2000

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			

Year 2000 Objectives

14.1, 14.5, 14.11, 14.14, 14.16, 22.4

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

Pregnant Women

Race/Ethnic Focus

African Americans

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, between 32 and 37 percent of African-American women who start care before the third trimester 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. The information gained from this study can be used in the design of interventions or 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:

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.

-
- b. The relationship between care characteristics and satisfaction does not differ between African-American women who receive medicaid assistance (medicaid recipients) and African-American women who do not receive medicaid assistance (non-medicaid recipients).
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 non-medicaid recipients.

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 Description and Sampling Plan

The study sample will comprise 590 African-American women obtaining prenatal care at one of four health centers that are part of Humana Health Care Plans, Inc., 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 non-medicaid clients.

Women will be recruited at each of the four sites on the day of their prenatal care appointment. To qualify for the study, women must be 18 years of age or older, length of gestation must be less than 29 weeks, and they 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 validity and reliability measures.

Pre-Award Evaluation

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

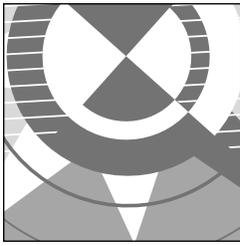
length of gestation at time of interview will be considered in the analysis. Questions concerning the timing of the interview and subsequent measures of satisfaction have been addressed by more rigorous description of the interview and the medical-record abstraction protocol.

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.



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 Broadway
Baltimore, MD 21205
(410) 550-5448
(410) 955-2303 fax
e-mail: pocampo@phnet.sph.jhu.edu

Project Number MCI-240731

Project Period 10/1/96-9/30/99

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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			

Year 2000 Objectives

6.3, 6.14, 22.4

Study Design

Observational

Time Design

Cross-sectional

Care Emphasis

Noninterventonal

Population Focus

Preschool Children, Parents

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

Children raised in poverty are at increased risk for poor developmental outcomes, and African-American children are more likely to live in poverty and to experience persistent poverty more often than other children. As a result of overrepresentation of African Americans among the socioeconomically disadvantaged, the research literature on socioeconomic differences in child-rearing and parenting behavior and the effects of those differences on child development is often interpreted as descriptive of normative patterns of parenting and child development in African-American populations.

Research Questions or Hypotheses

The goal of this project is to contribute to the developmental literature by examining the ecological, situational, and cultural factors that shape behavior and place African-American children on certain developmental trajectories. The findings of this study will have implications for the design of intervention programs for minority groups living in poverty.

Study Design and Methods

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 families and their children ages 3 to 4-1/2 who are living in Baltimore study neighborhoods 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 increased risk or resilience in African-American children.

Pre-Award Evaluation

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 con-

ceptual 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.

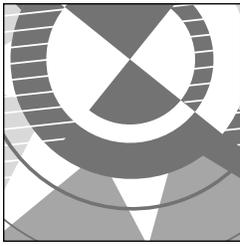
The investigator has been responsive to the concerns raised in the previous review. The research is well-designed and sophisticated in its approaches. It has many creative features that add to the potential contribution of the findings. The recommendation is for approval with the condition that the investigator 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.



Reducing Preterm Birth by Bacterial Vaginosis

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 MCI-24C701

Project Period 10/1/97-9/30/2002

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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			

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 Americans

Summary

Statement of the Problem

Despite the dramatic decrease in the infant mortality rate over the past several years, preterm and low-birthweight 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 twice the number of preterm live births and more than twice the low-birthweight births as white women. Despite advances in the science of obstetrics, we have a limited understanding of the basic causes of preterm labor, low birthweight, and intrauterine growth retardation.

It is known that the determinants of low birthweight include genetic, social, environmental, and behavioral factors, as well as underlying medical or biological conditions. However, in many cases of premature birth, no association with a pathologic factor can be identified. Newly published experimental data suggest that infections of the genital tract may contribute to as many as 40 percent 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 child-bearing women today. BV doubles the risk of spontaneous preterm delivery, and, in data from experimental models, has been associated with a number of other adverse birth outcomes. The incidence of BV is nearly three times greater in pregnant African-American women than in pregnant white women. Half of the population of pregnant African-American

women with BV are asymptomatic, and current prenatal care in the 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 women with asymptomatic BV can contribute to a significant reduction in the high rates of preterm and low-birthweight births among pregnant African-American women.

Research Questions or Hypotheses

This community-based intervention study is designed to determine the effect of a BV screening/treatment program that will be integrated into existing prenatal services. The program will identify and treat asymptomatic and symptomatic pregnant African-American women with BV 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 of 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.

In this project, all study participants presenting at four urban clinics will be screened for BV at initial prenatal examination. Patients with confirmed BV will be treated with 250 mg of metronidazole 3 times a day for 7 days, or with .75 percent metronidazole vaginal cream twice a day for 5 days. These patients will be tested when they return following treatment therapy; if the infection is still present, they will be retreated.

The study involves a five-period cross-over design lasting more than 30 months. During this time, each clinic will enroll patients in either the treatment or the control component of the study during alternating 6-month periods.

Outcome variables include the incidence of preterm births, the 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's sex; maternal age; parity; prior incidence of low birthweight or preterm birth; and socioeconomic status.

Population Description and Sampling Plan

The sample will comprise an estimated 2,500 pregnant African-American women from 4 East Baltimore community clinics. Approximately 750 of these women are expected to be symptomatic and will be treated as usual. Of the remaining 1,750 asymptomatic women, half will be screened for BV in the treatment component at some point prior to 33 weeks' gestation. Those who test positive in the treatment component will receive immediate treatment and followup treatment as needed. Partners of asymptomatic women in the treatment component will also be assessed and treated whenever possible.

Analysis Plan

Data analysis will consist primarily of exploratory data analysis and logistic regression.

Pre-Award Evaluation

Originality and Importance

The purpose of this study is to implement a screening program for bacterial vaginosis (BV) within a community-based prenatal care system that serves high-risk women. The study aims to demonstrate that a reduction in preterm births among African-American women can be achieved as a result of the detection and treatment of asymptomatic BV.

Regional and National Significance

Reducing the incidence of preterm births is a topic of regional and national significance and is relevant to the mission of the Maternal and Child Health Bureau.

Scientific and Technical Merit

During the initial review, members raised a number of concerns. A primary concern, namely, that the application did not fit the guidelines for a Community Integrated Service Systems (CISS) research award, has been fully addressed in the current revision. The investigators have now included a very good summary of how the application meets each of the 13 special requirements. These are clearly spelled out and adequately addressed.

Other concerns identified in the initial review have been individually addressed as specific revisions in the current application. The investigators argue convincingly that their proposed study would complement the ongoing Maternal Fetal Medicine (MFM) Network study of BV; that study is seeking to determine whether treatment of BV will reduce the risk of preterm delivery in low-risk women with asymptomatic BV. This proposal will study an overall high-risk group and treat both symptomatic and asympto-

matic women diagnosed with BV. The proposed study population differs from that of the MFM Network in that this study is community-based rather than drawn from a selection of women in specific centers, and provides data on the feasibility of applying findings to community-based medical centers.

In the earlier review, concern was expressed about using two different treatment regimens, oral vs. vaginal treatment with metronidazole. Although both are acceptable treatments, there is still disagreement as to whether they should be viewed as equivalent. The investigators argue well that a very low number of women will likely need treatment with vaginal metronidazole; however, it is recommended that they consider this group separately in their analyses, at least preliminarily. Patient and partner information will also be collected on other sexually transmitted diseases. This information is routinely available in the patient's antepartum record, and more detailed information on the partner will be collected in the study. When feasible, the partner will be included in treatment.

Some issues still require clarification. Reviewers expressed concern that the BV status of patients enrolled during the nonintervention (control) periods would be unknown. Women enrolled during nonintervention periods will be screened for BV at time of delivery, but this will not yield information on the BV status of these women during their second trimester, at time of enrollment. Although this method is better than not collecting any information, the two groups will not be comparable, since BV may be acquired much later in pregnancy when it might not be a cause of preterm labor and delivery.

The investigators do not clearly state whether they will perform recruitment in the same way during the intervention and nonintervention periods. If formal recruitment is not performed during the nonintervention periods, it would have important implications for many other aspects of conducting the study

and analyzing the data. Even with formal consent in the two periods (because of the cross-over design), it would be important to monitor the percentage of refusal in each time period and to be cautious about the comparability of the populations being studied. The investigators also state that the study will “as a practical matter, enroll all women who meet the criteria outlined above.” The meaning of this is not clear: Will women who refuse to enroll have their medical records abstracted and included in the analysis?

The application does not specifically describe how the group of symptomatic women will be identified. Will every woman during both the intervention and nonintervention periods be asked a specific set of questions? Given the fact that the investigators focus on the asymptomatic group and use only that group to determine the number of subjects required, it is also important that the symptomatic women be identified in a consistent and systematic way in both the intervention and nonintervention periods.

Two questions remain concerning the role of the community workers. The application states that each clinic will have its own community worker 20 hours per week. First, this is not reflected in the revised budget, which lists the same personnel for the same number of hours as the previous submission (i.e., two workers at 30 hours each). Second, is the community worker present at the clinic only 20 hours per week, or are the individuals employed full-time by the clinic but with half of their salary paid by the study? The number of hours during which the community worker is physically present at the clinic has important implications for recruitment.

The issue of monitoring patients under treatment was raised in the last review, and the investigators addressed this by stating that there would be no additional monitoring because it might introduce confounding (since the intervention would no longer involve only treatment of BV). The proposal

now notes the following forms of monitoring followup for compliance and side effects: (1) Medication calendar; (2) followup appointment within 2–4 weeks; (3) counseling if compliance is less than 80 percent; (4) ability to receive care when presenting at unscheduled times; (5) daily review by community worker of clients’ missed appointments and followup class, and written followup from project personnel; and (6) provider/nurse contact with women receiving metronidazole to check for side effects. Is this the same followup currently used for other patients receiving treatment for BV?

The investigators have increased the study population from 2,000 to 2,500, and have presented new power calculations. These calculations are based on changes in outcome for asymptomatic women only (875 screened and unscreened subgroups). It is not clear why the investigators have chosen to base their power calculations on an odds ratio with an estimated standard error. They report an overall study power of 84 percent to detect a difference in the rate of preterm births. However, if one performs power calculations (which is the more direct way of comparing the expected rate of preterm births in the two asymptomatic groups [25.7 percent unscreened, 20.6 percent screened]), the power to detect a difference is only 72 percent. Overall, the study seems to lack adequate power.

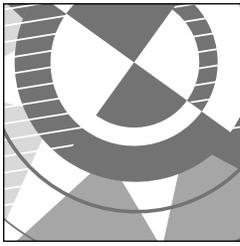
In addition, the investigators propose screening women in the unscreened group at delivery and comparing the rate of preterm births in the asymptomatic, BV-positive women from the screened and unscreened groups. The investigators suggest that this approach will improve the power of their comparisons. There are a substantial number of problems with this approach. First, the investigators estimate that they will be able to perform delivery screening on only 80 percent of women (though the basis of that estimate is not given). For delivery screening to be valid, data

need to be presented indicating that the ability to obtain a screen is not related to the presence of BV and prematurity. Also, for some women, BV status at delivery may not reflect BV status earlier in pregnancy. In addition, there are logistical problems, since collection of the specimens at delivery will need to rely on nonstudy personnel and may be inconsistent. Finally, if these specimens are not clinically indicated, who will pay for them? The addition of this element does not seem to add substantially to the protocol.

The extent of community integration involved in this study is also unclear. Community involvement relates to the study being conducted in four community clinics, with four community liaisons involved. Funding for these community liaisons was not apparent in the grant proposal.

Finally, some aspects of the study still seem unrealistic, although the community involvement component may be of help. For example, the participating women are supposed to keep detailed diaries of their medication regimen. It seems unlikely that this will be entirely successful, yet the proposal contains no discussion or provisions to address this issue, which lies at the heart of treatment compliance.

Overall, this revised application is an improvement. Concerns remain about adequate power and various aspects of the conduct of the study. The recommendation is for approval with the following conditions: (1) The plan to screen women in the unscreened group at delivery should be eliminated; and (2) the principal investigator should address in writing the issues described in this summary statement.



Improving Health/Development of Low Income Pregnant Women

Grantee

Butterworth Health System

Investigator

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

Project Number MCI-260743

Project Period 10/1/96–9/30/99

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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			
Year 5			

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, Postpartum Women

Race/Ethnic Focus

None

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 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 Description 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 prena-

tal 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.

Pre-Award Evaluation

Originality and Importance

Using community health workers (CHWs) to bridge sociocultural differences is an intervention strategy that is receiving increased attention. However, current research focuses on the differing effects of nurse versus CHW interventions. A model that teams CHWs and nurses and integrates services and welfare initiatives could provide a great opportunity for reaching low-income women and children.

Regional and National Significance

This project will provide data to evaluate a CHW-nurse team intervention targeting low-income women—clearly a population in need. Given the importance of developing and evaluating intervention programs for this population to help ensure the health of the Nation's mothers and children, this project is of regional and national significance.

Scientific and Technical Merit

This application is a revised version of a previously disapproved proposal. The concerns raised in the original review were the lack of specificity in describing the intervention, the tenuous links between the intervention and the outcomes, the lack of a complete cost analysis component, and several other methodological problems. The principal investigator has responded to these concerns both in a cover letter and by changes made to the proposal itself. In general, the principal investigator has been responsive to the concerns raised in the previous critique.

As noted in the previous review, this proposal is well-written and has a number of strengths. It addresses a problem of clear national significance: The health

and development of low-income pregnant women and their infants. It builds upon the Community Integrated Service Systems (CISS) initiative by adding an evaluation of a program that is already in place.

The literature review appears to be comprehensive. It points out that, although there are good data suggesting that home visiting by nurses and other professionals has positive benefits for low-income pregnant women, the effectiveness of programs that use CHWs rather than professionals needs to be evaluated. Such programs are becoming more common, may be more cost effective, and may reach a segment of this population that does not trust health care professionals. However, there has been no experimental trial of such an intervention, and a trial is necessary if CHW programs are to gain widespread support in the health care community.

Pilot data suggest that the conceptual framework underlying the CHW program—that stress and anxiety are negatively related to measures of self-esteem, mastery, and social support—is valid. But there has been no correlation of these measures to low birthweight or gestational age. Other pilot data supported by the March of Dimes suggest that the community worker model in fact reaches young women in low-income communities.

The review of the previous proposal noted that, although an ecological framework was mentioned, the conceptual models underlying the interventions were not truly ecological: There was no nesting of effects nor any framework in which to view the environment. The principal investigator responds that an ecological model is simply one that includes both person and environment as well as their transactions, and the investigator presents an elaborated graphic depicting the model. Whether the model is termed ecological or not, the conceptualization is not radically different from many other early intervention programs in that the stresses posed by living in poverty

are expected to be buffered by peer support, resulting in better outcomes.

There was also some confusion in the previous proposal about which variables were considered primary outcomes and which were secondary. The principal investigator has delineated these more clearly: The primary outcomes are personal stress, personal psychological resources, and maternal life-course development. The intervention is hypothesized to reduce personal stress and enhance the use of personal resources and maternal life-course development. Secondary outcomes include birthweight, gestational age, measures of parenting and infant development, costs to the parent and to government agencies, prenatal medical risks, and the mother's need for support.

Although a rationale for measuring the primary outcomes twice prenatally and three times in the postnatal period was requested, it was not provided. The proposal simply says that "change across time" is the focus of the study. It would certainly be more economical to use a simple before-and-after design with a control group to evaluate the effect of the intervention on the primary and secondary outcomes. The need for multiple measures and points is still not clear.

The previous review noted that the intervention activities were not well-specified. The principal investigator has responded by including the activities that the paraprofessional advocates and parent volunteers will conduct during the intervention. Although the inclusion of this material was helpful, there still appears to be no detailed plan for how often each activity will be undertaken, how many activities might be scheduled for a home visit, and how the activities will be conducted differently for women who cannot read or for women who do not speak English. How the empowerment intervention will be implemented remains unclear, which means that its generalizability may be limited.

A further concern is that the principal investigator does not address the cultural appropriateness of the empowerment intervention for the diverse groups expected to be in the study. The principal investigator anticipates that the sample will be approximately one-third white, one-third African American, and one-third Hispanic. Are some of the intervention activities (i.e., the “self-esteem” and “assertiveness” activities) going to be equally appropriate for all of these groups? Are the primary outcomes equally valid for these groups? It appears that not enough care has been taken to ensure that the evaluation instruments are appropriate for the study’s diverse sample.

The distribution of racial/ethnic groups does not appear to be equal across the four clinic sites. If this is true, the intervention and evaluation site and race/ethnicity will be confounded. Even if racial/ethnic groups are equally distributed across clinics, the analysis has made no provision for estimating any effects due to recruitment site. In the proposed study, subjects are nested within clinics, yet this is not taken into account in the analysis.

The recruitment protocol is another concern. It will depend on a telephone or home visit contact by a research assistant, not a peer. If this trial is to have maximum impact, it must enroll the women at highest risk who are presently choosing to opt out of the standard home visiting program. If peer support is proposed as a way to empower low-income women, why not have CISS advocates/volunteers who are most skilled in working with such women do the recruitment?

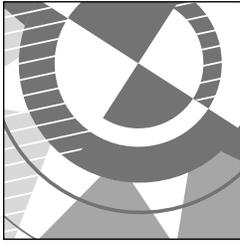
Because study participants will be repeatedly tested, there are probably not enough requested personnel to keep up with the data collection. As indicated in the timeline, it will be necessary to collect primary outcome data on 150–200 subjects per month for 12 months. Yet, only two full-time research assistants are proposed for the study. The workload of these indi-

viduals will be very high, especially since only one of them will speak Spanish.

The budget underestimates the need for research assistants and overestimates the request for coinvestigators. Fifty percent of the principal investigator’s time will be spent on the project, and there is a 1.0 FTE field coordinator for the project. A full-time secretary and 200 hours of consulting are also included in the budget.

Although the resubmitted proposal is an improvement and addresses an important national problem, a number of limitations still need to be resolved. The recommendation is for approval with the condition that the principal investigator

1. Justify the appropriateness of the intervention itself (e.g., in terms of empowerment) for the culturally diverse sample;
2. Defend the appropriateness of the primary outcome measures for the culturally diverse sample;
3. Offer assurance that the recruitment procedures will help enroll women who are most at risk because of their mistrust of health professionals;
4. Provide information about the number of contacts and activities performed in the intervention group; and
5. Address the issue of differences by clinic in sample characteristics and the implementation of the program and its measures.



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 55454-1015
(612) 626-7934
(612) 624-0315 fax
e-mail: EPIVAX.EPI.UMN.EDU

Project Number MCI-270756

Project Period 10/1/96-9/30/99

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			

Year 2000 Objectives

2.8, 14.5, 14.6, 14.14

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

Neonates, Pregnant Women

Race/Ethnic Focus

None

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 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 Description 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

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 liter-

ature 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.



Factors Associated with Nutritional Intake in Adolescents

Grantee

University of Minnesota

Investigator

Dianne Neumark-Sztainer, Ph.D., M.P.H., R.D.
School of Public Health
1300 South 2nd Street #300
Minneapolis, MN 55454
(612) 624-0880
(612) 624-0315 fax
e-mail: neumark@epivax.epi.umn.edu

Project Number MCI-270834

Project Period 7/1/97–6/30/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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			

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

Race/Ethnic Focus

African Americans, Asian-Pacific Islander,
Hispanics—General, Native Americans

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.

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 Description 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

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.



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 MCI-290644

Project Period 10/1/96–9/30/99

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			

Year 2000 Objectives

8.2

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

Adolescents

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

Little attention has been paid to how African-American adolescents make important life decisions. Although deciding whether to stay in school is one of the most important decisions made by youth, little is known about this decision-making process. Understanding why most youth persevere and receive their high school diplomas, while some 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 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. The stability of adolescent attitudes and perceptions will be examined, as will differences in the profiles of adolescents who drop out of school early compared with those who drop out later.

Study Design and Methods

Questionnaire packets will be administered to study subjects in groups of 20 at the beginning of their junior and senior years. Data will be collected on the

number of unexcused absences, suspensions, and expulsions, as well as on academic rank. Other study measures will 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 Description and Sampling Plan

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

Analysis Plan

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

Pre-Award Evaluation

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 pro-

vided 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.



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
 e-mail: choward@rghnet.edu

Project Number MCJ-360752

Project Period 10/1/96–9/30/99

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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			
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

None

Summary

Statement of the Problem

H *Healthy People 2000* goals state that 75 percent of women in this country 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 to 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 with 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 breastfeed successfully 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 for adverse breastfeeding outcomes, and those exposed to later pacifier introduction and no supplemental feeding at lower risk.

The specific study hypotheses are as follows:

1. Early pacifier use (within 2–5 days of birth) as compared with 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 with late pacifier use (after 4 weeks of age) 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 with 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 and the number 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 in a sample of breastfed infants the effects of artificial nipple exposure 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 cup feeding or bottlefeeding in the supplemental feeding intervention.

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 Description 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 the normality of continuous variables will be checked. Comparability of the intervention groups will be analyzed with 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

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.

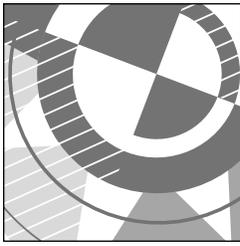
The research will be carried out in a community hospital with 2,800 deliveries each year. This hospital includes a high proportion of women who deliver healthy infants and choose to breastfeed them. The data collection forms are already available. The principal investigator has developed these for another 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.



Alternatives for Developmental Screening in Primary Care

Grantee

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

Investigator

Harris Huberman, M.D.
40 Worth Street
Room 720
New York, NY 10013
(212) 766-2535
(212) 766-2542 fax

Project Number MCI-360833

Project Period 10/1/97–9/30/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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 Children

Race/Ethnic Focus

African Americans, Hispanics—General

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 2.
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 completed by the primary caregiver 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, 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 fam-

ily, 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 Description 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 H, 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 8 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 H 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.

Pre-Award Evaluation

Originality and Importance

The main goal of the proposed research is to determine whether the use of a parent-completed developmental questionnaire will be a reliable screen for use in low-income urban areas characterized by high-risk families and unstable housing situations. The proposed study involves a randomized clinical controlled trial that seeks to compare three approaches to developmental screening within a public health agency/primary care clinic context. The proposal addresses a research question of importance to the Maternal and Child Health Bureau, and the investigators contend that answers to the research questions posed by the study could support the utility of a public health/primary care strategy and help lead to a cost-efficient model adaptable for wider use in at-risk programs.

Regional and National Significance

The proposed research has the potential to provide important information to the MCH community about approaches to developmental screening in public health clinics. The degree to which income, maternal education, risk status, and other factors predict outcomes within high-risk families is of great importance to the lives of children in unstable situations. All of these factors affect the communities in which these families live. The prospective findings are likely to have a high degree of applicability in the deliv-

ery of health care. Clearly, this research project has both regional and national significance.

Scientific and Technical Merit

This application, initially reviewed at the MCHB Research Program's review cycle in November 1996, was deferred at that time, pending clarification of two issues. The reviewers asked for a more comprehensive and detailed data analysis plan that would include the suggested analyses on racial/ethnic data. As suggested by the review panel, the investigators have sought statistical consultation and have revised their data analysis plan to more adequately address the research questions. The revised analysis plan is much improved, and a consulting statistician has been included as part of the research team.

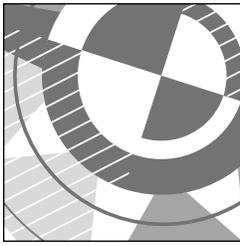
The reviewers requested additional information on the reliability and validity of the ASQ with a low-income Hispanic population (similar to the population to be included in the proposed research). The researchers have provided additional information that, although based on small samples, appears promising enough to justify a more intensive data collection effort as proposed in this study.

As noted in the earlier review, the budget is appropriate but could be reduced. The sample informed consent form submitted by the researchers is still unclear in some areas. For example, the statement that "the benefit of the study will be to help assure that my child receives these assessments regularly" may be misleading. The review committee also believes that it is important to review the Spanish-language version of the consent form (which was not submitted for review), because literal translations can be confusing.

The reviewers judged the application to be very well written and technically strong. The research plan is logically and sequentially presented, and its details

are justified with economy and clarity. The study will have broad policy implications for infant screening practices. A particular strength of the proposed research is that it builds on a close collaboration between a public health agency and primary care providers. The use of the ASQ is another strength, since this scale is designed for parent response and has gained acceptance in the early intervention community. The research questions that address whether receiving a parent newsletter would facilitate children/parents remain-

ing in their medical home and would encourage parents to complete the screening instruments will potentially provide useful information. The researchers have been very responsive to the concerns raised by the review panel, and the issues have been clarified. Approval is recommended, with the condition that funding should not proceed until the MCHB Research Program receives a copy of the Spanish-language version of the informed consent form.



Home Nursing to Avoid Pediatric Hospitalization

Grantee

University of Rochester

Investigator

Kenneth McConnochie
 School of Medicine and Dentistry
 Department of Pediatrics
 601 Elmwood Avenue
 Rochester, NY 14642
 (716) 275-7813
 (716) 273-1079 fax

Project Number MCI-360836

Project Period 10/1/97-9/30/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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 Children,
 Adolescents

Race/Ethnic Focus

None

Summary

Statement of the Problem

Hospitalization accounts for almost 50 percent 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 hospitalized children could be delivered in alternative settings. The study team proposes a home nursing enhancement of primary care (HNEPC) as a new alternative to hospitalization for children who have common illnesses.

Research Questions or Hypotheses

The purpose of this study is to evaluate the home nursing program in Monroe County, New York. The main study phase will address the following questions:

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 for episodes eligible for randomization and on overall community hospitalization rates?
4. What will be the cost of care for episodes randomized to different groups?
5. Will quality of care for illness episodes in the treatment group be equal to or better than in the control group?

Study Design and Methods

Following are the essential characteristics of the HNEPC design: (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) the 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. Funding for the preparation phase has been secured.

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

During the main study phase, 1,590 patients with acute illness episodes who present to the hospital emergency department will be randomized to either 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 those in the control group.

To address the efficacy and effectiveness of the intervention in terms of quality of care, outcome variables to be measured will include number of illness days, amount of time needed to return to normal activity, medical record review, impact of illness on family, family/nurse/provider satisfaction with quality of care, and subsequent use of hospitalization. Potential confounding variables to be assessed include socioeconomic variables and severity of illness.

Population Description and Sampling Plan

Of the expected 9,399 patients ages 1 month to 19 years in the likely clinical groups presenting to the emergency department, a total of 1,767 will be eligible for randomization based on meeting the inclusion criterion. After refusals are accounted for, a total of 1,590 patients will be included, with 795 assigned to the treatment group and 795 to the control group. After patients are accepted in the randomization component of the study, their care will be determined by joint decision of the provider and the family. HNEPC will be available only in the treatment component of the study.

Analysis Plan

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

Pre-Award Evaluation

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 like-

lihood 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.

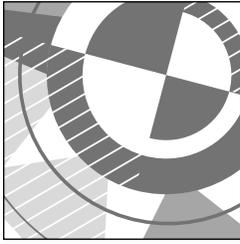
Responding to the first and third points, the research team proposed a scientific advisory board consisting of specialists and experts in four main areas: Community and preventive medicine, nursing, biostatistics, and health services-economic decision analysis. Furthermore, two consultants would be added, 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.



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 27599-8180
 (919) 966-4529
 (919) 966-7532 fax

Project Number MCI-370632

Project Period 6/1/96-5/31/00

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			

Year 2000 Objectives

8.2, 8.3

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Parents, Young Adults

Race/Ethnic Focus

African Americans

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 subjects. The study seeks to address the problem of identifying the ecological, personal, and situational factors associated with outcomes for participants in young adulthood.

Further study of long-term outcomes from early intervention is also important from a practical point of view. Billions of dollars are allocated annually to improve the educational performance of low-income children. Adult outcomes from a previous intervention program, the Perry Preschool Project, suggested that every dollar spent on early childhood education resulted in an eventual savings of \$8 because of increased employment and reduced crime. The Abecedarian Project, which provided similar but more intensive early educational treatment, affords a unique opportunity to learn whether the findings of the Perry Preschool Project can be replicated in another sample.

Research Questions or Hypotheses

The assessment of the long-term outcomes of the Abecedarian Project addresses a major scientific question: The malleability of intellectual/cognitive development given early environmental support and enrich-

ment. The current followup study will examine the degree to which early educational treatment is reflected in different developmental trajectories and in the concurrent life adjustment of young adults. 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. Specifically, the project will document whether earlier effects of care contribute to adult competence, and whether contextual and personal variables modify the effect and are related to the trajectory of development. Parental outcomes will also be examined among participants for whom the preschool intervention represented a significant family support: free child care.

Study Design and Methods

This is a prospective, longitudinal, randomized clinical trial. The Wechsler Adult Intelligence Scale-Revised will measure general intelligence. The Woodcock-Johnson Psycho-Educational Battery-Revised will 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 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. The Scale of Independent Living, an instrument developed specifically for this study, 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 assess locus of control. The Multi-Group Ethnic Identity Measure (MEIM) will measure three aspects of racial identity: Positive ethnic attitudes and sense of belonging, ethnic identity achievement, and ethnic behaviors and practices. Adapted from the Saranson's Life Events Scale, the Taylor Life Events Inventory will be used with low-income families and modified to include events in the past year relevant to young adults.

Population Description and Sampling Plan

The original sample was first recruited between 1972 and 1977. All study participants had incomes within then-current Federal poverty guidelines, and 98 percent were African American. Infants with physical disabilities or syndromes associated with retardation were ineligible for inclusion. The original sample comprised a total of 111 children from 109 families. The current study will follow 105 young adults from 103 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 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

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.

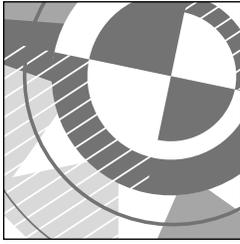
Data will be obtained from the young adults

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.



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 MCI-390715

Project Period 2/1/97-1/31/2001

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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			

Year 2000 Objectives

6.3, 6.13, 6.14, 17.2, 17.15, 22.4, 6.5

Study Design

Quasi-experimental

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

School Age Children, Parents

Race/Ethnic Focus

African Americans

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

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 Description 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

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.

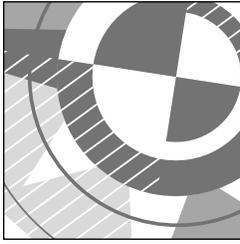
The review panel requested additional information on the meaning of study findings concerning lower performance by BPD infants at 3 years on receptive, but not on expressive, language skills. In the revised application, the investigators speculated that the receptive language deficit may be due to undetected 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.



Early Cortisol Replacement to Prevent BPD: Pilot Study

Grantee

Pennsylvania State University

Investigator

Kristi L. Watterberg, M.D.
Milton S. Hershey Medical Center
P.O. Box 850
Hershey, PA 17033
(717) 531-8412
(717) 531-8985 fax

Project Number MCJ-420633

Project Period 6/1/96–5/31/98

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	97,912	51,218	149,130
Year 2	110,362	57,730	168,092
Year 3			
Year 4			
Year 5			

Year 2000 Objectives

14.1, 17.2

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates

Race/Ethnic Focus

None

Summary

Statement of the Problem

Bronchopulmonary dysplasia (BPD), chronic lung disease following neonatal lung injury, affects a majority of extremely low birthweight (ELBW) babies (< 1,000 grams birthweight) and is a leading cause of morbidity and mortality in this population. Oxygen toxicity and barotrauma have been postulated as etiologic factors; increasing evidence also implicates inflammation in its pathogenesis. Corticosteroids are essential for the resolution of inflammation and have a myriad of other effects on lung development, structure, and function. Both basal cortisol concentrations during the first week of life and cortisol secretion in response to adrenocorticotrophic hormone (ACTH) stimulation at the end of the first week of life are significantly lower in babies who subsequently develop BPD than in those who recover. ELBW babies also have been reported to show symptoms consistent with adrenal insufficiency early in life, responsive to hydrocortisone (HC) supplementation. Early, high-dose steroid therapy in the first 2 weeks of life has been reported to decrease the incidence of BPD; however, these very large doses also produce unwanted side effects and may not be necessary.

Research Questions or Hypotheses

This pilot study is designed to estimate the benefits and safety of supplementation with physiologic doses of HC during the first 12 days of life to decrease the incidence of subsequent BPD. The results of

this pilot study will be tested to calculate an appropriate sample size for a future multicenter trial. The secondary hypothesis is that this therapy will improve physiologic stability during the treatment period.

Study Design and Methods

The study design is a randomized, placebo-controlled, single-center trial. The relationship of clinical outcome to the adrenal axis will be assessed for 17-OH progesterone, II-desoxycortisol, dehydroepiandrosterone, and cortisol, through analysis of blood samples obtained at days 1 and 6, and for ACTH on day 6. After the infant's completion of HC therapy, cortisol response to ACTH will be tested. The relationship of these factors to inflammation will be assessed by analyzing tracheal lavage specimens for markers of lung inflammation (interleukins 1 β , 6, and 8; elastase; and inflammatory cells) and by measuring cell adhesion molecules (CD18 and CD62L) on peripheral blood neutrophils with flow cytometry.

Population Description and Sampling Plan

Forty intubated newborns between 500 and 999 grams birthweight will be enrolled before 48 hours of life and treated with HC or placebo for 12 days. Primary measures of efficacy will be survival without oxygen dependence at 28 days of life and 36 weeks postconception. Secondary clinical variables will be indicators of adrenal insufficiency during the therapy period.

Analysis Plan

Evaluating acute and long-term clinical outcome measures in conjunction with laboratory measures of adrenal hormones and inflammation will allow a pre-

liminary assessment of both the clinical efficacy of early cortisol replacement therapy and the relationship between that level of efficacy and one pathophysiologic mechanism: inflammation. This pilot study would thus provide a basis for both multicenter clinical trials of efficacy and further elucidation of the pathophysiology of BPD.

Pre-Award Evaluation

Originality and Importance

Bronchopulmonary dysplasia (BPD) affects about 30 percent of all babies weighing less than 1,500 grams at birth and is a leading cause of morbidity and mortality in this population. Oxygen toxicity and barotrauma have been postulated as etiologic factors; increasing evidence also points to inflammation as a factor.

Corticosteroids are essential for reducing inflammation. Cortisol secretion in response to ACTH stimulation at the end of the first week of life is significantly lower in babies who subsequently develop BPD than in those who recover. It also has been reported that immature babies with symptoms consistent with adrenal insufficiency are responsive to hydrocortisone supplementation.

Regional and National Significance

This study will help determine whether supplementation with physiologic doses of hydrocortisone (HC) during the first 12 days of life will decrease the incidence of subsequent BPD by dampening an exaggerated inflammatory response. The study will also provide information on whether this therapy will improve physiologic stability during the treatment period.

The study will investigate the effect of cortisol replacement therapy on adrenal hormone concen-

tration and the ability of the adrenal gland to respond to ACTH. The effect of replacement therapy on markers of inflammation in lung lavage fluid and peripheral blood leukocytes will also be determined. Therefore, this study clearly is of regional and national significance.

Scientific and Technical Merit

This submission is a revision of a previously disapproved application. The hypotheses posed by this double-blinded, randomized, placebo-controlled trial are carefully stated and testable. An extensive literature review is presented in support of the hypotheses. Preliminary work done by the investigators supports the proposal and demonstrates their expertise and capabilities to perform the work as proposed.

The magnitude of the HC dose will be modified based on a pilot study currently underway to evaluate the pharmacokinetics of exogenous HC. The dose will be given for 9 days and will be tapered for 3 days at half the original dose. Adverse effects—in particular, disseminated candidal infections—are anticipated to occur after 12 days, but other factors may affect this, and the need for long therapy cannot be examined in this study.

The description of the laboratory studies (involving adrenal hormone analysis, tracheal aspirate measures, and cell surface adhesion molecules) appears adequate. The proposal addresses quality control methods for consistency of treatments, data collection, and comparability of lab tests.

Exclusion and inclusion criteria are addressed, but questions remain. Of interest is the occurrence of congenital sepsis in patients and their need to withdraw from HC therapy. What is the likelihood of this happening, and will sepsis rates be monitored? The exclusion of these patients will surely affect the sam-

ple size of a later trial.

The application does not clearly explain the factors that are not known but must be known to plan the major trial (e.g., the effect of mortality censoring on the ability to assess the benefits of cortisol, and the need to withdraw from study medications). Power analysis is not an issue here, but monitoring selected outcomes and situations to determine the feasibility of a future study is.

A sample of 40 babies is quite big for a pilot study. The proposed data analyses seem appropriate, but performing them on all 40 infants may be overkill.

The principal investigator and coinvestigator will remain blinded to the study. How will this be accomplished? Who will be responsible for breaking randomization codes, and who will make recommendations to continue/discontinue/modify the study?

No interim analyses will be performed, and there is not much information about the nature of the expected attrition. Will the attrition be in the form of refusal to participate or withdrawal from the study?

Members of this research team have published numerous articles on this topic and are well-qualified to conduct the proposed research. The budget for the statistical analysis seems very generous in light of the sample size.

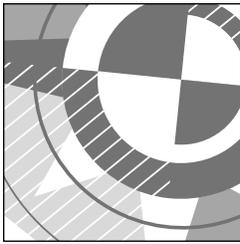
The research questions posed by this study are important. The application document is well-written and, for the most part, technically sound. The recommendation is for approval, with the condition that the principal investigator clarify whether all eligible babies will be enrolled sequentially, at intubation, at 12–48 hours, or at other times. A strong case can be made for including all 500–999-gram babies, since mechanical ventilation occurs early or is not always used for BPD (BPD as defined equals 28 days of oxygen use). As a second condition for approval, the principal investigator must provide explicit criteria for the following:

1. Under what conditions would the investigators feel ethically bound to stop the trial?

2. Because the babies being studied are extremely sick, it is likely that there will be tremendous pressure to break codes in the case of certain infants. What will be the criteria for individual babies exiting the trial?

3. Data collection forms should be provided.

4. Handling of certain variables (sex, severity of illness, use of antenatal steroids, presence of maternal chorioamnionitis, etc.) must be made explicit for the analytic phase.



Predicting the Need for Hospitalization in Childhood Asthma

Grantee

University of Pennsylvania

Investigator

Marc Gorelick, M.D.
School of Medicine, Department of Pediatrics
Center for Clinical Epidemiology and
Biostatistics
712 Blockley Hall, 423 Guardian Drive
Philadelphia, PA 19104-6021
(215) 898-1484
(215) 573-5315 fax
e-mail: gorelick@cceb.med.upenn.edu

Project Number MCJ-420832

Project Period 8/1/97-7/31/2000

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 Children, School Age Children,
Adolescents

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

Substantial health resources in the United States are devoted to the 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 have not been defined to distinguish those children needing hospitalization from those who can be safely discharged from an emergency department.

The creation of a new tool to improve accuracy of prediction of short-term outcomes in acute childhood asthma will reduce 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 that 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 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 val-

idated 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 and clinical information. This assessment will be obtained from the parents in roughly five domains: Demographic data; precipitating history of the current asthmatic episode; asthma history; use of asthma medication; and information on access to medical care. Short-term outcomes of this prospective study will be assessed by telephone interview or in visits with all subjects. Patients requiring admission will be defined as those actually admitted who continue to have wheezing or oxygen saturation less than 95 percent 12 or 24 hours after presentation, as well as those discharged from the emergency department who subsequently require admission within 7 days of the initial visit.

Population Description and Sampling Plan

Approximately 768 children ages 2 years and older who are treated for acute asthma through the emergency department of the Children's Hospital of Philadelphia will constitute the sample for this study. The population is primarily African American.

To assess relapse, all parents of patients initially discharged will be interviewed by phone on days 1 and 7 after initial presentation.

A random sample of 20 percent of initially discharged patients will be asked to return for clinical assessment. Parents will be provided free treatment, transportation, and meal vouchers to maximize compliance.

Analysis Plan

The study will compare the clinic findings for those patients needing hospitalization and those capable of being discharged. Data analysis will include (1) assessment of interobserver reliability; (2) univariate analysis to assess for association between individual predictors and outcomes by means of *t* tests, chi-square tests, and tests for linear trends in ordinal data; (3) multivariate stepwise logistic regression with correction for overdispersion to develop an actuarial rule; and (4) recursive partitioning to develop rules based on the dichotomization of predictors.

Pre-Award Evaluation

Originality and Importance

This research application proposes a study to develop and validate an actuarial rule to distinguish between (1) children who present to an emergency room (ER) with acute asthma and are capable of being discharged following treatment, and (2) those who need additional hospitalization. The investigation of this research problem is timely, because treatment methods have changed and managed care has made everyone more cognizant of cost. The reasonably comprehensive and critical review of the published literature, together with the principal investigator's prior related research, supports a well-articulated rationale for conducting the study.

Regional and National Significance

The investigators argue that, given changes in medical treatment, development of more effective clinical tools, and limitations in measuring treatment outcomes for asthma episodes, the time is ripe for reevaluating the possibility of developing an effec-

tive actuarial rule for determining when hospitalization is necessary. The investigators assert that benefits could be obtained from enhancing the quality of life and functional health of the children and from cost savings related to inappropriate care. This technically strong proposal addresses a research question that has both regional and national significance.

Scientific and Technical Merit

This application was previously reviewed and recommended for deferral, pending clarification of several issues. The information submitted for clarification was judged satisfactory by the reviewers. The issue of protective factors has been addressed by incorporating a measure of family functioning and supportiveness into the predictive model. This should resolve the concern that family support may be a crucial factor in ensuring positive outcomes for home-based care.

A number of methodological concerns have also been addressed. For example, natural constraints within the hospital will serve to ensure that the respiratory therapists doing the followup are blinded to the study. On the other hand, the issue of inter-rater reliability has not yet been sufficiently addressed. The proposal suggests that the validation of outcome judgments made by the respiratory therapists would occur only during the pilot training phase; this ignores the issue of potential rater "drift" from the initial criterion. To ensure good quality control over the evaluation process, the therapists making the outcome judgments should be assessed on a regular basis to ensure that the process of judgment has not varied from its original form.

The investigators have done an excellent job in clarifying the proposed followup procedures. One concern remains: The extent to which those patients selected to return to the hospital at 12 and 24 hours

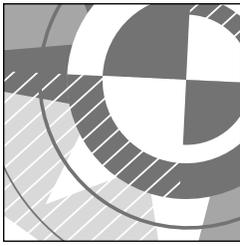
may be scheduled to return at odd hours, thus increasing the likelihood of noncompliance with the research protocol. For example, how many patients will be admitted at 2 a.m. and will be selected to return 24 hours later, at 2 a.m. the following day? It seems unlikely that families would agree to this procedure. Further consideration of the research protocol (which otherwise seems fine) should address this possible introduction of selection and compliance bias.

The investigators have successfully clarified issues related to medical instructions at discharge and to possible contamination of the study cohort. The investigators have also successfully addressed issues regarding the inclusion of variables with a specified level of measurement error, the use of CART models with smaller sample sizes, and the use of ROC models to evaluate the efficacy of prediction models on binary outcomes. One point of contention is the use of principal components versus factor analysis for data reduction purposes. Although this has been an issue in the literature, an easy compromise would be for the investigators to use both methods and compare the relative utility of the two procedures.

The methodology for the validation sample is another issue successfully addressed in the resubmission. Because the authors had already proposed to use shrinkage estimators and bootstrapping techniques to evaluate the stability of the actuarial model with respect to sampling variability, the use of a second sample from the same population to empirically address sampling variability issues seemed superfluous and too costly. The investigators acknowledged this concern, and have since procured a second study site whose population characteristics differ significantly from those of the proposed development sample. This new sample will provide a more stringent test of the generalizability of the actuarial rule than would have been possible with the validation sample initially proposed.

In addition, a cost-identification analysis has been included. This is important because it may begin to address issues of savings in direct medical costs, along with issues of enhanced or diminished quality of care.

The investigators have been responsive to the concerns raised in the prior review and have instituted clarifications and revisions to address these concerns. The recommendation is for approval.



San Antonio Triethnic Children's Blood Pressure Study

Grantee

University of Texas

Investigator

Shirley W. Menard, Ph.D., R.N.
 Health Science Center at San Antonio
 School of Nursing
 7703 Floyd Curl Drive
 San Antonio, TX 78284-7862
 (210) 567-2015
 (210) 567-2344 fax
 e-mail: Menard@UTHSCSA.EDU

Project Number MCJ-480747

Project Period 10/1/96-9/30/98

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	107,162	48,223	155,385
Year 2	98,278	44,199	142,418
Year 3			
Year 4			
Year 5			

Year 2000 Objectives

22.4

Study Design

Observational

Time Design

Cross-sectional

Care Emphasis

Noninterventional

Population Focus

School Age Children, Adolescents

Race/Ethnic Focus

African Americans, Hispanics—Mexican Americans

Summary

Statement of the Problem

Blood pressure (BP) measurement in children is important in detecting hypertension. Problems exist in four areas. First, there are unacceptably wide variations in reported normative BP levels by auscultation, due to unstandardized methods. Second, there are disparate recommendations by two national committees as to the selection of appropriate BP cuffs. Third, the popularity of the oscillometric method may bring additional problems (e.g., the demonstrated differences in BP readings obtained by oscillometry versus auscultation). Fourth, there is no reliable study comparing normative BP levels between populations of African-American, Mexican-American, and white children and adolescents.

Research Questions or Hypotheses

The purpose of this study is to develop normative BP data for African-American children and adolescents and to combine those data with data from a previous study in order to acquire normative BP data from three racial/ethnic groups: Mexican Americans, African Americans, and whites.

Study Design and Methods

The study will use auscultatory and oscillometric methods to evaluate BP in African-American children. Anthropometric measures, triceps and subscapular skinfold thickness measures, three BP measures for

each method of measurement (in a rotational sequence), and a dietary history will be obtained for each student. A mean BP, standard deviation, and percentile values for each group by age, race/ethnicity, and gender will be calculated for auscultatory and Dinamap values.

Population Description and Sampling Plan

Three elementary and middle schools and one high school have been selected for screening. A total of 2,800 to 3,000 students will be enrolled in the project.

Analysis Plan

Statistical tests for significant differences in BP levels and anthropometric measurements and body mass will be performed by analysis of variance followed by Tukey's test for each subgroup and each age group. The effects of multiple measurements and of the rotational sequence will be determined. Multiple regression analyses will be used to examine the influence of anthropometric measures and other variables on blood pressure for both methods.

Pre-Award Evaluation

Originality and Importance

This project will provide valuable information about normative blood pressure standards (calculated with both the auscultatory and oscillometric methods) among children of three racial/ethnic groups. It will also produce conversion factors for results obtained by these two methods.

The study will provide reliable blood pressure norms for children of three races and ethnicities and show whether there are racial/ethnic differences in

blood pressure levels. Relationships between blood pressure levels and other variables (age, gender, weight, height, arm measurements, skinfold thickness, nutrition, and activity level) will also be determined.

Regional and National Significance

Blood pressure standards that are based on scientifically appropriate methods and that can be used by clinicians are clearly of regional and national significance. This study will provide important data on blood pressure standards for a select population within maternal and child health.

Scientific and Technical Merit

This is a revision of a previously disapproved application. In general, the investigator has addressed the concerns of the earlier review in the body of the revised proposal as well as in a letter accompanying the proposal.

The main strength of the study is the importance of providing blood pressure standards that are based on scientifically appropriate methods and that can be used by clinicians. The proposal is well-written, the methods of data collection are carefully and clearly presented, and the investigator provides an excellent description of the flow of the data collection procedures. Procedures have been developed in the school setting to increase student participation. The anthropometric and blood pressure measurements to be obtained are clearly identified. The two methods used to measure blood pressure are alternated randomly for each student to ensure that there is no ordering effect for either method.

The investigator provides clear reasons why new standards need to be developed not only for non-Hispanic whites and Mexican Americans, but also for African Americans.

In this revised proposal, the investigator provides a procedure for referral and followup of children who are suspected to be hypertensive. In each case, the school nurse and the parent will be notified of the abnormal blood pressure and a letter will be sent home to the parents advising them to contact their doctor. For children without a doctor, the nurse will continue to monitor the blood pressure and a followup call will be made to parents to remind them to contact a physician if the blood pressure continues to be abnormal.

The investigator proposes to determine race by the parent's preference, by the parent's report of heritage, and by the research assistant's observation at the time of blood pressure measurement. If the observation of the research assistant differs from the parent's report, then the latter will be used. Therefore, it is unclear why this observation should be made at all.

The data analysis plan has been expanded to include the regression method used to establish normative blood pressure levels for the two methods, as well as regression models to examine the relationship of blood pressure and anthropometric method. The plan also includes a statistical assessment of the differences in values resulting from the two methods.

The previous reviewers were concerned about the generalizability of the data from San Antonio. The principal investigator has stated that there is a range of socioeconomic status and diversity in all three of the racial/ethnic groups. Although not generalizable to all areas of the country, the results can be used in many populations.

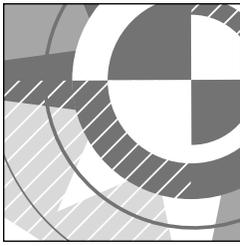
There are other concerns. The study team will collect data using the recollections of the children about their dietary intake over the past 24 hours. Although the study team acknowledges that the food frequency method is not appropriate to use with children, they do not discuss any previous studies that show

that valid dietary intake data can be obtained from elementary school children.

Although the investigator now has data from the previous study, he has included no papers and does not mention the preliminary analysis of the data. In addition, the hypothesis questions have not changed. Most noticeably, the question of how to express the normative data—by height or weight percentiles—is still unanswered. The earlier papers have presented the data by height, although the most recent abstracts present the data by weight and note that ethnic differences between whites and Mexican Americans all but disappear once weight is controlled for. The investigator still has not provided a multiple regression analysis as described in the initial application. The issue of anthropometric measures was a point in the earlier critique.

The concern about the differences in measurements between the old and new models of the Dinamap linkers. The investigators claim that the newer model is just more sensitive. Research published in scientific journals suggests that oscillometric measures will vary by the machine being used and norms have to be determined prior to interpreting the values. Consequently, the generalizability of the normative data may be limited to people using this particular machine and model unless comparative data on other equipment are obtained.

The letter of support from the San Antonio Independent School District is attached with the current application. However, the final approval from the school board is not attached, and there are still no letters from specific schools. The school district's approval does not bind the schools into cooperating. Nevertheless, the recommendation is for approval.



Maternal Birthweight and Reproductive Outcomes-Phase 2

Grantee

University of Washington

Investigator

Irvin Emanuel, M.D.
 Box 357236
 Seattle, WA 98195-7236
 (206) 543-8827
 (206) 616-8370 fax

Project Number MCI-530837

Project Period 9/1/97–8/31/98

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1			
Year 2			
Year 3	93,865	47,871	141,736
Year 4			
Year 5			

Year 2000 Objectives

14.1, 14.2, 14.5, 14.7, 14.14

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

Neonates, Infants, Pregnant Women, Postpartum Women

Race/Ethnic Focus

African Americans, Hispanics—Mexican Americans, Hispanics—Puerto Ricans, Native Americans

Summary

Statement of the Problem

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

Children and grandchildren of African-American physicians and dentists had higher rates of low birthweight than the general white population. Furthermore, the gap between African Americans and whites with respect to low birthweight and infant mortality has been increasing. Appeals have been made for new and more comprehensive research approaches to these problems. There is substantial evidence that low maternal birthweight is related to several problems of pregnancy outcome, and these relationships persist after the usual statistical adjustments. However, none of the studies of maternal birthweight have integrated information about pregnancy complications and perinatal morbidity and mortality. This study, therefore, has the promise of determining how the maternal birthweight effect is mediated.

Research Questions or Hypotheses

The primary goal of this project is to investigate the relationship of maternal birthweight and other maternal factors to future maternal complications of pregnancy, labor, and delivery, as well as to infant low birthweight and various newborn morbidities.

The project will continue the work begun in 1995 by the research team in studying maternal birthweight and reproductive outcomes.

Study Design and Methods

Data from this study will derive from a linkage of several existing statewide databases. The Birth Events Record Database (BERD) for 1987–95 includes virtually all delivery and newborn hospital discharge summaries and data from live birth, fetal death, and infant death certificates. Linked to this will be birthweight and other data from the birth certificates of mothers born in Washington State since 1949. Linkage to comparable data from fathers' birth certificates will permit evaluation of the comparative influence of maternal and paternal birthweights to infant outcome. Linkage to the statewide driver's license database will allow an evaluation of the comparable contribution of maternal birthweight and adult height and weight to multigenerational factors in infant and maternal outcomes.

Population Description and Sampling Plan

The primary sample for this continuation study will consist of 42,000 births in 4 racial/ethnic groups: White, African-American, Native American, and Hispanic. This is a collaborative effort among three departments at the University of Washington and the Fred Hutchison Cancer Research Center.

Analysis Plan

Relationships among pregnancy complications, abnormal outcomes, and the usual sociodemographic variables will be determined in an effort to define confounders and effect modifiers. Multivariate analysis will then be built with the variables identified.

Since most of the pregnancy complications and outcome variables are binary, the primary analysis will be logistic regression, assessing the association between low maternal/paternal birthweight and the outcomes of interest.

It is expected that the results of this study will lead to better understanding of causal factors, which in turn will suggest new approaches to intervention. The results are expected to offer additional support for the consideration of maternal birthweight as an important factor in determining the risk status of women, both before and during pregnancy.

Pre-Award Evaluation

Originality and Importance

The primary goal of the current ongoing study is to investigate the relationship of maternal birthweight and other maternal factors to future maternal complications of pregnancy, labor, and delivery, and to infant low birthweight and various newborn morbidities. These issues are of great interest, considering the current problems of preterm birth, their sequelae, and the consequences of survival for preterm and low-birthweight infants. The literature review is excellent and the principal investigator's experience is acknowledged in the field. The difficulties in separating generational issues from currently known and unknown risk factors is extremely important in the search for methods to improve birthweight and extend gestation to full term.

Regional and National Significance

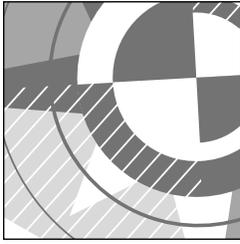
The results of the extended study are expected to lead to a better understanding of causal factors involved in the disparities in birth outcomes between whites and African Americans and between socioeconomic groups; greater understanding of these causal factors may in turn suggest new approaches to intervention. The rationale for extending the project is well justified. The proposed exploratory data analyses are intriguing and very beneficial to this multigenerational study; thus, the extension of this project has both regional and national significance.

Scientific and Technical Merit

This application requests a 1-year extension with funds to expand the scope of a currently funded project. Specifically, the investigators request additional

time and funds to add paternal and grandparental information to a project-created multigenerational data base, and to expand the scope of the analysis to include a number of maternal complications and infant morbidities that will then be related to the maternal birth-weight information. These additional data expansion and analytic activities have been made possible through new data base acquisitions and the availability of additional years' data to expand the original data set that was part of the current project.

The proposed extension of the project has many strengths, and the research team assembled is well qualified to carry out the activities. The principal investigator does a credible job of justifying the need for current parental adult weight and height data to be gathered from driver's license records and the expansion of the original data set to include two additional years' data now available. The recommendation is for approval.



Infant Temperament: Neonatal to 5 Years in Rural Appalachia

Grantee

Marshall University

Investigator

Margaret Fish, M.S., Ph.D.
School of Medicine
Department of Family & Community Health
Huntington, WV 25755
(304) 696-7194
(304) 696-7048 fax
e-mail: fishm@marshall.edu

Project Number MCI-540635

Project Period 6/1/96–5/31/01

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

Year 2000 Objectives

6.3, 22.4, 8.3

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

Preschool Children, School Age Children,
Parents

Race/Ethnic Focus

None

Summary

Statement of the Problem

The lack of cross-sectional and longitudinal data on individual differences in developmental trajectories in a 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 poverty versus culture in examining variables of interest.

Research Questions or Hypotheses

This study aims to increase the understanding of the developmental processes leading to more or less optimal socioemotional functioning and adjustment in both family and school contexts for rural children of low socioeconomic status (SES). The study also seeks to identify specific risk and protective factors in this population. Achieving both of these goals will lead to an increased ability to identify early those children who may be at risk and to provide appropriate and culturally relevant intervention programs.

Two research questions will be addressed: First, what level of continuity exists between certain temperament and mother-infant relationship qualities in infancy, and both preschool behavior problems and early school adjustment? Second, how do environmental factors such as poverty and low parental education levels, cultural values concerning education and achievement, and individual differences in temperament and mother-child relations interact

to influence early school adjustment and performance?

The study will test the following hypotheses:

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 have a higher incidence of preschool behavior problems and will be less sociable, positive, and persistent at age 4 if their mothers also had one or more of the following: Higher scores on negative personality traits, lower sensitivity during interaction, or 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 whose positive emotionality/social responsiveness remains high or increases during the first year and children with secure attachments to their mother at 15 months will experience fewer preschool behavior problems and will be securely attached to their mothers at age 4.
3. The major child outcome variables from each age in this study (attachment and verbal communication skills at 15 months; behavior problems, attachment, temperament, and verbal skills at age 4; and measures of social and cognitive functioning at age 5) will contribute significantly to variation in kindergarten adjustment. Continuity in positive factors and 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 emotionality/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 an earlier project studying infant temperament. The current project will conduct assessments at age 4, immediately before entering kindergarten, and during the kindergarten year. At age 4, the laboratory assessment includes child free play with the mother and a stranger (a preschool version of the strange situation), a cleanup task, two puzzles of increasing difficulty, and the PLS-3 scale of language development. Before the child enters kindergarten, the child and both parents will engage in free play and cleanup; the parents will then be interviewed concerning their aspirations/expectations for the child and their feelings about education, while the child repeats the PLS-3 and does counting, sorting, and completion games as well as a resistance-to-temptation task. During the spring of the child's kindergarten year, the teacher will complete the Classroom Behavior Inventory with scales measuring both social behavior and academic performance.

Child variables to be assessed include standard measures of attachment and behavior problems (age 4); 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); concepts and language skills needed for school (ages 4 and 5); and a standardized measure of classroom functioning (kindergarten).

Parental variables to be assessed include repeated measures of family demographics; maternal social support and relationship satisfaction (age 4); parenting attitudes (age 4); ratings of parent-child interaction (ages 4 and 5); and attitudes toward education and hopes/expectations for the child (age 5).

Population Description and Sampling Plan

This longitudinal sample will consist of 95 pairs of white mothers and their children (age 4) living in rural Appalachia; all of these mother-child pairs completed the first phase of the project. The mean age of the mother is 27, and the majority are married (68 percent) or living with a partner (10 percent). Mothers' and fathers' average level of education is 10.8 years; 46 percent are not high school graduates. Approximately 70 percent of the families report an annual income below \$10,000 and receive public assistance. Fifty-three percent of the children are male, and 72 percent are second or later in birth order. An estimated 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 child temperament, attachment, and cognitive functioning and to concurrent mother-child interaction and characteristics of the caregiving environment in a process model reflecting both direct and indirect influence. Discriminant function analysis will also be used to identify predictors that best distinguish groups that are secure versus insecure in attachment, high versus low on measurements of behavior problems, and problematic versus satisfactory in functioning on cognitive measures.

Pre-Award Evaluation

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

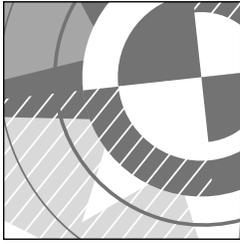
data point. It is probable that less than 80 subjects will be available to study at this data point.

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.



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 MCI-97-56-97

Project Period 7/1/97–6/30/2000

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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

Physicians (pediatricians)

Race/Ethnic Focus

None

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 Description 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

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 interven-

tions 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.

Technical and Scientific 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 activ-

ities 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.

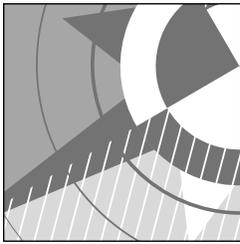
The aims of the study have been readjusted to include secondary questions related to impact on

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.

Active **PROJECTS ABSTRACTS**

Continuation Grants





Indicators of Maternity Care in Medicaid Managed Care

Grantee

The Regents of the University of California

Investigator

Carol Korenbrot, Ph.D.
 Institute for Health Policy Studies
 University of California at San Francisco
 1388 Sutter Street, 11th Floor
 San Francisco, CA 94109
 (415) 476-3094
 (415) 476-0705 fax
 e-mail: carol_korenbrot@quickmail.ucsf.edu

Project Number MCJ-060647

Project Period 10/01/1994–09/30/1997

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	139,099	35,888	174,987
Year 2	125,076	56,284	181,360
Year 3	127,306	57,288	184,594
Year 4			
Year 5			

Year 2000 Objectives

14.1, 14.2, 14.5, 14.14, 21.4, 22.4

Study Design

Observational

Time Design

Mixed

Care Emphasis

Interventional

Population Focus

Pregnant Women

Race/Ethnic Focus

African Americans, Hispanics—Mexican Americans, Hispanics—All Others

Summary

Statement of the Problem

The managed care approach to providing maternity care for medicaid-eligible pregnant women is being adopted at a rapid pace. However, managed care plans that contract with medicaid may not provide support services appropriate to meeting the special needs of low-income women. Enhanced perinatal service programs that include nutrition, psychosocial, and health education services are associated with improved health outcomes for women of low-income status, when compared to care that does not include such services.

At present, there is a lack of evidence concerning the extent to which medicaid managed care could jeopardize ongoing efforts to improve maternal and infant health through enhanced perinatal services for low-income pregnant women. Validated indicators for quality assessment of prenatal ambulatory care that incorporates enhanced or support services need to be available for medicaid managed care plans. State and Federal agencies responsible for the managed care contracts, the managed care plans themselves, and the consumers who may use the plans all want assurance that these plans are providing appropriate care and producing the best health outcomes possible.

Research Questions or Hypotheses

The specific aims of this study are as follows:

1. Develop potential indicators for maternity ambulatory care that incorporate nutrition, psychoso-

-
- cial, and health education services, through consensus building by an expert panel;
2. Test the validity of the indicators for their associations with poor health outcomes and their ability to predict poor health outcomes, using multivariate logistic regression; and
 3. Test whether the indicators vary for women with different provider settings of prenatal care and different payer sources of care, using multivariate regression analyses.

Study Design and Methods

In this study approach, an expert panel will develop indicators of inadequate ambulatory clinical and support services and will rate the variables proposed as indicators or risk adjusters. The association of indicators of inadequate ambulatory clinical and support services with provider setting and payer source characteristics is tested with multiple regression techniques adjusting for differences in case mix.

Population Description and Sampling Plan

The study sample consists of medicaid-eligible women who gave birth in California in 1989–90.

Analysis Plan

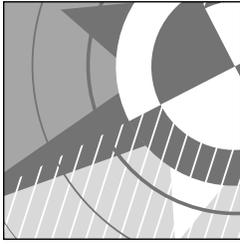
Multiple logistic regression is used to associate indicators of adequacy of care with adverse outcomes, after adjusting for confounding risks. The sensitivity, specificity, and negative and positive predictive values of detecting and predicting adverse outcomes will be investigated. The association between (1) indicators of inadequate ambulatory clinical and support services and (2) provider setting and payer source characteristics will be tested with multiple regression

techniques, adjusting for differences in case mix.

Development of indicators of quality of clinical ambulatory prenatal care for urinary tract infection, hypertension, and diabetes was unsuccessful. The data base of medicaid-eligible women in California proved inadequate for development of this indicator due to (1) a limited number of cases with the outcomes of interest in the data set, and (2) a limited number of antepartum variables from which to construct quality of care variables. Efforts were subsequently undertaken to link the cases identified in the medicaid-eligible data base as having a prenatal hospitalization with a statewide hospital discharge data base. These efforts resulted in linkage in 77 percent of the cases. This linkage rate between the data bases was deemed too low to allow valid analysis.

An indicator of adequacy of psychosocial services has been developed using the standard of care of one psychosocial assessment per trimester in prenatal care; thus, care is deemed appropriate when a woman has received at least one psychosocial assessment per trimester. The association between this measure of adequacy of ambulatory care and poor birth outcomes has been evaluated using multivariate regression, adjusting for risks for poor birth outcomes, adequacy of prenatal care utilization, type of provider setting, and type of psychosocial risk assessor.

An indicator of adequacy of all three support service assessments (nutrition, psychosocial, and health education) has also been evaluated. Once again, the standard of care used is one assessment of each kind per trimester in prenatal care. The association between adequacy of all ambulatory care services and poor birth outcomes has been evaluated using multivariate regression, adjusting for risks for poor birth outcomes, adequacy of prenatal care utilization, and type of provider setting. In addition, site-specific observed and expected rates of poor birth outcomes have been evaluated using chi-square tests.



Watchful Waiting Versus Antibiotics As Soon As Possible

Grantee

Kaiser Permanente

Investigator

Gabriel J. Escobar, M.D.
Division of Research
3505 Broadway
Oakland, CA 94611-5714
(510) 450-2128
(510) 450-2071 fax
e-mail: gje@dor.kaiser.org

Project Number MCI-060803

Project Period 04/01/1995–03/31/1997

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	42,356	12,984	55,340
Year 2	77,633	23,817	101,450
Year 3			
Year 4			
Year 5			

Year 2000 Objectives

14.1, 22.4

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

Neonates, Pregnant Women

Race/Ethnic Focus

None

Summary

Statement of the Problem

Neonatal bacterial infections occur infrequently (between 1 and 5 per 1,000 live births). However, each year 4.4 to 10.5 percent of all infants in the United States (180,000–429,000) are suspected of having such infections and are hospitalized in intensive care nurseries. The annual cost of these hospitalizations, most of which are associated with negative evaluations, may be as high as \$1.7 billion. Despite these huge costs and workup-to-positive ratios as high as 100:1, delayed diagnoses still occur. Further, no agreement exists with respect to which infants to evaluate, how to evaluate them, when to initiate antibiotic therapy, or how long to treat infants who have negative cultures. Careful studies could result in significant cost savings in perinatal care.

Research Questions or Hypotheses

The study seeks to (1) define guidelines for appropriate observation and care in cases of suspected neonatal bacterial infection; and (2) determine which infants suspected of bacterial infection can be managed without antibiotic therapy.

Study Design and Methods

Guidelines will be developed by establishing predictor-outcome relationships among study subjects. Predictors include demographics (race, birthweight), maternal risk factors (prolonged rupture of mem-

branes), laboratory tests (complete blood count), and clinical signs (neonatal hypothermia). Adverse outcomes are broadly defined and include culture-confirmed infection, clinical deterioration consistent with infection despite negative culture results, rehospitalization within 1 week of discharge, and death.

Infants will be placed into one of four groups, based on whether they were/were not treated within 6 hours of presentation, and whether they experienced an adverse outcome. Guidelines will be defined based on a 1-year cohort of infants meeting the following criteria: (1) Birthweight \geq 2,000 grams, (2) evaluation for possible infection (whether or not they receive treatment), and (3) blood culture and/or complete blood count obtained as part of that evaluation.

Population Description and Sampling Plan

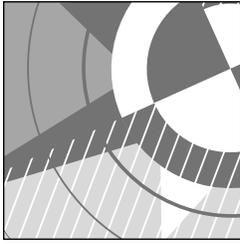
The study population consists of all infants born between October 9, 1995, and October 31, 1996, at six Kaiser Permanente (KP) hospital facilities in California: Hayward, Oakland, Sacramento, San Francisco, Santa Clara, and Walnut Creek. All infants

meeting study criteria are included. The study expects to enroll approximately 2,000 to 4,000 newborns. The six facilities involved have populations similar to those in the rest of the Kaiser Permanente Northern California Region. The racial distribution of KP births during 1990–91 was 59 percent white, 16 percent Hispanic, 9.4 percent African American, and 13 percent Asian American.

Infants will be identified using three methods: (1) All birth records at the facilities will be examined to determine whether the index test (complete blood count) was performed; (2) all laboratory data on newborns will be electronically downloaded and collated against chart review; and (3) nurses will also be asked to assist in identifying potential study subjects.

Analysis Plan

Guidelines will be developed by using data from infants who were not treated within 6 hours of their first evaluation. These guidelines will then be applied to a data set based on all infants in the study. This will permit an inference as to which infants could have antibiotic therapy deferred safely (“watchful waiting”).



Use of Child Health Services by Hispanic Families

Grantee

University of Illinois at Chicago

Investigator

Sharon Telleen, Ph.D.
School of Public Health
2035 West Taylor Street, Room 231
Chicago, IL 60612
(312) 996-3818
(312) 996-5356 fax
e-mail: telleen@uic.edu

Project Number MCJ-170805

Project Period 10/01/1995–09/30/1998

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	108,224	52,315	160,539
Year 2	139,276	94,022	233,298
Year 3	110,932	61,345	172,277
Year 4			
Year 5			

Year 2000 Objectives

2.4, 7.1, 7.4, 8.3, 8.10, 8.11, 9.1, 9.2, 9.3, 9.6,
11.1, 11.4, 13.1, 13.2, 13.12, 14.16, 17.4, 20.11

Study Design

Observational

Time Design

Cross-sectional

Care Emphasis

Noninterventional

Population Focus

School Age Children, Parents

Race/Ethnic Focus

Hispanics—Mexican Americans,
Hispanics—Puerto Ricans

Summary

Statement of the Problem

Hispanics are the fastest growing minority in the United States. According to a 1991 report by the American Medical Association's Council on Scientific Affairs, Hispanics are at increased risk for certain medical conditions, yet have proportionately fewer Hispanic health providers to serve their needs than do other ethnic groups. Further, Hispanic children are at risk for continuing health problems. *The Healthy People 2000* objectives have identified health problems specific to Hispanic children, particularly those from low-income families. Through the use of pediatric well-child visits, immunizations, and oral health care, many of these health conditions are preventable. These preventable health conditions form the basis of choice for the study's outcome variables—health service use and health practices.

Though Mexican-American and Puerto Rican children from low-income families are eligible for medicaid assistance, many of these children do not receive services. Despite their health needs, Mexican Americans demonstrate the lowest level of health care use among all ethnic groups. In contrast, Puerto Ricans have one of the highest utilization rates. However, data are lacking on the social and cultural factors related to these variations in health care use.

Information on the parents' use of health practices to protect their children's health and on the cultural and social reasons for those practices is sparse in the public health literature. Wasserman, Brunelli, Rauh, and Alvarado (1994) report some culturally based

child-rearing practices with implications for health practices, and these need to be further explored in this study. Finally, the relationship between attitudes and beliefs and the use of health services needs to be examined, since attitudes and beliefs influence behavior.

Research Questions or Hypotheses

The purpose of this research study is to examine the influence of social context and acculturation—as mediated by access to health services, social support, knowledge of health services and practices, and parental beliefs and attitudes—on the parents' use of health services for their preschool children, based on a sample population of Mexican-American and Puerto Rican families who have migrated to a major urban city in the Midwest.

The *Healthy People 2000* objectives for Hispanic children will frame the preventive health services questions asked about health practices and use of health services. These objectives include: (1) Reducing asthma morbidity among children ages 14 and younger; (2) reducing the prevalence of dental caries (both treated and untreated) among all Hispanic children; (3) improving nutrition among low-income Hispanic children; (4) increasing the proportion of children who receive primary care services; and (5) increasing the use of immunization services.

Study Design and Methods

The study will examine the influence of social context (social environment and acculturation), availability and accessibility of health services, and provider outreach on the use of health services by Mexican Americans and Puerto Ricans. In addition, mediating variables will be examined for their influence on health service use and health practices. These mediating vari-

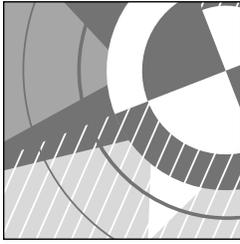
ables include knowledge of health services and health practices, parental beliefs and attitudes regarding their self-efficacy, attribution of responsibility, sense of control over their children's health, and social supports.

Population Description and Sampling Plan

A total of 64 Mexican-American and Puerto Rican mothers and fathers of children ages 5–6 residing in three predominantly Hispanic communities on Chicago's West Side will participate in focus groups to discuss child health practices and health care use by residents in their communities. In the second phase, 200 Mexican-American and 200 Puerto Rican mothers of children ages 5–6 will be interviewed, based on questions developed in response to the focus groups.

Analysis Plan

The analysis plan for phase 1 centers on recurring themes and keywords from the focus group discussions. The responses to the open-ended questions in the focus groups will be analyzed to determine whether they are appropriate as multiple choice questions for the phase 2 interview. The analysis plan for phase 2 includes an assessment of the psychometric properties of the standardized scales, using Cronbach's Alpha. Only scales with an alpha value of .70 or greater will be included in the analysis. The analysis will examine the effect of ethnicity and health beliefs on the use of health services.



Adverse Effects of Cow Milk in Infants

Grantee

University of Iowa Hospitals and Clinics

Investigator

Ekhard E. Ziegler, M.D.
Department of Pediatrics
200 Hawkins Drive, #W117 GH
Iowa City, IA 52242-1083
(319) 356-2836
(319) 356-8669 fax

Project Number MCJ-190808

Project Period 10/01/1995–09/30/1998

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	119,520	54,979	174,499
Year 2	124,191	58,370	182,561
Year 3	129,000	60,630	189,630
Year 4			
Year 5			

Year 2000 Objectives

2.4, 2.10

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Infants

Race/Ethnic Focus

None

Summary

Statement of the Problem

In spite of recommendations to the contrary, many older infants (ages 9–12 months) are fed cow milk. The iron nutritional status of infants who are fed cow milk is less satisfactory than that of infants who are fed formula. In addition to having low iron content, cow milk adversely affects iron status through two mechanisms: Inhibition of iron absorption and provocation of occult intestinal blood loss. This study addresses these two adverse effects of feeding cow milk to babies during infancy.

Research Questions or Hypotheses

This study examines two research questions:

1. To what extent does the feeding of cow milk inhibit the absorption of iron from the diet? This research study hypothesizes that less iron will be incorporated (absorbed) when babies are fed cow milk than when fed formula.
2. What are the consequences of cow milk-provoked intestinal blood loss? Specifically, the study seeks to determine what percentage of infants have medically significant blood loss, the extent of the blood loss, whether blood loss is accompanied by clinical signs, and whether blood loss depletes iron stores.

Study Design and Methods

To answer the first question, the study will use a

crossover design. Iron absorption will be determined twice for each infant, once while the infant is being fed cow milk and once while being fed formula. A stable nonradioactive isotope, ^{58}Fe , will be given with test meals over 3 days. Incorporation of ^{58}Fe into erythrocytes 4 weeks after ingestion of ^{58}Fe will serve as a surrogate of iron absorption.

To address the second question, infants will be fed formula for 1 month, followed by cow milk for 3 months. The infants' stools will be examined frequently for hemoglobin concentration, their iron nutritional status will be monitored, and their parents will record feeding-related signs and symptoms as well as stool characteristics. In infants who respond to cow milk with medically significant blood loss, 96-hour stool collections will be performed on three occasions for quantitative determination of blood loss. Iron status will be checked frequently in order to avoid iron deficiency in the infants.

Population Description and Sampling Plan

The population for both research questions will be normal-term infants living in or near Iowa City. Ninety percent of Iowa City's population is white. Infants will be recruited from the community at large through advertisements, personal contacts, and word-of-mouth. A large proportion of the infants are from families affiliated with the University of Iowa, such as graduate students, resident physicians, or faculty and staff. There are no restrictions with regard to gender or ethnic background.

The population for the first research question will comprise 32 normal-term infants who will be studied between 9 and 12 months of age. For the second question, normal-term infants will be screened to identify responders (i.e., infants who respond to the feeding of cow milk with a measurable increase in fecal hemo-

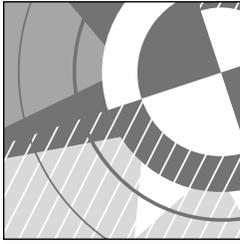
globin excretion). Screening will continue until 25 responders have been identified. It is estimated that as many as 92 infants may have to be screened. Of the 25 responders, it is estimated that 20 will complete the study as planned.

Analysis Plan

Erythrocyte incorporation of ^{58}Fe , which serves as a surrogate for iron absorption, will be calculated using established procedures and will be expressed as a percentage of the administered dose and also as milligrams of dietary iron incorporated. Data analysis will use analysis of variance procedures appropriate for a crossover design. It is anticipated that iron incorporation will be significantly less when cow milk is fed than when formula is fed.

Interpretation of data will include comparison with estimated requirements for absorbed iron and daily turnover of hemoglobin iron. For example, should the difference in erythrocyte incorporation be equivalent to or greater than 20 percent of the requirement for absorbed iron (0.55–0.75 mg/d), the conclusion will be that cow milk exerts a clinically meaningful inhibitory effect on non-heme iron absorption.

The second question will provide descriptive information regarding cow milk-induced intestinal blood loss. Information will include data regarding the frequency and severity of cow milk-induced intestinal blood loss, the quantity of blood—and thus iron—that may be lost, and whether iron loss can lead to iron depletion. In addition, the question of whether responders can be identified (or at least suspected) on the basis of clinical signs alone will be answered. It is anticipated that, as in our previous study, only a minority of responders will show blood loss that is clinically meaningful.



Free β and HCG in Screening for Down Syndrome

Grantee

Foundation for Blood Research

Investigator

George J. Knight, Ph.D.
 P.O. Box 190
 69 U.S. Route One
 Scarborough, ME 04070-0190
 (207) 883-4131
 (207) 883-1527 fax

Project Number MCJ-230802

Project Period 03/01/1995–02/28/1997

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	113,364	61,812	175,176
Year 2	33,713	18,382	52,095
Year 3			
Year 4			
Year 5			

Year 2000 Objectives

14.13

Study Design

Observational

Time Design

Mixed

Care Emphasis

Noninterventional

Population Focus

Pregnant Women

Race/Ethnic Focus

African Americans, Asians—Chinese, Asians—Filipinos, Asians—All Others, Hispanics—All Others

Summary

Statement of the Problem

Approximately half of the 4 million pregnancies annually in the United States are now screened for fetal Down syndrome in the second trimester, using biochemical markers. These measurements include alpha-fetoprotein (AFP), either alone or in some combination with human chorionic gonadotropin (hCG) and unconjugated estriol (uE3). In 1990, the free β -subunit of hCG was reported to be superior to the intact hCG molecule as a marker for Down syndrome. Although the original claim (20 percent gain in detection) was based on a flawed case-control study, reanalysis of subsequent case-control studies indicates that a small gain in detection (0.3–4 percent) may, in fact, exist. Reagent kits for performing free β -subunit measurements are not yet available for clinical use in the United States; manufacturers, however, are likely to seek approval by the Food and Drug Administration (FDA) soon.

Research Questions or Hypotheses

Anticipating the move for FDA approval, this study aims to develop accurate estimates of screening performance for free β -subunit measurements in a U.S. population of pregnant women and to compare these directly with estimates derived from intact hCG measurements as a step toward providing a rational basis for decision making by State health departments, laboratories, physicians, and individual pregnant women.

Study Design and Methods

The estimates of screening performance are to be based on multivariate modeling, using parameters obtained from Down syndrome cases and pregnancies with normal karyotypes. The study plan takes advantage of the availability of a bank of frozen serum samples, obtained from a previous study. In that study, 5,385 pregnant women provided information about their pregnancies and donated a serum sample just prior to amniocentesis. Fetal chromosome results were subsequently available for all of those pregnancies. Complete ascertainment of Down syndrome cases in that study population, in combination with the availability of relevant pregnancy information, provides a unique opportunity to develop an unbiased estimate of free β -subunit performance, both alone and in combination with uE3 and/or AFP.

Population Description and Sampling Plan

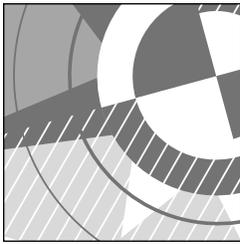
Fifty-four Down syndrome cases and 5,282 pregnancies with normal karyotypes will constitute the sample for this study.

Analysis Plan

After completion of the study, free β -hCG measurements will be used in calculating population parameters and in calculating risk for fetal Down syndrome. The resulting risks will be used to model the performance of free β -hCG as a screening test, both univariately and in combination with AFP and unconjugated estriol. It is known that such variables as race, ethnicity, maternal weight, multiple gestation, maternal smoking, and method of assessing gestational age have an important effect on other maternal serum markers. Information on these variables is

available for almost all study subjects, which will allow evaluation of their impact on the screening performance of free β -hCG.

It is known that free β -subunit can be spontaneously generated from intact hCG in serum samples that have been stored at elevated temperatures or that have experienced long delays in shipment. The specimens for this study were shipped under the best conditions currently in use in the United States and then stored frozen. To determine whether these shipping conditions are optimal, 1,000 fresh samples sent for routine prenatal screening will be assayed for free β -hCG to allow assessment of potential differences in population parameters obtained using fresh vs. shipped frozen samples. If any differences exist, it will be possible to evaluate their impact on both detection and false-positive rates. In addition, recommendations for optimal shipping and storage of serum samples will be developed.



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) 706-00653 fax

Project Number MCJ-240301

Project Period 1/1/96–12/31/2000

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

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, Adolescent Parents,
 Grandparents

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

In 1990, nearly one of eight 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, nurturance, 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, to 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 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 co-residence, 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, moth-

ers 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 Description 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 covariants 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 (inter-

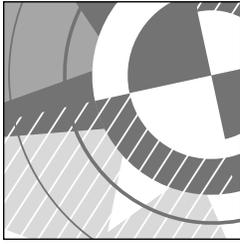
vention vs. control) by time would indicate that the two groups responded differently over time and would suggest an effect of the intervention.

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.



Growth and Development: Longitudinal Followup

Grantee

University of Maryland Medical School

Investigator

Maureen M. Black, Ph.D.
Department of Pediatrics
700 West Lombard Street
Baltimore, MD 21201
(410) 706-5289
(410) 706-0653 fax
e-mail: mblack@umabnet.ab.umd.edu

Project Number MCI-240621

Project Period 09/01/1992–08/31/1997

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	142,893	66,967	209,860
Year 2	91,125	45,198	136,323
Year 3	99,899	44,955	144,854
Year 4	84,295	37,933	122,228
Year 5	97,422	43,300	140,722

Year 2000 Objectives

2.4, 7.4

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Preschool Children, School Age Children

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

This project is designed to evaluate the long-term effects of home intervention on the health, growth, and development of low-income, inner-city children diagnosed with nonorganic failure to thrive (NOFTT). The longitudinal study builds on a randomized clinical trial of home intervention previously funded by the Maternal and Child Health Bureau (Home Intervention for Infants with Failure to Thrive, MCI-240568, 1988–93). The study will follow the intervention children and their matched controls (both with a history of NOFTT), plus a comparison group of adequately growing children from low-income urban families, through their preschool years until they reach first grade.

Approximately 90 percent of the children are from African-American families and most of the families are headed by single mothers who have not completed high school. The study will examine the impact of child characteristics (age, gender) and family characteristics (maternal age at delivery, level of education) on children's growth and development.

Research Questions or Hypotheses

This study will test the following hypotheses:

1. Low-income urban children with an early history of NOFTT will experience long-term deficits in growth and development when compared with children from a similar socioeconomic background who grew adequately during their infancy.

-
2. Among the children with an early history of NOFTT, those who received the home intervention will have better growth and development than those who did not receive the home intervention.
 3. Parent-child interaction, family functioning, and social support mediate the relationship between early growth status and children's growth and development.
 4. Parent-child interaction, family functioning, and social support mediate the relationship between intervention and children's growth and development among children with an early history of NOFTT.

Study Design and Methods

In keeping with the developmental/ecological theory guiding this research, we will focus on children's growth, development, academic performance, and behavior. Children will be studied at ages 4 and 6 years in laboratory settings, in their homes, and in school. Multiple assessment strategies will be used, including direct observations of parent-child interaction, questionnaires, and standardized assessments. We will examine the traditional indexes of growth (height and weight) as well as changes in body composition (muscle mass and fat stores) in order to assess the relationship between growth and children's developmental status. Intervening variables include parent psychological functioning, family functioning, and parent-child interaction. In addition to the evaluation of early home intervention and the relationship between indicators of growth and development, this longitu-

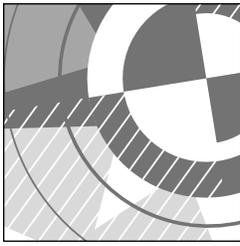
dinal followup of low-income, inner-city minority children will provide information on the protective factors that enable some children to have healthy growth and development in spite of overwhelming environmental challenges.

Population Description and Sampling Plan

Children meeting growth criteria for NOFTT have been recruited from a primary pediatric clinic and followed for 18 months. Of the 144 children with NOFTT who were recruited, approximately half were randomized to receive home intervention for 12 months. Retention has been excellent, with 121 children (83 percent) remaining in the project. A comparison group of 115 children without growth problems (matched by age, gender, and socioeconomic status) has been recruited from a primary pediatric clinic. The longitudinal project will follow both groups of children through their preschool years until they reach first grade.

Analysis Plan

Data will be analyzed using structural equation modeling, multivariate analysis of covariance, and repeated measures multivariate analysis of variance. The primary purposes of the analyses are to evaluate outcomes in the NOFTT group, compare the intervention and the comparison groups, and evaluate the mediating influences of several parent and family variables.



Regulatory Disorders and Developmental Outcomes

Grantee

University of Maryland at College Park

Investigator

Stephen W. Porges, Ph.D.
 Department of Human Development
 3304 Benjamin Building
 College Park, MD 20742-1131
 (301) 405-2807
 (301) 405-2832 fax
 e-mail: porges@umdd.umd.edu

Project Number MCI-240622

Project Period 10/01/1992-09/30/1997

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	110,312	41,890	152,202
Year 2	115,071	44,811	159,882
Year 3	126,492	35,894	162,386
Year 4	122,076	58,596	180,672
Year 5	121,171	32,870	154,041

Year 2000 Objectives

6.3, 6.14

Study Design

Quasi-experimental

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

Infants, Toddlers, Preschool Children

Race/Ethnic Focus

None

Summary

Statement of the Problem

Many children who develop behavioral and emotional disorders are not identified until they enter school. The overall goal of this project is to identify during infancy the measurable precursors of severe behavioral and emotional disorders. If the assessment strategies in this study are successful, they will have immediate application in identifying infants at greatest risk for severe behavioral and emotional disorders. Additionally, the research will provide insight into the etiology of behavioral and emotional disorders. This knowledge will aid clinical researchers in developing effective early identification and prevention strategies to address infant vulnerabilities.

Research Questions or Hypotheses

It is hypothesized that behavioral and emotional disorders have measurable antecedents during infancy. Specifically, it is hypothesized that 9-month-old infants with regulatory disorders (manifested by problems in self-consoling, attention, response to changes in routine, sleeping, feeding, and sensory reactivity) will differ from infants without regulatory disorders (controls) at 9, 24, and 36 months of age. It is hypothesized that infants with regulatory disorders will exhibit deficits in sensory processing, cognitive processing, psychophysiological reactivity, and emotional regulation. In addition, it is hypothesized that socioenvironmental risk factors (such as low socioeconomic status, family size, and parenting stress) will contribute

to the outcome risk of infants with regulatory disorders.

Study Design and Methods

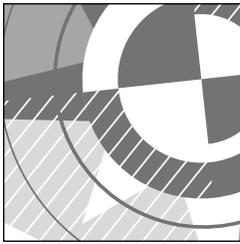
In order to test the stated hypotheses, the study design will include two groups of infants—those with regulatory disorders and those without regulatory disorders (controls). The infants with regulatory disorders and the controls will be assessed at 9 months and followed at 24 and 36 months. A comprehensive battery administered at each assessment point will include measures in the four domains (sensory processing, cognitive processing, psychophysiological reactivity, and emotional regulation). Mothers will complete questionnaires on child temperament, child behavior problems, parenting stress, and demographic information. At 36 months, children will receive an evaluation to assess behavioral and emotional difficulties.

Population Description and Sampling Plan

Eighty infants with regulatory disorders and 80 controls (matched for socioeconomic status, minority group status, presence or absence of father in the home, number of children in the family, and parenting stress) will be recruited for the study. Subjects will be defined as having a regulatory disorder if they have problems in two or more of the following areas: (1) Sleep disturbance, (2) difficulties in self-consoling, (3) feeding difficulties, (4) distress with changes in routine, or (5) distress related to routine caregiving and play experiences that offer a sensory challenge.

Analysis Plan

Data analysis will focus on (1) differences between the controls and the infants with regulatory disorders at each of the three assessment points, (2) the relation between regulatory disorders at 9 months and psychiatric disorders at 3 years, and (3) the joint contribution of regulatory disorders and socioeconomic risk to outcome at 3 years of age.



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
e-mail: aduggan@jhu.edu

Project Number MCI-240637

Project Period 05/01/1994–04/30/1999

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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

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 Children,
Parents

Race/Ethnic Focus

Asians—Filipinos, Asians—Japanese, Asians—
All Others, Hawaiian Natives

Summary

Statement of the Problem

Hawaii's Healthy Start Program is a well-established outreach program providing (1) community-based screening to identify newborns at environmental risk for child abuse and neglect, and (2) 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 5 years of life.

Nationally, home visiting programs in general and the Healthy Start Program in particular receive strong endorsement. Efforts to establish community-based home visiting programs have been impeded by several unresolved issues: (1) Mixed results of past evaluations, (2) limited study of non-nurse home visiting, (3) evaluation of demonstration projects rather than established programs, (4) little research on the types of families most likely to benefit, and (5) uncertain cost benefits of home visiting. These issues render evaluation findings essential for informed policy and program development.

Research Questions or Hypotheses

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, will be conducted over 5 years. At each hospital, Healthy Start Program early identification workers follow the usual screening/assessment protocol to identify infants born into environmentally at-risk families. All families living in Healthy Start Program catchment areas are screened and assessed. Those scoring ≥ 25 on Kempe's Family Stress Checklist are defined as being at risk. If the family is at risk, the early identification worker describes the Healthy Start Program 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 Healthy Start intervention group, a main control group, or a testing control group. Each intervention group family is referred to the Healthy Start Program site serving its community and is offered home visiting services following the usual Healthy Start Program protocol. Each main control group family is referred to other community programs as usual. Members of the testing control group differ from the main control group in that they are interviewed at baseline and at year 3 only. This will allow us to assess the effects, if any, of repeated measurements on outcomes by comparing the testing control group with the main control group.

Families will be followed for 3 years, with baseline and annual data collected (for intervention and main control groups) for 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 will be measured through a review of medical records for first contact of care and 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 will be measured through medical records review and social services review 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 (NCAST) Scales; and (3) home environment, measured by Caldwell's and Bradley's Home Observation for Measurement of the Environment (HOME) Scale. Child health (another outcome variable indicator) is defined as general health status, measured by the Rand Health Inventory Scale. In addition, morbidity will be measured by determining emergency room use, hospitalizations, hospital days, illnesses and injuries, and abuse and neglect reports from Child Protective Services, and by administering the Conflict Tactics Scale and the Hart/Brassard Psychological Maltreatment Rating Scale.

Data are also collected on child development, which is defined by (1) physical development, measured by the Bayley Motor Scale Index, and (2) mental development, measured by the Bayley Mental Scale Index and the Stanford-Binet Intelligence Test. School readiness, 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 sup-

port, maternal health and psychological well-being, maternal health care, child health care, need for parenting services, maternal and paternal substance abuse, paternal characteristics, and family income will be collected at baseline and at followup interviews.

Population Description and Sampling Plan

Families are eligible for this study if (1) the mother gives birth at a hospital during the period of intake (November 1994–October 1995), (2) the family is eligible for the Healthy Start Program, (3) the family is identified as being at risk by an early identification worker following usual Healthy Start Program protocol, (4) the family is not currently enrolled in the Healthy Start Program for a prior birth, and (5) the mother does not need a translator. (Less than 3 percent of those eligible for the Healthy Start Program need a translator.) To ensure that all eligible families are invited to participate in the study, the evaluation fieldwork coordinator maintains a log of all families at risk. This log is compared monthly with the Healthy Start Program computerized log of all family screening/assessments and their disposition, to assure that recruitment is carried out according to evaluation protocol.

The study sample is drawn over 12 months from families living in catchment areas for the six programs with geographically defined target areas on Oahu. An estimated 5,232 babies will be born to families living in these catchment areas during this 12-month period. The projected number of eligible families identified as being at risk will total 1,560. We would need to offer study participation to 848 families in order to achieve the total desired recruitment of 720 families (assuming an 85 percent initial participation rate). Disproportionate stratified sampling is used to generate equal sample sizes within the intervention group,

main control group, and testing control group for each of the six programs in Oahu. The necessary sample size has been determined, based on preliminary study findings on program-specific enrollment and retention rates. The goal is to follow a sufficient number in each program site to allow assessment of program efficacy as well as effectiveness and to be able to conduct meaningful analyses of population subgroups.

With respect to attrition, we project that 80 percent of families enrolling in the evaluation will be followed successfully for 3 years. This will yield final sample sizes of 288 in the Healthy Start group (48 in each of the 6 Healthy Start Program sites), 240 in the main control group (40 per program), and 48 in the testing control group (8 per program). The following steps will be taken to minimize attrition: (1) Recruitment procedures will emphasize the responsibilities of participation and the importance of remaining in the study all 3 years, (2) participating families will be reimbursed for the baseline and followup interviews, (3) ample tracking information will be obtained at baseline and updated at followup, (4) parental permissions will be obtained to gain access to identifying information in existing information systems to aid tracking and followup, and (5) families will be sent a small gift every 4 months to maintain their commitment to the study and to allow early detection of changes in address.

All Healthy Start Program families will be followed for 3 years, regardless of whether they move to another area of Hawaii or drop out of the program. Control group families will maintain their control group status for 3 years. We expect that some control group families will have a subsequent birth during the 3 years of followup. To avoid contamination, these births within the control group families will not be eligible for the Healthy Start Program.

The racial/ethnic composition of the sample is as follows: 26 percent of the mothers report their pri-

mary ethnic affiliation as Native Hawaiian, 23 percent Filipino, 16 percent Samoan or Tongan, 15 percent white, 7 percent Chinese, 5 percent Japanese, and 8 percent other. More than half (57 percent) of the mothers were adolescents (≤ 19 years old) at the time they gave birth to their first child. Forty-five percent of the families experience some form of domestic violence. In 55 percent of the families, either the mother or father abuses alcohol or other drugs.

Analysis Plan

The comparability between study participants and nonparticipants will be 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 Healthy Start Program and control groups will be assessed for these measures and for baseline interview variables.

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

Outcome variables measured in this study will be of three basic types: Binary (e.g., any emergency room use), counts (e.g., number of emergency room visits), and indexes or scales to determine appropriate transformations and groupings. The methodology will employ exploratory data analysis in the context described by Hoaglin, Mosteller, and Tukey. Internal

consistency of composite scores for scaled indexes will also be investigated

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

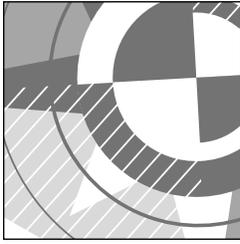
Within both the Healthy Start Program and the control groups, families will be categorized in terms of characteristics at the time of the child's birth. These include family ethnicity, initial risk assessment score, family substance abuse, family violence, and maternal age. For each outcome, multivariable models will be used to test for differences in outcome between the Healthy Start Program group and the control group in the presence of differences in initial risk and the degree of resolution of other outcomes. For normally distributed outcomes, the general linear model will be used; for dichotomous outcomes, the logistic model will be used; and for low incidence outcomes measured as counts, the log-linear model will be used.

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

Within both groups, levels of use and associated costs will be measured for health services, child protective services, police and legal services, and other community services. For families in the Healthy Start Program group, direct program costs will also be measured. Tests for significant differences in total costs per child between program and control group fami-

lies will be computed using *t* tests; controls for other factors influencing costs can be introduced via regression analysis. Alternative statistical tests may also be applied if the distribution of the cost data does not

allow for transformation to normality. Significance of cost differences also will be tested for the specific cost categories listed above and for portions of cost paid directly by government sources.



Injury Prevention in an Urban Pediatric Clinic

Grantee

Johns Hopkins University

Investigator

Andrea C. Gielen, Sc.D.
School of Hygiene and Public Health
615 North Wolfe Street
Baltimore, MD 21205
(410) 955-2397
(410) 614-2797 fax
e-mail: agielen@phnet.sph.jhu.edu

Project Number MCI-240638

Project Period 05/01/1994–04/30/1998

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	143,714	95,237	238,951
Year 2	147,856	99,422	247,278
Year 3	193,203	130,698	323,901
Year 4	195,592	130,069	325,661
Year 5			

Year 2000 Objectives

9.1, 9.2, 9.4, 9.8, 9.21

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates, Infants, Toddlers, Parents

Race/Ethnic Focus

None

Summary

Statement of the Problem

It is widely known that injury is the leading cause of death for children in the United States and that children ages 0–4 have especially high injury morbidity and mortality rates. A significant proportion of these injuries occur in and around the child's home. Such injuries have been found to disproportionately affect low-income and ethnic minority families.

Pediatricians have been identified as key players in childhood injury prevention efforts, yet little is known about the extent and effectiveness of their counseling on parents' efforts to "child-proof" the home. Moreover, limited attention has been paid to gaining a better understanding of the unique needs of low-income, inner-city families in relation to modifying injury hazards in a home.

Research Questions or Hypotheses

The overall aim of this research is to identify interventions that enhance parents' injury prevention practices with regard to fall, burn, and poisoning injuries to infants and toddlers. This study will evaluate the extent to which clinic-based interventions of varying levels of resource intensity improve parents' injury prevention practices in a sample of economically disadvantaged families living in an urban area.

Study Design and Methods

Advancing our understanding of the unique needs of the participating families involves (1) the study of improved pediatric counseling, (2) an onsite resource center, and (3) a home visit by injury prevention specialists. Enhanced anticipatory guidance is designed to heighten parents' perceptions concerning the risk and seriousness of injury and to help them overcome specific injury prevention barriers associated with living conditions in the inner city. The onsite resource center developed through this study will improve access to needed safety supplies at cost. The home visit intervention used in this study will provide technical assistance for using and/or installing safety supplies.

The study design is a randomized controlled trial involving two cohorts of parents to be enrolled during well-child visits when their infants are between 2 weeks and 6 months of age and followed until 12 months of age. Cohort 1 ($N=200$) will be randomized to receive standard care or enhanced anticipatory guidance. When cohort 1 followup has been completed, an onsite resource center will be opened and cohort 2 ($N=200$) will be recruited. All cohort 2 parents will receive anticipatory guidance and access to the resource center; one-half of cohort 2 will also be randomly assigned to receive a home visit intervention. All parents will be interviewed at enrollment and when their child is 12 months of age. In-home observations will be used to confirm self-reported injury prevention practices. Data also will be collected to examine the relationship between parents' injury prevention practices and risk perceptions, beliefs about barriers, and housing quality.

Findings from the evaluation of these interventions will have important implications for the provision of injury prevention services in well-child clinics, especially those operating with limited resources

and serving families living in impoverished urban areas.

Population Description and Sampling Plan

Parents (or female caregivers) who bring their children to the primary care clinic are the target population for this study. The Harriet Lane Primary Care Clinic (HLPC) provides health supervision and acute care health services to 6,300 children, 86 percent of whom receive medicaid benefits or have no health insurance. The majority (82 percent) of patients receiving care are African American and live in the surrounding East Baltimore neighborhood, one of the most economically disadvantaged areas of the city. Nearly two-thirds of East Baltimore's adult population has not completed high school; one in three families lives below the Federal poverty level.

Any HLPC parent whose child is 0–6 months of age and whose pediatrician is a first-year or second-year resident is eligible to participate unless (in the pediatrician's judgment) the child has a significant clinical reason to be excluded (e.g., severe developmental delay). Participants are recruited as they come to HLPC for a scheduled or walk-in visit. Each participant is approached in the waiting room by the interviewer, who explains the study to the parent, completes the informed consent process, and conducts the baseline interview. Two hundred parents (primarily the female caregivers), have been recruited for cohort 1; an additional 200 parents will be recruited for cohort 2.

Analysis Plan

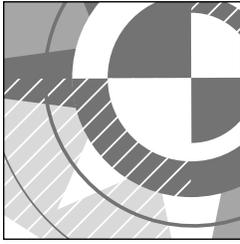
An analysis plan for the study data was developed in keeping with the study design, which randomizes parents into different treatment conditions within

two cohorts. Thus, for group comparisons within each cohort, standard chi-square tests and *t* tests are appropriate for testing intervention effects. For group comparisons across cohorts, probability distributions of the sociodemographic factors from each treatment group will be examined to identify potential cohort bias. In the absence of cohort bias, the four control/experimental groups will be treated as four randomized groups and standard testing techniques will be applied for analysis. In the presence of cohort bias, statistical techniques such as analysis of variance (ANOVA) and regression will be used to control confounding factors/covariants and to identify the intervention effects.

Standard *t* tests will be used to test the difference between two groups when the outcome variable is defined to be the total practices (score=0, 1, 2, 3, 4, or 5). The *t* test can be applied to either normally distributed or nonparametric data. When the total practices scores are not normally distributed, sufficiently large sample sizes (≥ 30 for each group) are required to guarantee the validity of asymptotic *t* tests. Exploratory techniques using statistical software packages (SAS or SPSS) will be used to examine parametric/non-parametric features of the data. For each of the six dichotomous outcome variables, chi-square tests will be employed for two sample comparisons.

Some of the complex comparisons, such as the overall intervention effect, will be analyzed using ANOVA to compare the mean number of total practices across all four study groups. For multiple comparisons of intervention and control groups, a multiple *t* test will be used to test the potential difference among groups. Critical values of the tests will be determined by the Dunn-Bonferroni tables.

To explore the general relationships of the intermediate variables (i.e., predisposing, reinforcing, and enabling factors) to individual injury prevention practices, logistic regression models will be employed to examine their correlation and to identify the statistical significance of their influence on the dichotomous outcomes. With respect to the total practices score (a continuous outcome variable), linear regression models will be used to determine correlation and statistical significance. In some analyses, the influence of the interventions on the intermediate variables will be examined. When these variables are ordinal measures (e.g., satisfaction with pediatric advice), regression models for ordinal-level response variables will be used. In all regression analyses, appropriate transformations of the response variable and the covariants will be searched in order to identify the best regression model fit.



Development of Monitoring Methods for Perinatal Outcomes

Grantee

Johns Hopkins University

Investigator

Patricia O'Campo, Ph.D.
School of Hygiene and Public Health
Department of Maternal and Child Health
624 North Broadway
Baltimore, MD 21205
(410) 550-5448
(410) 955-2303 fax

Project Number MCI-240639

Project Period 04/01/1994–03/31/1997

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	49,864	29,502	79,366
Year 2	42,083	27,513	69,596
Year 3	50,786	32,834	83,620
Year 4			
Year 5			

Year 2000 Objectives

14.1, 14.5

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

Neonates, Infants

Race/Ethnic Focus

None

Summary***Statement of the Problem***

Monitoring rare health events such as adverse perinatal outcomes presents program planners and researchers with a challenging task. Despite decades of experience with monitoring national or statewide rates of infant morbidity and mortality in the United States, adequate methods are not available to monitor short-term changes in perinatal outcomes in smaller jurisdictions such as cities or counties.

Research Questions or Hypotheses

The overall goal of this research is to contribute methodological advancements for monitoring rare perinatal outcomes in small geographic areas such as counties, cities, ZIP Codes, or census tracts. Currently, such monitoring methods are not widely available to maternal and child health practitioners and policy-makers.

Study Design and Methods

Two distinct monitoring techniques will be developed: Spatial stochastic process methods and industrial quality assurance methods. Spatial stochastic process methods are one of the most sensitive tools available for detecting unusual events or changes in the underlying rate of events. The method we develop will be geographically based, since the spatial stochastic process methods will be coupled with current computerized mapping technology. Industrial qual-

ity assurance methods, on the other hand, are advantageous in that they have few data and computer resource requirements and are simple to implement and perform.

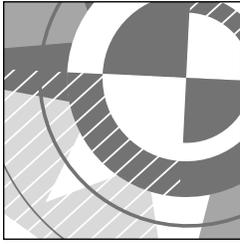
Data for developing these monitoring methods will come from four sources: Baltimore City vital records, U.S. Census (1990), routinely available data from various Baltimore City government agencies, and commercially available data on social characteristics of Baltimore's ZIP Codes, census tracts, and census block groups. Both methods, once developed, will be assessed and compared with respect to data requirements, computer resource requirements, ease of implementation, and monitoring utility. The monitoring methods will enhance current efforts toward identifying high-risk communities and detecting short-term changes in rates of adverse outcomes in small geographic areas. The developed monitoring methods will not be limited to perinatal outcomes; rather, results from this research should have widespread application to surveillance systems and evaluation activities in all realms of maternal and child health.

Population Description and Sampling Plan

Computerized vital records (both birth and death files) for Baltimore City for the period 1985–95 will be used for this study. For many of the analyses, all births in Baltimore City will be used; for some of the analyses, selected high-risk areas of the city will be used.

Analysis Plan

The spatial methods will incorporate risk factors and autocorrelation of space-time characteristics. Mapping of events will provide changing patterns of infant mortality in the city and identification of clusters of events in space and time. Secondary data from births, infant deaths, census records, and Healthy Start prenatal and pediatric data bases will be available for analysis over the years 1988–92. Simulation of data will also be used to evaluate the methods with respect to implementation and ease of use.



Preventing Mental Health Problems in Ill Children

Grantee

The Johns Hopkins University

Investigator

Henry T. Ireys, Ph.D.
Department of Maternal and Child Health
Hampton House
624 North Broadway, Room 187
Baltimore, MD 21205
(410) 550-5442
(410) 955-2303 fax
e-mail: HIreys@phnet.sph.jhu.edu

Project Number MCJ-240804

Project Period 10/01/1995–09/30/1999

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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			

Year 2000 Objectives

6.3, 17.14, 17.20

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

School Age Children, Parents

Race/Ethnic Focus

None

Summary

Statement of the Problem

More than two decades of epidemiologic 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 disabilities and chronic illnesses and for 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

The intervention will be evaluated using a longitudinal, repeated measures, randomized controlled trial design. Participants will be randomized to either a comprehensive intervention group or a low-dose control group. The intervention will be 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 two important sources of self-esteem (body-esteem and perceived social acceptance) in children, and (2) enhance types of support (informational, affirmational, and emotional) and parenting confidence in mothers. The child life professional will work with enrolled children; the veteran parent will work with their mothers.

Data will be collected via interviews with children and parents at enrollment (T1), 12 months (T2, just prior to the end of intervention), and 20 months (T3). Through brief telephone calls every 4 months, contact will be maintained with the participants and data will be gathered on health and mental health service use. Data will also be gathered from teachers and specialty care providers.

Population Description and Sampling Plan

A sample of 300 families with children ages 7–10 will be recruited for this study.

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 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 underly-

ing 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?).

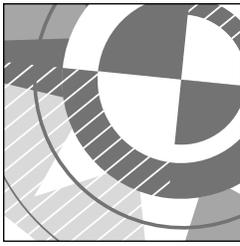
The first aim of the study is to assess the intervention’s success in reaching its specific objective, which is to enhance psychological and social resources for the participants. We will compare the experimental and control groups for each resource variable at each time point. Means will be compared using *t* tests. In addition, we will compare the experimental and control groups 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 using paired *t* tests. If concordance is small, separate analyses will be run 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 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.



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 02181
(617) 283-2460
(617) 283-3645 fax
e-mail: oalarcon@lucy.wellesley.edu

Project Number MCI-250643

Project Period 10/01/1994–09/30/1999

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
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

Year 2000 Objectives

22.4

Study Design

Quasi-experimental

Time Design

Mixed

Care Emphasis

Noninterventional

Population Focus

School Age Children, Parents

Race/Ethnic Focus

Hispanics—Puerto Ricans

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. 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 Maternal and Child Health Bureau priorities for studying the healthy growth of minority children as well as to the research agenda set forth in the Surgeon General's National Hispanic/Latino Health Initiative. Thus, the study employs culturally appropriate theories, models, and methodologies involving Hispanic researchers at all levels of research activities and uses 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. mainland, considering variations in socioeconomic status (SES), gender, and color; (2) describe Puerto Rican children's experiences with migration and the impact of migration on their healthy development (physical and mental) and school performance; 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, racism, and discrimination diminish these resources, children's healthy development will be jeopardized.
3. Families and external institutions can moderate the impact of migration, prejudice, 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 (in 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 annually through face-to-face interviews with the children and their primary caregivers and through 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, self-esteem, ethnic identity, and perception of safety at school. Family variables to be examined include socioeconomic status, parental job stress, racial identification, family structure, parental depression and anxiety, home envi-

ronment, and parenting styles. Other variables of interest are the use of traditional and nontraditional health practices and the utilization of the child as a translator and negotiator of the “anglo” world.

The final survey instrument is a composite of some existing measures, translated and modified by others so that they are culturally syntonic with Puerto Rican populations, as well as new measures developed for this study. Three new measures are The Color of My Skin, Self Esteem, and Ethnic Identity and Discrimination, for children ages 6–10. The final survey instrument is available in English and Spanish. The study uses the dual focus technique for translation and new item development. In this method, a concept is developed simultaneously in English and Spanish, with the method guided primarily by concept rather than language.

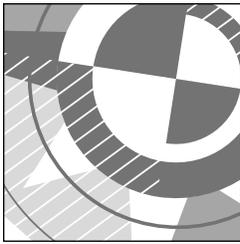
Population Description and Sampling Plan

An initial sample of 291 children and their primary caregivers was recruited, with an attrition rate of 5 to 10 percent expected at each data collection point. Attrition is expected to be highest for the lowest SES group, so these families were oversampled. Families were identified through schools and community agencies and through door-to-door contact in communities with a large Puerto Rican population. These families were screened for inclusion in the study. The study children are considered Puerto Rican if they so identify themselves or if one of their parents is Puerto Rican.

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.



Early Intervention Collaborative Study: Age 10 Follow-up

Grantee

Brandeis University

Investigator

Jack P. Shonkoff, M.D.
The Florence Heller Graduate School
P.O. Box 9110, MS 035
Waltham, MA 02254-9110
(617) 736-3883
(617) 736-3881 fax
e-mail: Shonkoff@binah.cc.brandeis.edu

Project Number MCI-250644

Project Period 02/01/1994–06/30/1998

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	113,059	55,851	168,910
Year 2	139,036	77,165	216,201
Year 3	174,629	86,266	260,895
Year 4	190,202	72,187	262,389
Year 5			

Year 2000 Objectives

6.14, 8.3, 17.2, 17.14

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

School Age Children, Parents

Race/Ethnic Focus

None

Summary

Statement of the Problem

Contemporary early intervention services, guided by Part H of the Individuals with Disabilities Education Act, are designed to enhance the responsiveness of the caregiving environment in a way that is assumed to have an impact far beyond the brief early intervention experience. Little longitudinal research has been conducted to evaluate the relationship between child and family outcomes and characteristics of children and families enrolled and services provided in early intervention programs. Currently, little is known about how the children who received such early intervention services will perform during their school years, and which children and families are most likely to do well or do poorly (thus requiring more professional assistance).

Research Questions or Hypotheses

The broad goals of this study are to (1) identify predictors and mediators of child development and family adaptation over time; and (2) construct an integrated, empirically validated conceptual framework to inform public policy, aid the design of service programs, and guide further research for children with special health needs and their families. The study also aims to elucidate predictors of long-term vulnerability and resilience among recipients of early intervention services in order to inform policy decisions regarding short-term resource allocation and long-term service planning for children with special health needs and their families.

Study Design and Methods

This study is a continuation of a nonexperimental, prospective, longitudinal investigation funded by the Maternal and Child Health Bureau: MCJ-250583, Early Intervention Collaborative Study: Preschool Phase (Apr. 1, 1989 through Dec. 31, 1993) and MCJ-250533, The Early Intervention Collaborative Study: Phase One (Jan. 1, 1986 through June 30, 1989). Six 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 5. Early study outcomes included aspects of children's cognitive and social development and family adjustment.

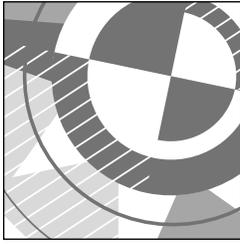
Followup home-based child and family assessments and school-based data collection will be conducted at age 10. Core child outcomes include three aspects of social competence: Adaptive skills, behavior problems, and social connectedness. Core family outcomes include three aspects of parent well-being: Marital satisfaction, sense of competence as a parent, and depression.

Population Description and Sampling Plan

The sample comprises children with early developmental delays or disabilities and their families who received early intervention services from community-based programs in Massachusetts and New Hampshire between 1985 and 1991. The study sample is 55 percent male and 89 percent Caucasian. At age 5, the sample included 50 children with Down syndrome, 61 children with I.Q. scores ≤ 75 (excluding children with Down syndrome), and 50 children with I.Q. scores > 75 . Seventeen percent of the families had annual incomes below \$15,000 and 49 percent had incomes above \$35,000.

Analysis Plan

Both descriptive analyses and hypothesis testing will be conducted using analysis of variance, multiple regression, structured equation models, and hierarchical linear modeling.



Homeless Mothers and Children: A Longitudinal Study

Grantee

Harvard University Medical School

Investigator

Ellen Bassuk, M.D.
Better Homes Fund
181 Wells Avenue
Newton Center, MA 02159
(617) 964-3834
(617) 244-1758 fax

Project Number MCJ-250809

Project Period 12/01/1995–11/30/1996

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	159,151	63,660	222,811
Year 2	59,781	23,852	83,633
Year 3			
Year 4			
Year 5			

Year 2000 Objectives

4.6, 6.3, 7.4, 7.5, 7.14, 8.3, 14.5, 14.11, 14.16,
17.2, 17.15, 20.11, 21.4

Study Design

Observational

Time Design

Mixed

Care Emphasis

Noninterventional

Population Focus

Infants, Toddlers, Preschool Children, School
Age Children, Adolescents, Pregnant Women,
Nonpregnant Women, Parents

Race/Ethnic Focus

None

Summary

Statement of the Problem

While the causes of family homelessness can be traced to broader economic and psychosocial issues—particularly the gap between income and rent, the availability of decent affordable low-income housing, and the high poverty rates among families headed by women—much remains to be learned about the course of homelessness and the experience of residential instability over time. Such information is critical for designing effective interventions and for developing prevention strategies. This study of population-based community samples of homeless and housed women and their children holds considerable promise in developing an understanding of the course of homelessness in families, the ways in which these homelessness factors differ from factors affecting vulnerability, and the consequences of homelessness for women and children.

Research Questions or Hypotheses

By following a sample of homeless and housed families for 24 months and collecting additional data over time, the study team will be able to: (1) Examine the natural course of homelessness among families and the extent to which it is chronic or episodic; (2) compare and contrast factors that increase risk of homelessness with those that prolong it; (3) examine mediating factors, especially social support resources and their effects on residential stability for homeless women and their children; (4) describe the conse-

quences of homelessness for women with respect to service utilization, victimization, and other life stressors; and (5) examine the consequences of homelessness, other risk factors, and protective factors (such as mother's mental health) on the development, socioemotional adaptation, and academic achievement of children over time.

Study Design and Methods

This longitudinal study will build on an existing population-based case-control comparison of homeless and housed families and the strong collaborative relationships that have been developed in the community. The prospective study will involve followup interviews of both mothers and their children (approximately 1,000 children) at 12 and 24 months subsequent to their initial baseline interview completed for the cross-sectional study.

A battery of standardized measures will be used to operationally define and measure the maternal and child variables of interest. Child outcomes (including mental and physical health, socioemotional functioning, and educational achievement) will be measured using standardized instruments, including the Children's Depression Inventory, the revised Children's Manifest Anxiety Scale, the Child Behavior Checklist, the Diagnostic Interview Schedule for Children (DISC), and the Vineland Adaptive Behavior Scales. Mediating variables including social support, other resources, and children's traits will be measured using the Harter Scales (parallel forms for school-age and preschool children). For school-age children, social support will be measured using "My Family and Friends," and peer relations will be measured using the Index of Peer

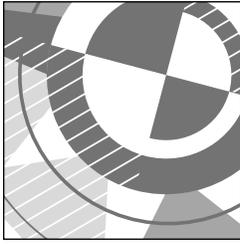
Relations. The Emotionality, Activity, Sociability (EAS) Temperament Scale will be used for infants and toddlers ages 4 months to 30 months. With the exception of the DISC, Kaufman Brief Intelligence Test (K-BIT), and health questions, all of the outcome measures will be administered at 12 and 24 months followup.

Population Description and Sampling Plan

The sample comprises 220 homeless families and 216 housed families in the community of Worcester, Massachusetts. The racial/ethnic composition of the sample is 36 percent white, 15 percent black, 36 percent Puerto Rican Hispanic, 6 percent other Hispanic, and 7 percent mixed or other race.

Analysis Plan

The longitudinal random effects model, a form of repeated measures analysis that can handle dropouts due to attrition, will be used to examine changes in quantitative outcomes such as children's and mothers' mental health over study followup. The presence of quadratic (nonlinear) changes will be explored graphically. Respondent measures that vary during the study period, such as social support and residential stability, will be incorporated as time-varying covariants to measure the longitudinal correlation that develops over time among these key factors. Similarly, Cox's regression will be used to model the course of homelessness as a discrete outcome (i.e., homeless or not), allowing for time-varying covariants to examine associations over time with such factors as substance abuse and mental health problems.



Does Lead Burden Alter Neuropsychological Development?

Grantee

University of Minnesota School of Medicine

Investigator

Elsa G. Shapiro, Ph.D.
Box 486 UMHC
420 Delaware Street, SE
Minneapolis, MN 55455
(612) 625-7466
(612) 625-7950 fax
e-mail: shapi004@marron.tc.umn.edu

Project Number MCI-270302

Project Period 12/01/1995–11/30/2000

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 Children

Race/Ethnic Focus

African Americans, Asians—All Others,
Hispanics—Mexican Americans, Hispanics—
Puerto Ricans, Hispanics—All Others, Native
Americans

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 nutri-

tion 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 this important neuropsychological deficit.

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 13 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.

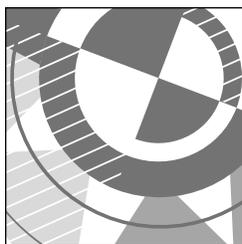
The neuropsychological and experimental measures will be administered by trained technicians indigenous to the community and representative of the racial/ethnic makeup of the neighborhood. In addition, electrophysiological measures of attention and memory will be administered to a subgroup of lead-burdened 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 Description and Sampling Plan

Approximately 560 children from a racially and ethnically diverse inner-city neighborhood of low socioeconomic status in Minneapolis will constitute the study sample for this research.

Analysis Plan

Using hierarchical linear models, the researchers will analyze the relationship of 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.



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
e-mail: deina001@maroon.tc.umn.edu

Project Number MCI-270801

Project Period 01/01/1995–12/31/1999

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

Year 2000 Objectives

8.11, 11.4

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates, Infants, Toddlers, Preschool children,
Parents

Race/Ethnic Focus

African Americans, Asians—All Others,
Hispanics—Mexican Americans, Hispanics—
Puerto Ricans, Hispanics—All Others, Native
Americans

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.

Study Design and Methods

Two groups will be receiving educational materials in this randomized trial—a basic group and an

intensive group. The basic education materials will consist of face-to-face advice given routinely to patients by health care providers, as well as pamphlets (typically in English) commonly found in doctors' offices or distributed by the local health department. All participants will have 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 will receive 20 intervention sessions over the course of 1 year. The intervention will be conducted primarily in the mother's home, in her own language, by a peer teacher from her own community and racial/ethnic group who has assisted in developing the form and content of the educational materials. Quarterly booster sessions tailored to the developmental stage of the child will then be conducted for the remainder of the study.

The intensive education phase (year 1) and booster sessions will be tailored to the racial/ethnic background of the participant; members of different racial/ethnic groups, through participation in focus groups conducted by the research team, have expressed interest in receiving more information through different media. Intensive intervention and booster sessions will focus on sanitation, hygiene, and nutritional guidelines for the prevention of lead burden.

Prenatal exposure to lead will be measured via maternal blood levels and cord blood lead levels. Lead levels of the children will be assessed three times per year, during which 5 mL of venous blood will be analyzed with atomic absorption spectroscopy. At enrollment and at relocation, remodeling, or rehabilitation of the home, samples of paint, dust, water, and soil will be taken from each participant's home. Dust samples will continue to be collected twice a year throughout the study as changes in household sanitation resulting from participation in the intensive education intervention would be likely to affect only this source of lead contamination.

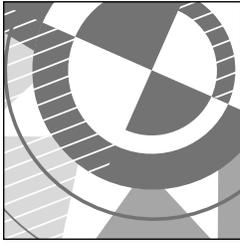
Population Description and Sampling Plan

A total of 537 mothers from the Phillips neighborhood of Minneapolis and parts of adjacent neighborhoods will be recruited during the prenatal period or during their offspring's early infancy. They will be randomly assigned within racial/ethnic groups (African American, Native American, white, Southeast Asian, Hispanic) to an intensive education or a 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 µg/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.



Mom/Kid Trial: A Multicomponent Abuse Prevention Program

Grantee

University of Missouri

Investigator

Lizette Peterson-Homer, Ph.D.
Psychology Department
210 McAlester Hall
Columbia, MO 65211
(573) 882-6083
(573) 882-7710 fax
e-mail: psyfiz@mizzou1.missouri.edu

Project Number MCI-290635

Project Period 10/01/1993–09/30/1999

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	248,324	111,746	360,070
Year 2	279,479	125,811	405,290
Year 3	283,707	130,505	414,212
Year 4	315,230	124,602	439,832
Year 5	221,596	101,934	323,530

Year 2000 Objectives

7.4

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Toddlers, Preschool Children, Parents

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

Estimates of the number of children who suffer serious abuse range from 1 to 2.5 million each year. More than 1,000 children are known to die at the hands of caregivers each year, and recent data suggest that actual rates of fatal abuse for children under age 4 may be double the rate suggested by vital statistics data. Known risk factors for abuse include being of low-income status, having a preschool-age child, using physical discipline, experiencing high levels of anger, holding unrealistic expectations for the child, and failing to enjoy a positive relationship with the child. Thousands of programs and millions of dollars have been allocated to treat child abuse, yet there has been very little empirical evaluation of such treatment interventions. Most experts agree that prevention is likely to prove much more effective than intervention, yet even fewer prevention programs have data to support their effects.

Research Questions or Hypotheses

This project's two experimental studies are designed to examine the effectiveness of a multicomponent preventive program aimed at mothers who are at high risk for child abuse. The primary goal is to create a complete set of lesson plans and stimulus materials with empirically demonstrated effectiveness that could be readily implemented at other child abuse treatment and prevention sites. The project will also examine individual differences in response to treatment (in

order to determine the psychosocial and historical characteristics of the women who benefit most from the program) and will provide initial data on the process of treatment. Such process measures include using a daily diary to track the point during treatment when affective changes occur and to examine how subjects' reactions to treatment (e.g., motivation, relationship with staff) predict treatment response. Ultimately, such data can describe the characteristics of the subjects who benefit most from such preventive treatment.

Study Design and Methods

In the first study, half of the subjects will be randomized to a nontreatment control group, and half will receive 16 sessions of group therapy. The content of the group therapy is built upon a model that suggests that child-rearing skills must be taught, but in order to be used effectively, these skills must be supported by (1) a base of knowledge concerning the developing child, (2) reasonable beliefs and attitudes about parenting, (3) positive affect and motivation, and (4) strong self-identification with the parental role (teacher, protector) and the maternal role (nurturer).

Each of these components is a direct part of a specific curriculum lesson, referenced in broad terms throughout other lessons and served by specific techniques. Skills or tools, for example, include problem solving, time management, relationship enhancement, abilities to effect change in child behaviors, compliance training, nonphysical discipline, and health and safety behaviors.

Knowledge of the child's developmental abilities is taught directly, referenced throughout the curriculum, and reinforced through the technique of taking perspective. Beliefs and attitudes are addressed directly in the lesson Gentle but Strong Parenting, yet every lesson targets attitudes or beliefs that act as barriers to effective parenting and teaches the technique

of reconstructing dysfunctional beliefs. Affective changes are addressed directly through teaching anger management, and self-regulation of affect is addressed in each lesson. The techniques of "tuning in" to the joy of parenting and planned demonstrations of physical affection from mother to child and from child to mother ("warm fuzzies") are topics of explicit exercises every week.

Defining and accepting the maternal role as protector and nurturer is taught directly and presented in every session, and role-relevant self-reinforcement (being a good mother) is rehearsed as a cognitive skill. Women also enter into a self-contract to use certain tools or skills they select as part of their identification as a parent; during graduation from the group, this contract is read in the presence of group members and significant others.

In the first study, a home visitor makes referrals for other psychosocial needs and personalizes the learning, which is implemented in the home by practice exercises, daily activities to build mother-child bonding, and the "tuning in" exercises. Networking is accomplished through establishing group partners who help one another through the weekly exercises.

Seven domains of data will be collected: Screening information, demographic and background information, premeasures and postmeasures of treatment outcome, continuous measures of treatment outcome, detailed process measures of response to treatment both within the group and during the home visit, data on social service referral and utilization, and followup data. Background information will include history of violence within family of origin and later conjugal relationships, levels of social support, and history of drug and alcohol use, including maternal substance use while pregnant with the target child. Premeasures and postmeasures include the Child Abuse Potential Inventory, Eyberg Child Behavior Inventory, Child Anger Scale, Problem-Solving Abilities, Parent Opinion

Questionnaire, Home Observation for Measurement of the Environment Inventory, and three measures developed for this study—Family Chaos: Interview and Observation, Problem Solving, and the Parental Efficacy Inventory. Also developed for this study are two structured observations of child compliance (parent control strategies and mother-child interaction) as well as a self-monitored daily diary that will be used to measure positive and negative maternal affect and to document the mother's use of discipline over the 4 months. At the end of the first study, staff members will assist the home visitor in designing materials that can be used to improve group sessions.

A second study, building on the first, will compare the revised group treatment intervention (without the home visitation, but with brief telephone support and curriculum individualization) and this same revised intervention with the addition of a weekly home visiting intervention. A control group is not used in this second study. The focus, instead, is on direct testing of the effectiveness of the intervention's home visiting component (beyond the effects of the group intervention and brief telephone support alone), based on the assumption that the first study already will have established the superiority of the multicomponent group intervention over nonintervention.

Population Description and Sampling Plan

Subjects are recruited in five waves for the first study and five waves for the second study. Twelve subjects in each wave are initially assigned to the experimental group and 12 to the control group. A

targeted total of 120 mothers will participate in each of the two studies. Mothers are included if they (1) are of low-income status, (2) have a target child between the ages of 18 months and 5 years, (3) use physical discipline, and (4) experience anger toward the child. The study excludes mothers who do not speak English, plan to move within the next 4 months, have more than 2 years of college education, are active clients of child protective services, or have major psychopathology or moderate-to-severe mental retardation.

The population from which the sample is drawn is 63 percent white, 26 percent African American, and 11 percent other minorities. Mothers rather than fathers are the focus of the study because the majority of high-risk families identify the mother as the primary caregiver, and the nature of the group therapy intervention necessitates a single gender.

Analysis Plan

The major hypothesis is that the efficacy of the treatment condition will be demonstrated by significant results from multivariate analyses of variance (MANOVAs) grouped by domain of the premeasures and postmeasures of outcome, then documented by followup univariate tests. The contribution of individual characteristics and of process measures as predictors of treatment outcome will be explored by creating an outcome composite criterion and by using simultaneous multiple regression. Changes in the continuous measure of outcome (i.e., the diaries) will be accomplished through blocking the data and using repeated measures ANOVAs, and through the use of time series analysis of trends.



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
 e-mail: JENKINEC(a)NYSOMR.EMI.
 COM@MISSIVE

Project Number MCI-360587

Project Period 09/01/1994–08/31/1999

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			

Year 2000 Objectives

14.13, 21.6

Study Design

Quasi-experimental

Time Design

Mixed

Care Emphasis

Noninterventonal

Population Focus

Pregnant Women

Race/Ethnic Focus

None

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**

	Total Samples	CVS	AF	Full Mutation	Pre- mutation	Normal
1996	27	22	5	13	1	13
Cumulative	111	67	44	44	8	59
1996	16	14	2	9	1	6*
Cumulative	57	40	17	20	5	32
1996	11	8	3	4	—	7
Cumulative	54	27	27	25	3	26
Termination of pregnancy	9	—	—	7	2	—
Termination of pregnancy	7	—	—	7	—	—

Note: AF = atrial fibrillation
*One normal female confirmed with cord blood sample.

Since several examples of “spontaneously” occurring (noninduced) fragile X chromosomes have been observed in prenatal cultures and subsequently found to be fragile X mutations, the investigators have stressed that cytogenetic laboratories continue to be aware of fragile sites. The investigators recommend that pregnant women be offered molecular testing immediately when fragile X chromosomes are observed spontaneously.

The combination protocol previously developed and employed is being improved. Additional studies are being carried out to reduce turnaround time by limiting sample size for both PCR and Southern analyses. The investigators are continuing to improve this protocol by developing a novel PCR-Southern blot procedure and demonstrating that this new procedure can significantly reduce turnaround time for the Southern analysis. In addition, the investigators have been able to show that it is possible to distinguish between full mutation samples and control prenatal samples using monoclonal antibodies. Through continued development, prenatal detection proce-

dures will be improved so that results may be made available the same day or within 1 day of receipt of 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.

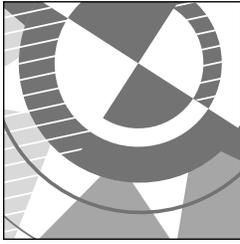
Fetal cells will be simultaneously tested using PCR and direct DNA testing (Southern hybridization and analysis) and will be retrospectively analyzed with monoclonal antibodies, which are able to indicate the full mutation. Retrospective study is necessary to validate the protocol and to pinpoint the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

Population Description 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.



Antenatal Formula Distribution: Effect on Breastfeeding

Grantee

University of Rochester School of Medicine

Investigator

Cynthia R. Howard, M.D.
School of Medicine and Dentistry
Department of Pediatrics
601 Elmwood Avenue
Rochester, NY 14642
(716) 336-3926
(716) 336-3929 fax
e-mail: choward@rghnet.edu

Project Number MCJ-360648

Project Period 10/01/1994–09/30/1997

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	117,305	33,901	151,206
Year 2	99,295	28,796	128,091
Year 3	18,459	5,353	23,812
Year 4			
Year 5			

Year 2000 Objectives

2.10, 2.11*, 14.9*

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates, Infants, Pregnant Women,
Nonpregnant Women

Race/Ethnic Focus

African Americans, Hispanics—Puerto Ricans,
Hispanics—All Others

Summary

Statement of the Problem

H *Healthy People 2000* has established breastfeeding objectives for the Nation, namely that 75 percent of women will breastfeed their infants initially and 50 percent will continue breastfeeding at 5–6 months. Despite broad historical and scientific evidence to support breastfeeding, only about 50 percent of the women in the United States initially breastfeed their infants, and as few as 20 percent are still breastfeeding at 6 months.

Recently, some formula manufacturers have begun distributing formula samples and business reply cards for free formula antenatally through physicians' offices. In many instances, women planning to breastfeed have obtained formula in this manner at home by the time they deliver their infant. No current studies examine whether antenatal formula distribution has an effect on either the decision to breastfeed or the success and duration of breastfeeding. However, given the known negative effect of early formula supplementation and hospital discharge packets on breastfeeding, similar effects might be expected from antenatal formula distribution by physicians. Of additional concern, the reply cards offer the availability of formula with low iron concentration, which fails to provide adequate amounts of iron in the diet of infants who are fed formula exclusively.

Research Questions or Hypotheses

This study will examine the influence of commercial formula advertising and formula distribution (through physicians' offices) on breastfeeding initiation and duration. We hypothesize that the distribution of commercial formula promotional materials to pregnant women by prenatal providers (1) decreases breastfeeding initiation rates, (2) increases early supplementation of breastfeeding (infants younger than 2 weeks of age), (3) decreases the duration of exclusive breastfeeding, (4) decreases the period of time before solid foods are introduced on a daily basis, (5) decreases the period of time before the infant is weaned, (6) decreases the possibility that the mother will attain her personal goal for breastfeeding duration, and (7) increases the use of low-iron formula in the first 6 months of life.

Study Design and Methods

This study is a prospective, blinded, randomized trial. The study protocol incorporates antenatal and postnatal components. In the antenatal portion, 520 women in 2 obstetric practices will be randomized to receive either commercial infant formula promotion materials or noncommercial infant feeding education materials at their first prenatal visit. Noncommercial materials will provide information about breastfeeding and formula feeding while conforming to the World Health Organization's code for marketing of breastmilk substitutes (i.e., no advertising or formula samples). The noncommercial materials are designed to provide neutral infant feeding information and to be distinctly different from the commercial packets that promote formula feeding. The major outcome of interest in the antenatal portion of the study—the choice of infant feeding method—will be ascertained in interviews conducted during the postpartum hos-

pital stay. These interviews will also provide information about potentially confounding factors.

Informed consent will be obtained for the postnatal portion of the study, which will evaluate the effect of exposure to commercial infant formula promotion materials on breastfeeding duration. Those women who choose to breastfeed their infants and agree to participate will be followed for 6 months with serial telephone interviews. The postnatal portion of the study will evaluate the effects of antenatal exposure on breastfeeding duration, rates of formula supplementation, timing of introduction of solid foods, and potential for attaining personal breastfeeding goals.

Population Description and Sampling Plan

Women will be recruited from two private practices at Rochester General Hospital. All women who present for their first prenatal visit to either practice while the sample is being formed will be randomized to the study. One practice provides care for a primarily (95 percent) white, privately insured population, while the other practice provides care for a racially and ethnically diverse population (51 percent white, 32 percent African American, and 17 percent Hispanic). Forty-seven percent of the patients are from Northeast Rochester, an area where approximately one-quarter of the population lives below the Federal poverty level.

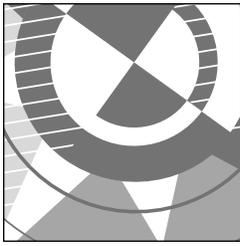
Analysis Plan

For the antenatal portion of the study, the decision to breastfeed will be treated as a binary outcome (yes/no). Continuous variables will be compared between groups, by using Student's *t* test (transforming any non-normal variable distributions, if necessary,

or using nonparametric methods). Categorical variables will be tested for differences by chi-square statistics, and 95 percent confidence intervals for proportions will be calculated to examine the variance of the point estimates. In addition, the effect of exposure to formula will be tested by calculating the relative risk of deciding to breastfeed, and stratified and logistic regression analyses will test for potential confounding variables in this relationship.

In the postnatal portion of the study (examining the effect of antenatal exposure to formula on breastfeeding duration), duration will be treated as a binary

variable (continued breastfeeding to 6 months) and analyses will be similar to those for the antenatal portion. Duration of breastfeeding will also be treated as a continuous variable (duration in weeks). Mean differences between the two groups will be tested by Student's *t* test or nonparametric methods. Time-to-event analysis (Cox proportional hazards "survival" analysis) will also test for the relative risk associated with the failure or success of breastfeeding with multivariate modeling to control for confounding variables. We will also test various models for potential effect modification by subject characteristics.



Diarrheal Illness Surveillance in Child Day Care

Grantee

University of North Carolina

Investigator

Kristen Weigle, M.D.
CB#7400
2104F McGavran-Greenberg Hall
University of North Carolina
Chapel Hill, NC 27599-7400
(919) 966-7439
(919) 966-2089 fax
e-mail: KRIS_WEIGLE@UNC.EDU

Project Number MCJ-370641

Project Period 10/01/1994–09/30/1997

Costs	Direct Costs Awarded	Indirect Costs Awarded	Total
Year 1	120,000	52,288	172,288
Year 2	175,295	78,006	253,295
Year 3	34,789	15,481	55,270
Year 4			
Year 5			

Year 2000 Objectives

20.8

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates, Infants, Toddlers

Race/Ethnic Focus

None

Summary

Statement of the Problem

Increasingly, both mothers and fathers of young children in the United States work outside the home; hence, children are frequently cared for in out-of-home settings. The fastest growing type of child care facility, large centers caring for children younger than 2 years of age, are also the type of setting most strongly associated with an increased risk of infectious illnesses. In response to this growing concern, numerous health authorities, including the Centers for Disease Control and Prevention, the American Public Health Association, and the American Academy of Pediatrics, have recommended strategies to reduce the spread of infectious pathogens in child care centers. Although these recommendations are based on established principles of infection control, it has not been demonstrated that, in the absence of close monitoring, training of child care center staff in hand washing and other hygienic practices leads to an overall reduction in illness such as diarrheal disease.

Research Questions or Hypotheses

This study will examine whether diarrheal illness rates are reduced by surveillance of diarrheal illness, either alone or in combination with a hygienic education program.

Study Design and Methods

A total of 45 child care centers will be randomly assigned to 1 of 3 groups: Illness surveillance, illness surveillance and hygienic education, or control group. Trainers and sponsors from the child care centers assigned to the intervention groups will receive separate training through a series of workshops, self-instruction, demonstrations, and assessment exercises. They will then implement the illness surveillance or the illness surveillance with hygienic education program in their centers.

Population Description and Sampling Plan

Each of the 45 child care centers in the study provided care for at least 30 children under 36 months of age and at least 5 children under 12 months of age. These centers, recruited from 114 licensed centers in Durham, Wake, and Orange Counties in North Carolina, were identified from a list of all centers in these counties provided by the North Carolina Division of Child Development, Child Day Care Section. The study will enroll the parents of approximately 630 children within the 45 centers. The children must be younger than 24 months of age and must attend the center for at least 20 weeks, and the parents must consent to participate in bimonthly telephone interviews.

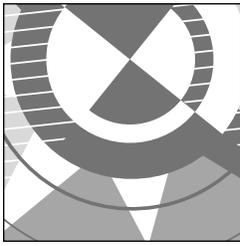
Analysis Plan

The research team will assess the children's illness rates by parental telephone interviews conducted during 9 months and will compare the rate of diarrheal illness in the intervention centers with that of the control centers.

The unit of analysis will be the child care classroom. For each classroom, the incidence density rate

will be calculated for all moderately severe diarrhea. Children who change classrooms will contribute time and risk to each classroom. For information not originally collected at the classroom level, classrooms will be assigned a summary value. For child-specific information, the classroom will be assigned the mean value (age) or a proportion (percent sharing bedroom at home). For center-specific information, each classroom will be assigned the value of the center.

Through unadjusted and adjusted linear regression, the research team will estimate the differences in mean incidence density rate (IDR) between intervention and control classrooms. These differences will be expressed as the number of excess episodes per child year occurring in control classrooms compared to intervention classrooms. For each comparison, we will use a one-sided *t* test to determine whether to reject the null hypothesis of no difference in mean diarrheal rates.



African American Children's Transition to School

Grantee

University of North Carolina

Investigator

Joanne Erwick Roberts, Ph.D.
 Frank Porter Graham Child Development Center
 105 Smith Level Road, CB #8180
 Chapel Hill, NC 27599-8180
 (919) 966-7164
 (919) 966-7532 fax
 e-mail: joanne_roberts@unc.edu

Project Number MCI-370649

Project Period 10/01/1994–09/30/1999

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

Year 2000 Objectives

8.3, 17.15, 20.9

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

School Age Children, Parents

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

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

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

Research Questions or Hypotheses

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

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

Study Design and Methods

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

Population Description and Sampling Plan

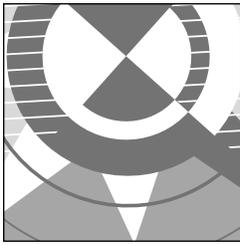
This study will involve 75 African-American families and their children who were recruited during early infancy. The children included in the study have relatively normal prenatal and perinatal histories, are generally healthy, and were enrolled in one of nine local child care centers by the age of 1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

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

Analysis Plan

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

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



Pediatric Health Supervision to Promote Literacy

Grantee

Case Western Reserve University

Investigator

Robert D. Needlman, M.D.
 Rainbow Babies and Children's Hospital
 General Academic Pediatrics
 11100 Euclid Avenue
 Cleveland, OH 44106
 (216) 844-8260
 (216) 844-8444 fax

Project Number MCI-390631

Project Period 10/01/1993–09/30/1998

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

Year 2000 Objectives

8.3

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Infants, Toddlers, Preschool Children

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

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

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

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

Research Questions and Hypotheses

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

Study Design and Methods

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

Population Description and Sampling Plan

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

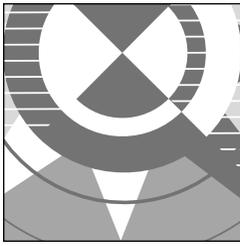
Over the first year of the study, 325 children were recruited in this manner. Following collection of baseline data, including a home evaluation, parent interview, and parent testing, subjects were randomized to receive either the experimental intervention (books) or the control intervention (toys) at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

Analysis Plan

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

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

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



Cost-Effective Emergency Department Screening for UTI Febrile Children

Grantee

Children's Hospital of Philadelphia

Investigator

Kathy Shaw, M.D.
Joseph Stokes Jr. Research Institute
34th and Civic Center Boulevard
Philadelphia, PA 19104
(215) 590-1944
(215) 590-4454 fax

Project Number MCJ-420648

Project Period 10/1/94-9/30/97

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

Year 2000 Objectives

Study Design

Observational

Time Design

Cross-sectional

Care Emphasis

Noninterventional

Population Focus

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

Race/Ethnic Focus

None

Summary

Statement of the Problem

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

Research Questions or Hypotheses

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

Study Design and Methods

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

Population Description and Sampling Plan

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

Analysis Plan

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



Behavior Problems in School-age Children of Teen Mothers

Grantee

University of Washington

Investigator

Robert J. McMahon, Ph.D.
Department of Psychology
Box 351525
Seattle, WA 98195-1525
(206) 543-5136
(206) 685-3157 fax
e-mail: mcmahon@u.washington.edu

Project Number MCI-530589

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

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

Year 2000 Objectives

6.3, 6.13, 6.14

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventional

Population Focus

School Age Children, Adolescent Parents,
Parents

Race/Ethnic Focus

None

Summary

Statement of the Problem

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

Research Questions or Hypotheses

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

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

Study Design and Methods

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

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

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

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

Population Description and Sampling Plan

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

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

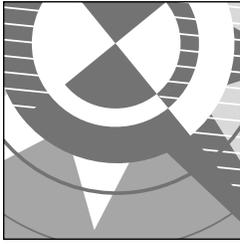
purposely seeks to address potential gender differences in the development of conduct problems and in the risk and protective factors. Because of the small numbers of non-white families participating in the study, it is unlikely that racial or ethnic health issues could be explored in secondary data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

Analysis Plan

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

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

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



Early Child Care Study of Children with Special Needs

Grantee

University of Washington

Investigator

Cathryn L. Booth, Ph.D.
Room 106-108 South Building
WJ-10
Seattle, WA 98195-7920
(206) 543-8074
(206) 685-3349 fax
e-mail: ibcb@u.washington.edu

Project Number MCI-530640

Project Period 04/04/1994–03/31/1999

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

Year 2000 Objectives

8.3

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

Infants, Toddlers, Preschool Children, Parents

Race/Ethnic Focus

None

Summary

Statement of the Problem

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

Research Questions or Hypotheses

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

Study Design and Methods

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

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

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

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

Population Description and Sampling Plan

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

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

Analysis Plan

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

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

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

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

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

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

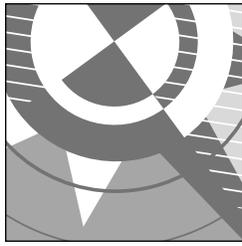
Some of the research hypotheses deal with the moderating effects of child, family, and home environment characteristics on globally observed relationships between child care and child outcomes. A number of analytic approaches are planned to deal with this construct; the two most direct approaches are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

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

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

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

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



Maternal Birthweight and Reproductive Outcomes

Grantee

University of Washington

Investigator

Irvin Emanuel, M.D., M.S.
 Department of Epidemiology
 Box 357236
 Seattle, WA 98195-7236
 (206) 543-8827
 (206) 616-8370 fax
 e-mail: emanuel@u.washington.edu

Project Number MCI-530807

Project Period 09/01/1995–08/30/1998

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

Year 2000 Objectives

14.1, 14.2, 14.5, 14.7, 14.14, 17.10

Study Design

Observational

Time Design

Longitudinal

Care Emphasis

Noninterventonal

Population Focus

Neonates, Infants, Pregnant Women

Race/Ethnic Focus

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

Summary

Statement of the Problem

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

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

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

Research Questions or Hypotheses

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

Study Design and Methods

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

Population Description and Sampling Plan

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

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

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

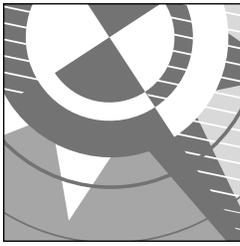
Analysis Plan

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

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

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

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



Clinician Help for Mothers of Infants with Lung Disease

Grantee

University of Wisconsin School of Nursing

Investigator

Karen F. Pridham, Ph.D.
 600 Highland Avenue H6/252
 Clinical Science Center
 Madison, WI 53792-2455
 (608) 263-5282
 (608) 263-5332 fax
 e-mail: kpridham@macc.wisc.edu

Project Number MCI-550806

Project Period 10/01/1995–09/30/1998

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

Year 2000 Objectives

2.4, 14.14

Study Design

Experimental

Time Design

Longitudinal

Care Emphasis

Interventional

Population Focus

Neonates, Infants, Parents

Race/Ethnic Focus

African Americans

Summary

Statement of the Problem

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

Research Questions or Hypotheses

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

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

vention group and the standard care group in their pattern of growth through the first postterm year.

The hypotheses are as follows:

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

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

Study Design and Methods

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

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

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

Population Description and Sampling Plan

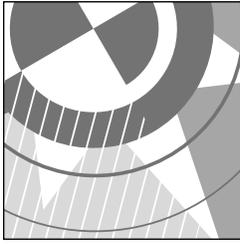
The study population will consist largely of central-city African-American mothers at least 16 years of age and their infants weighing < 1,000 grams at birth. The two NICU sites from which families will be recruited are St. Joseph's Hospital and Sinai Samaritan Hospital. Both provide neonatal care to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

Analysis Plan

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

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

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



Healthy People 2000 Objectives by Active Projects 1996-97¹

Physical Activity And Fitness:

- 1.1* Reduce coronary heart disease deaths to no more than 100 per 100,000 people.
- 1.2* Reduce overweight to a prevalence of no more than 20 percent among people aged 20 and older and no more than 15 percent among adolescents aged 12 through 19.
- 1.3* Increase to at least 30 percent the proportion of people aged 6 and older who engage regularly, preferable daily, in light to moderate physical activity for at least 30 minutes per day.
- 1.4 Increase to at least 20 percent the proportion of people aged 18 and older and to at least 75 percent the proportion of children and adolescents aged 6 through 17 who engaged in vigorous physical activity that promotes the development and maintenance of cardiorespiratory fitness 3 or more days per week for 20 or more minutes per occasion.
- 1.5 Reduce to no more than 15 percent the proportion of people aged 6 and older who engage in no leisure-time physical activity.
- 1.7* Increase to at least 50 percent the proportion of overweight people aged 12 and older who have adopted sound dietary practices combined with regular physical activity to attain an appropriate body weight.

Nutrition:

- 2.3* Reduce overweight to a prevalence of no more than 20 percent among people aged 20 and older and no more than 15 percent among adolescents aged 12 through 19.
- 2.5* Reduce dietary fat intake to an average of 30 percent of calories or less and average saturated fat intake to less than 10 percent of calories among people aged 2 and older.
- 2.6* Increase complex carbohydrate and fiber-containing foods in the diets of adults to 5 or more daily servings for vegetables (including legumes) and fruits, and to 6 or more daily servings for grain products.
- 2.7* Increase to at least 50 percent the proportion of overweight people aged 12 and older who have adopted sound dietary practices combined with regular physical activity to attain an appropriate body weight.
- 2.8 Increase calcium intake so at least 50 percent of youth aged 12 through 24 and 50 percent of pregnant and lactating women consume 3 or more servings daily

¹An asterisk (*) next to the number indicates duplicate objectives that appear in two or more priority areas.

of foods rich in calcium, and at least 50 percent of people age 25 and older consume 2 or more servings daily.

- 2.11* Increase to at least 75 percent the proportion of mothers who breastfeed their babies in the early postpartum period and to at least 50 percent the proportion who continue breastfeeding until their babies are 5 to 6 months old.

Tobacco:

- 3.4* Reduce cigarette smoking to a prevalence of no more than 15 percent among people aged 20 and older.
- 3.6 Increase to at least 50 percent the proportion of cigarette smokers aged 18 and older who stopped smoking cigarettes for at least one day during the preceding year.
- 3.8 Reduce to no more than 20 percent the proportion of children aged 6 and younger who are regularly exposed to tobacco smoke at home.
- 3.16 Increase to at least 75 percent the proportion of primary care and oral health care providers who routinely advise cessation and provide assistance and followup for all of their tobacco-using patients.

Family Planning:

- 5.11* Increase to at least 50 percent the proportion of family planning clinics, maternal and child health clinics, sexually transmitted disease clinics, tuberculosis clinics, drug treatment centers, and primary care clinics that screen, diagnose, treat, counsel, and provide (or refer for) partner notification services for HIV infection and bacterial sexually transmitted diseases (gonorrhea, syphilis, and chlamydia).

Mental Health and Mental Disorders:

- 6.3 Reduce to less than 10 percent the prevalence of mental disorders among children and adolescents.
- 6.5 Reduce to less than 35 percent the proportion of people aged 18 and older who experienced adverse health effects from stress within the past year.
- 6.13 Increase to at least 50 percent the proportion of primary care providers who routinely review with patients their patients' cognitive, emotional and behavioral functioning and the resources available to deal with any problems that are identified.
- 6.14 Increase to at least 75 percent the proportion of providers of primary care for children who include assessment of cognitive, emotional, and parent-child functioning, with appropriate counseling, referral, and followup, in their clinical practices.

Violent and Abusive Behavior:

- 7.7 Reduce rape and attempted rape of women aged 12 and older to no more than 108 per 100,000 women.
- 7.9 Reduce by 20 percent the incidence of physical fighting among adolescents aged 14 through 17.

Educational and Community-Based Programs:

- 8.2 Increase the high school graduation rate to at least 90 percent, thereby reducing risks for multiple problem behaviors and poor mental and physical health.
- 8.3 Achieve for all disadvantaged children and children with disabilities access to high quality and developmentally appropriate preschool programs that help prepare children for school, thereby improving their prospects with regard to school performance, problem behaviors, and mental and physical health.
- 8.12 Increase to at least 90 percent the proportion of hospitals, health maintenance organizations, and large group practices that provide patient education programs, and to at least 90 percent the proportion of community hospitals that offer community health promotion programs addressing the priority health needs of their communities.
- 8.14 Increase to at least 90 percent the proportion of people who are served by a local health department that is effectively carrying out the core functions of public health.

Environmental Health:

- 11.1 Reduce asthma morbidity, as measured by a reduction in asthma hospitalizations to no more than 160 per 100,000 people.

Maternal and Infant Health:

- 14.1 Reduce the infant mortality rate to no more than 7 per 1,000 live births.
- 14.2 Reduce the fetal death rate (20 or more weeks of gestation) to no more than 5 per 1,000 live births plus fetal deaths.
- 14.5 Reduce low birth weight to an incidence of no more than 5 percent of live births and very low birth weight to no more than 1 percent of live births.
- 14.6 Increase to at least 85 percent the proportion of mothers who achieve the minimum recommended weight gain during their pregnancies.
- 14.7 Reduce severe complications of pregnancy to no more than 15 per 100 deliveries.
- 14.9* Increase to at least 75 percent the proportion of mothers who breastfeed their babies in the early postpartum period and to at least 50 percent the proportion who continue breastfeeding until their babies are 5 to 6 months old.
- 14.11 Increase to at least 90 percent the proportion of all pregnant women who receive prenatal care in the first trimester of pregnancy.
- 14.14 Increase to at least 90 percent the proportion of pregnant women and infants who receive risk-appropriate care.
- 14.16 Increase to at least 90 percent the proportion of babies aged 18 months and younger who receive recommended primary care services at the appropriate intervals.

Heart Disease and Stroke:

- 15.2 Reduce stroke deaths to no more than 20 per 100,000 people.

-
- 15.9* Reduce dietary fat intake to an average of 30 percent of calories or less and average saturated fat intake to less than 10 percent of calories among people aged 2 and older.
 - 15.10* Reduce overweight to a prevalence of no more than 20 percent among people aged 20 and older and no more than 15 percent among adolescents aged 12 through 19.
 - 15.11* Increase to at least 30 percent the proportion of people aged 6 and older who engage regularly, preferably daily, in light to moderate physical activity for at least 30 minutes per day.

Cancer:

- 16.6* Reduce cigarette smoking to a prevalence of no more than 15 percent among people aged 20 and older.
- 16.7* Reduce dietary fat intake to an average of 30 percent of calories or less and average saturated fat intake to less than 10 percent of calories among people aged 2 and older.
- 16.8* Increase complex carbohydrate and fiber-containing foods in the diets of adults to 5 or more daily servings for vegetables (including legumes) and fruits, and to 6 or more daily servings for grain products.
- 16.10 Increase to at least 75 percent the proportion of primary care providers who routinely counsel patients about tobacco use cessation, diet modification, and cancer screening recommendations.

Diabetes and Chronic Disabling Conditions:

- 17.2 Reduce to no more than 8 percent the proportion of people who experience a limitation in major activity due to chronic conditions.
- 17.4 Reduce to no more than 10 percent the proportion of people with asthma who experience activity limitation.
- 17.12* Reduce overweight to a prevalence of no more than 20 percent among people aged 20 and older and no more than 15 percent among adolescents aged 12 through 19.
- 17.13* Increase to at least 30 percent the proportion of people aged 6 and older who engage regularly, preferably daily, in light to moderate physical activity for at least 30 minutes per day.
- 17.14 Increase to at least 40 percent the proportion of people with chronic and disabling conditions who receive formal patient education including information about community and self-help resources as an integral part of the management of their condition.
- 17.15 Increase to at least 80 percent the proportion of providers of primary care for children who routinely refer or screen infants and children for impairments of vision, hearing, speech and language, and assess other developmental milestones as part of well-child care.
- 17.20 Increase to 50 the number of States that have service systems for children with or at risk of chronic and disabling conditions, as required by Public Law 101-239.

HIV Infection:

18.13* Increase to at least 50 percent the proportion of family planning clinics, maternal and child health clinics, sexually transmitted disease clinics, tuberculosis clinics, drug treatment centers, and primary care clinics that screen, diagnose, treat, counsel, and provide (or refer for) partner notification services for HIV infection and bacterial sexually transmitted diseases (gonorrhea, syphilis, and chlamydia).

Sexually Transmitted Diseases:

19.11* Increase to at least 50 percent the proportion of family planning clinics, maternal and child health clinics, sexually transmitted disease clinics, tuberculosis clinics, drug treatment centers, and primary care clinics that screen, diagnose, treat, counsel, and provide (or refer for) partner notification services for HIV infection and bacterial sexually transmitted diseases (gonorrhea, syphilis, and chlamydia).

19.13 Increase to at least 90 percent the proportion of primary care providers treating patients with sexually transmitted diseases who correctly manage cases, as measured by their use of appropriate types and amounts of therapy.

Immunization and Infectious Diseases:

20.1 Reduce indigenous cases of vaccine-preventable diseases as follows: diphtheria among people aged 25 and younger to zero; tetanus among people aged 25 and younger to zero; polio to zero; measles to zero; rubella to zero; congenital rubella syndrome to zero; mumps to 500; and pertussis to 1000.

20.4 Reduce tuberculosis to an incidence of no more than 3.5 cases per 100,000 people.

20.9 Reduce acute middle ear infections among children aged 4 and younger, as measured by days of restricted activity or school absenteeism, to no more than 105 days per 100 children.

20.11 Increase basic immunization series among children under age 2 to at least 90 percent and among children in licensed child care facilities and kindergarten through post-secondary education institutions to at least 95 percent.

Clinical Preventive Services:

21.2 Increase to at least 50 percent the proportion of people who have received, as a minimum within the appropriate interval, all of the screening and immunization services and at least one of the counseling services appropriate for their age and gender as recommended by the U.S. Preventive Services Task Force.

21.4 Improve financing and delivery of clinical preventive services so that virtually no American has a financial barrier to receiving, at a minimum, the screening, counseling, and immunization services recommended by the U.S. Preventive Services Task Force.

21.5 Assure that at least 90 percent of people for whom primary care services are provided directly by publicly funded programs are offered, at a minimum, the

screening, counseling, and immunization services recommended by the U.S. Preventive Services Task Force.

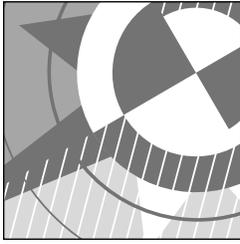
- 21.6 Increase to at least 50 percent the proportion of primary care providers who provide their patients with the screening, counseling, and immunization services recommended by the U.S. Preventive Services Task Force.

Surveillance and Data Systems:

- 22.4 Develop and implement a national process to identify significant gaps in the Nation's disease prevention and health promotion data, including data for racial and ethnic minorities, people with low incomes, and people with disabilities, and establish mechanisms to meet these needs.

INDEXES

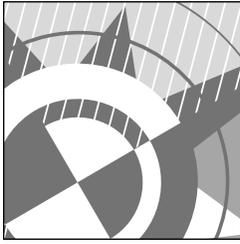




Project Index

Adverse Effects of Cow Milk in Infants	101
African American Children's Transition to School	148
Alternatives for Developmental Screening in Primary Care	54
Antenatal Formula Distribution: Effect on Breastfeeding	143
Behavior Problems in School-age Children of Teen Mothers	155
Choices of Life for Adolescence Success	47
Clinician Help for Mothers of Infants with Lung Disease	164
Cost-Effective Emergency Department Screening for UTI Febrile Children	153
Crossing Cultural Boundaries: An Ethnographic Study	11
Development of Monitoring Methods for Perinatal Outcomes	121
Diarrheal Illness Surveillance in Child Day Care	146
Does Education Limit Lead Burden?	135
Does Lead Burden Alter Neuropsychological Development?	133
Early Child Care Study of Children with Special Needs	158
Early Cortisol Replacement to Prevent BPD: Pilot Study	70
Early Intervention Collaborative Study: Age 10 Follow-up	129
Effect on Breastfeeding of Pacifiers and Bottle Feeding	50
Evaluation of Hawaii's Healthy Start Program	113
Factors Associated with Nutritional Intake in Adolescents	43
Free β and HCG in Screening for Down Syndrome	103
Growth and Development: Longitudinal Followup	109
Health Care Utilization: Pediatric Organ Transplantation	18
Home Nursing to Avoid Pediatric Hospitalization	58
Home Versus Group Visits After Early Postpartum Discharge	15
Homeless Mothers and Children: A Longitudinal Study	131
Improved Prenatal Detection of the Fragile X Mutation	140
Improving Health/Development of Low Income Pregnant Women	35
Indicators of Maternity Care in Medicaid Managed Care	95
Infant ETS Exposure: Clinic-Based Maternal Counseling	3
Infant Temperament: Neonatal to 5 Years in Rural Appalachia	84
Injury Prevention in an Urban Pediatric Clinic	118

Interparental Conflict and Adolescent Violence	7
Maternal Birthweight and Reproductive Outcomes-Phase 2	81
Maternal Birthweight and Reproductive Outcomes	161
Mom/Kid Trial: A Multicomponent Abuse Prevention Program	137
Office Systems to Improve Preventive Care for Children	88
Pediatric Health Supervision to Promote Literacy	150
Poverty and the Ecology of African-American Children	26
Predicting the Need for Hospitalization in Childhood Asthma	74
Preventing Mental Health Problems in Ill Children	123
Prospective Investigation of Twin Gestation	40
Psychosocial Sequelae of Bronchopulmonary Dysplasia and Very Low Birthweight-Phase Two	66
Reducing Preterm Birth by Bacterial Vaginosis	30
Regulatory Disorders and Developmental Outcomes	111
Role of Early Family Supports in Adult Self-Sufficiency	62
San Antonio Triethnic Children's Blood Pressure Study	78
Satisfaction with and Utilization of Prenatal Care	22
Social Context of Puerto Rican Child Health and Growth	126
Three-generation Intervention Among Adolescent Mothers	105
Use of Child Health Services by Hispanic Families	99
Watchful Waiting Versus Antibiotics As Soon As Possible	97



Subject Index

- Access to Health Care 22, 99
Adolescent Nutrition 43
Adolescent Parents 105, 155
Adolescents 7, 18, 43, 58, 74, 131
African Americans 11, 22, 26, 30, 43, 47, 54, 66, 74, 78, 95, 103, 105, 109, 133, 135, 137, 143, 148, 150, 161, 164
Alaskan Natives 161
Anticipatory Guidance 118, 150
Asians 43
Asians—All Others 103, 113, 133, 135
Asians—Chinese 103
Asians—Filipinos 103, 113
Asians—Japanese 113
Asthma 74
Attachment 155
Attachment Behavior 84
Bacterial Infections 97
Behavior Disorders 66, 111, 155
Blood Pressure Determination 78
Body Composition 43
Breastfeeding 50, 143
Bronchopulmonary Dysplasia 70
Case Management 74
Cerebral Palsy 129
Child Abuse 137
Child Abuse Prevention 113
Child Care 62, 146, 158
Child Neglect/Maltreatment 137
Children with Special Health Care Needs 11, 18, 54, 66, 74, 111, 123, 129, 158, 164
Chronic Illnesses and Disabilities 18, 66, 74, 123, 164
Clinics 30
Communicable Diseases 146
Community Based Health Services 30, 58
Community Health Aides 35
Community Integrated Service System 35
Compliance 18
Cost Effectiveness 58, 74, 153
Counseling 3
County Health Agencies 58
Cultural Sensitivity 11, 26, 47, 84
Decision Making Skills 47
Delayed Development 66, 129
Developmental Disabilities 66
Developmental Evaluation 54, 62
Developmental Screening 54, 133
Diarrhea 146
Dissemination 11
Domestic Violence 7
Down Syndrome 103, 129
Early Childhood Development 54, 62
Early Intervention 54, 129, 158
Emergency Room Personnel 153
Failure to Thrive 109
Families 11, 105
Family Centered Health Care 11
Family Characteristics 66
Family Environment 3, 7, 26
Family Relations 155
Family Support Programs 18, 105, 123

Feeding Disorders 111
 Fragile X Syndrome 140
 Gestational Weight Gain 40
 Growth and Development 111, 126, 129, 148
 Hawaiian Natives 113
 Health Care Utilization 18, 22, 58, 74
 Health Education 35, 146
 Health Professionals 11
 Health Promotion 88
 Health Services Use 99, 118
 Hispanics 3, 7, 43, 54, 78
 Hispanics—All Others 95, 103, 133, 135, 143, 161
 Hispanics—Mexican Americans 95, 99, 133, 135, 161
 Hispanics—Puerto Ricans 99, 126, 133, 135, 143, 161
 Home Visiting 109, 113, 118, 137
 Home Visiting Programs 15, 58
 Home Visiting Services 15, 58
 Homelessness 131
 Hygiene 146
 Illness in Child Care 146
 Infant Health Care 15
 Infant Morbidity 3, 15, 30
 Infant Mortality 30, 121
 Infant Temperament 84
 Infants 3, 11, 15, 50, 54, 58, 101, 111, 113, 118, 121, 131, 133, 135, 143, 146, 150, 158, 161, 164
 Injury Prevention 118
 Lead Poisoning 133, 135
 Learning Disabilities 66
 Literacy 150
 Low Birthweight 30, 66, 81, 161, 164
 Low Income Population 26, 54, 62, 81, 95, 109, 137, 148, 150, 161
 Managed Care 95
 Marital Conflict 7
 Maternal Nutrition 40
 MCH Research 3, 7, 11, 15, 18, 22, 26, 30, 35, 40, 43, 50, 54, 58, 62, 66, 70, 74, 78, 84, 105, 153
 Medicaid 22, 95
 Medicaid Managed Care 22
 Mental Health 123
 Mental Retardation 140
 Mexicans 7, 18, 78
 Multiple Births 40
 Native Americans 43, 133, 135, 161
 Neonatal Mortality 30, 70
 Neonates 15, 30, 50, 70, 97, 113, 118, 121, 135, 143, 146, 161, 164
 Nonpregnant Women 131, 143
 Nutrition 40, 43
 Nutrition—Infancy and Childhood 101, 143
 Pacific Islanders 43
 Paraprofessional Personnel 35
 Parent Education 135
 Parent-Child Interaction 129, 137, 155
 Parenting 137, 155, 164
 Parents 7, 18, 66, 99, 113, 118, 123, 126, 129, 131, 135, 137, 148, 155, 158, 164
 Patient Education 88
 Pediatricians 88
 Peer Counseling 135
 Peer Support Programs 35
 Perinatal Health 15, 30, 121
 Postpartum Women 15, 50
 Pregnant Women 22, 30, 35, 95, 97, 103, 131, 140, 143, 161
 Premature Labor 30
 Prenatal Care 22, 30, 40, 95
 Prenatal Diagnosis 140
 Prenatal Screening 30, 43, 103

Preschool Children 11, 54, 58, 74, 84,
109, 111, 113, 131, 133, 135, 137,
150, 158

Preterm Birth 30

Preventive Health Care 88

Preventive Health Education 88

Primary Care 54, 58

Psychological Problems 18, 66

Psychosocial Factors 105

Psychosocial Services 18

Pulmonary Disease 66

Quality Assurance 58, 121

Research 3, 26, 35, 40, 50, 62, 70, 78,
84, 105, 153

Rural Population 84

School Age Children 11, 58, 66, 74, 99,
109, 123, 126, 129, 131, 148, 155

School Dropouts 47

Screening 153

Sensory Impairments 111

Sexual Behavior 7

Sleep Disorders 111

Smoking During Pregnancy 3

Specialized Care 18

Standards of Care 15, 74

State Programs 54

Support Groups 35

Surveys 43

Toddlers 11, 54, 58, 111, 113, 118, 131,
133, 135, 137, 146, 150, 158

Twins 40

Urban Population 11, 153

Urinary Tract Infections 153

Violence 7

Violence Prevention 7