MATERNAL AND CHILD HEALTH BUREAU
DIVISION OF RESEARCH, TRAINING AND EDUCATION
RESEARCH PROGRAM

PORTFOLIO OF ACTIVE RESEARCH PROJECTS

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Preface

This document lists the Maternal and Child Health Bureau (MCHB) research projects funded in Fiscal Years 2001 through 2004 that are currently active. The following information is included for each active project: Grant Number, Title, Abstract, Principal Investigator, Grantee Organization, and Project Period. For additional information, please contact the MCHB Research Program at (301) 443-2207.
1. **R40 MC 06630-01, Single Home Visits to Improve Health Outcomes**

Because adherence to postnatal care guidelines is poor, newborns and mothers are often placed at undue risk for adverse medical and social outcomes. This proposal aims to improve health care delivery to and reduce health disparities for "well" newborns and mothers after hospital discharge by using single postnatal home nurse visits. The PI has previously shown a reduction in poor outcomes for infants receiving a home visit after discharge when studied retrospectively. The proposed research will build on his previous study and prospectively evaluate the impact of a single home nursing visit on morbidities and health disparities for at-risk newborns and mothers in a randomized, controlled trial. Outcomes for newborns include hospital readmission, acute care utilization, compliance with primary care visits, and breastfeeding rates. For mothers, confidence in parenting, satisfaction with care, and incidence of postpartum depression will be evaluated. A cost-effectiveness analysis will also be performed. This application addresses 3 of the current MCHB Strategic Research Issues. First, this study seeks to improve health outcomes for minorities and Medicaid recipients while improving compliance with care guidelines, addressing Strategic Research Issue #II that seeks to study health services and systems of care efforts to eliminate health disparities and barriers to health care access. Next, by attempting to show improved health outcomes through the use of a home visit, Strategic Research Issue #III related to quality of care, health care delivery, and use of emergency medical services will be covered. Finally, in addressing the outcomes of postpartum depression and parenting confidence as well as the health outcomes for newborns such as breastfeeding rates, this application also will attend to Strategic Research Issue #IV that promotes healthy development of MCH populations.

**Principal Investigator:** Ian M. Paul, M.D., M.Sc., Assistant Professor, Pennsylvania State University Department of Pediatrics, Hershey, Pennsylvania. Period of Support: 01/01/2006 – 12/31/2009.

2. **R40 MC 06632-01, Increasing Retention in Home Visitation**

Virtually all child abuse prevention programs lose a sizable proportion of otherwise eligible participants to disengagement and attrition. Among those who are retained, many do not adhere to program protocols. Although a number of factors have been implicated in attrition and decreased program adherence, diminished motivation and commitment to sustained participation in long-term prevention programs has emerged as a prominent contributor. We propose to conduct a randomized controlled clinical trial of Motivational Interviewing (MI) to enhance retention and promote program adherence in 284 first time mothers receiving home visitation, a widely used approach to child abuse prevention. MI is a client-centered strategy that focuses specifically on increasing motivation and commitment to change. MI will be evaluated in two models of home visitation: Nurse Home Visitation and Healthy Families America. Mothers in four agencies (two each of NHV and HFA) will be randomly assigned to MI or Home Visitation As Usual (HVAU) conditions. Half of the home visitors will be extensively trained in MI procedures, and intervention fidelity will be monitored. The other half (HVAU) will receive an attention control training. It is hypothesized that (1) the MI condition will be superior to HVAU in terms of retention and program adherence, (2) MI will result in benefits in both the HFA and NHV models, (3) mothers with higher levels
of depression and trauma history will be more likely to be retained relative to their counterparts with lower levels of depression and trauma history, and (4) retained mothers in the MI condition will have better outcomes than retained mothers in the HVAU condition. This proposal addresses MCHB Strategic Research Issues 3 (assure quality of care for MCH populations) and 4 (promoting the healthy development of MCH populations) by seeking to improve delivery and impact of home visitation, and providing young children and their families with a higher quality of care by helping them sustain commitment to an early prevention program.

**Principal Investigator:** Robert T. Ammerman, Ph.D., Professor, Cincinnati Children’s Hospital Medical Center, Behavioral Medicine & Clinical Psychology, Cincinnati, Ohio. Period of Support: 01/01/2006 – 12/31/2009.

3. **R40 MC 06631-01, Effectiveness of a treatment for pediatric obesity**
The prevalence and incidence of pediatric obesity has been increasing at an alarming rate. More than twice the number of children and adolescents are obese today as compared to 20 years ago, and children are becoming obese at earlier ages. Children with obesity are at risk for a variety of concurrent physical and mental health problems. Further, children who are obese are more likely to become adults who are obese, resulting in increased risk for premature mortality as well as decreased relational and social quality of life. The pediatric obesity literature suggests a number of efficacious treatment components. However, the literature is limited in that few studies have examined the clinical effectiveness of these interventions in a "real-world" setting. Rather, the generalizability of research findings is constrained by sample characteristics and recruitment methods that may not reflect clinical practice. Further, outcomes have typically not included broad measures of quality of life, client satisfaction, and cost-benefit information, all of which have been recommended for effectiveness studies. The proposed investigation is designed to contribute to MCHB Strategic Research Issue #4 by studying the effectiveness of a family-based intervention to promote healthy weight and treat obesity in children and adolescence, as well as cost-effectiveness and consumer satisfaction. Exploratory aims include the examination of specific predictors of adherence to treatment. The proposed investigation utilizes a randomized clinical trial to insure maximum internal reliability. Participants will include 120 children and their parents who are seeking treatment for pediatric obesity at two university based outpatient clinics. Participants will be randomly assigned to immediate treatment or waitlist control conditions. Results will provide evidence of the clinical effectiveness, cost-effectiveness, and consumer satisfaction of the intervention, all of which will help with the translation of empirically supported therapies into clinical practice. Further, results will delineate specific factors related to participant adherence that may be targeted as components of therapy in future efficacy studies.

**Principal Investigator:** Ric G. Steele, Ph.D., Assistant Professor, University of Kansas, Institute for Life Span Studies, Lawrence, Kansas. Period of Support: 01/01/2006 – 12/31/2009.
4. R40 MC06633-01, How Insurance Instability Impacts Children
The purpose of this study is to examine patterns and correlates of unstable insurance patterns for children, focusing on instability for vulnerable populations. It will do so by describing health insurance coverage patterns for all children and specific subgroups of children, exploring factors that may contribute to unstable insurance patterns, and assessing prevalence of trigger events, such as divorce, marriage or job changes that may be antecedents of coverage loss. Health insurance coverage is an important component for optimal health care for children. Recently published studies have described unstable patterns and correlates for the under 65 population, but there are no similar thorough studies focusing on children. Yet, patterns may be different for children due to the greater availability of public coverage. The problem of gaps in coverage is of particular concern for our nation's most vulnerable children - those from low-income, immigrant, and racial/ethnic minority groups. Further, gaps in coverage are likely to disproportionately affect those children enrolled in public insurance programs because of the requirements for periodic re-assessment of eligibility. Given the lack of knowledge about insurance stability in children, this study aims to: 1) describe and define unstable insurance patterns for children, 2) describe antecedents of coverage loss for children as a whole and for subgroups of children, and 3) contrast the frequency and duration of gaps in coverage by insurance types (public vs. private) and for subgroups of children. The results of this study will provide important information that is directly applicable to designing improvements in the health care infrastructure and systems of care to reduce insurance instability for children. In addition, this study can help elucidate the association of unstable insurance coverage with public vs. private coverage and for racial and ethnic subgroups. This study will be based on data collected in the Medical Expenditure Panel Survey for 2000 to 2002, which is a nationally representative, longitudinal survey that includes health information on children. In order to address our hypotheses, we will use univariate statistics and bivariate comparisons, and develop multivariate models to examine correlates of unstable insurance coverage.

Principal Investigator: Gerry Fairbrother, Ph.D., Professor, Children’s Hospital Medical Center, Cincinnati, Ohio. Period of Support: 01/01/2006 – 12/31/2007.

5. R40 MC 06635-01, Racial-Ethnic Disparities in Low Birthweight: A Multi Level Study in LA County
Low birth weight (LBW) is a leading cause of racial-ethnic disparities in perinatal mortality and morbidities in the US and in Los Angeles County (LAC). The reasons for the persisting disparities in LBW are largely unknown. We hypothesize that racial ethnic disparities in LBW are mediated in large part by pregnancy and lifetime exposures to interpersonal and institutionalized racism, acting directly on maternal stress biology and behavior or indirectly through family, neighborhood and institutional stressors. The effects of racism are moderated by social support and cultural factors. To test this hypothesis, we propose a multilevel study using the Los Angeles Mommy and Baby Survey (LAMBS). The LAMBS will survey 3,130 mothers in LAC with a recent live birth using a mixed-mode methodology similar to the Pregnancy Risk Assessment Monitoring System (PRAMS). However, LAMBS differs from PRAMS in two important ways. First, LAMBS is based on a multistage clustered design, first sampling
neighborhoods (90 "high-risk" and 45 "low-risk" neighborhoods), and then sampling births within these neighborhoods with over-sampling of LBW births. Second, LAMBS is designed as a multilevel survey, assessing not only individual-level factors but also interpersonal, neighborhood, and institutional influences including racism. The LAMBS' multistage clustered sampling and expanded questionnaire will allow for multilevel analysis of the multiple determinants of racial-ethnic disparities in LBW.

**Principal Investigator:** Michael C. Lu, M.D., Assistant Professor, The Regents of the University of California, David Geffen School of Medicine at UCLA, Los Angeles, California. Period of Support: 01/01/2006 – 12/31/2008.

6. R40 MC 06636-01, Maternal Sexual Infections and Adverse Child Outcomes

This research is responsive to MCHB Strategic Research Issue #IV - promoting the healthy development of MCH populations. The overall goal of this project is to answer the research question: Do sexually associated infections during pregnancy result in an increased risk for fetal death, mental retardation (MR) and developmental delay (DD)? In order to answer the research question, we will analyze data from a cohort of over 152,000 Medicaid maternal-child pairs in a retrospective cohort design. The study will examine maternal sexually associated illnesses, diagnostic procedures, and treatments used during the prenatal period, and their association with infant and childhood morbidity and mortality. Sexually associated diseases will include sexually transmitted diseases, infections associated with intercourse (including UTI during pregnancy) and some possibly associated with sexual activity (bacteria vaginosis and candidiasis). A major strength of this study is the large sample size available for analysis. Another notable strength is the ability to link mother and child files that incorporate medical diagnoses and prescription information as well as early childhood data. We have the capability to exclude children with known causes of MR/DD since we have diagnosis and treatment codes. By excluding these children, we will be able to focus on the role of sexuality associated diseases in otherwise unexplained cases of MR/DD; further, we will avoid the dilution of measurable effects that would likely occur if known causes were kept in the analysis. Our use of prospectively collected data alleviates the potential problem of bias in reporting sexually associated infections in relation to childhood outcomes. The benefit of this research is to provide information about the impact of treated and untreated sexually associated conditions on fetal and infant outcomes. There is potential for prevention if treated sexually associated conditions are not associated with adverse outcomes and untreated conditions are associated with adverse outcomes. Medicaid program recipients (including minority children, children with special health care needs and children of low socioeconomic status) will directly benefit from this project since the findings can be used to inform prevention and treatment.

**Principal Investigator:** Suzanne McDermott, Ph.D., Professor, University of South Carolina Research Foundation, Family & Preventive Medicine, Columbia, South Carolina. Period of Support: 01/01/2006 – 12/31/2009.
7. **R40 MC 00254-05, Intergenerational Pathways to Competence -II.**

This proposal is for a competing continuation to allow the completion of the scope of work proposed for R40 MC 00254 - Intergenerational Pathways to Competence in Minority Families.

The aims of the original grant were to collect adult data on individuals who had earlier been involved in randomized trials of early childhood educational intervention, including data on establishment of families, parenting effectiveness, and data from children aged 3 and older born to the adults. Adult participants were enrolled as infants in two consecutive randomized trials of early childhood intervention fro poor children: the Abecedarian Project and Project CARE. Data on families, parenting skills (attitudes and practices), home environments, and childcare arrangements for young children will be collected from all adults who are parents. In addition, psychological evaluations of children born to these adults will include: parent ratings of socioemotional functioning and behavior ratings and for children who are at least 3 years old, individual standardized tests of reading and math skills, multigenerational models that link factors from the generation of parents of the original infant sample (drawn from extant data sets), data on the second generation in early and middle childhood and young adulthood, and child outcomes in the third generation will be tested. The long-term outcomes of early child care, types of early intervention for children, and direct support for parents will be the primary focus of this research. These data will have immediate and direct impact on public policy developments in the areas of early childhood education, child care, parenting and healthcare.

**Principal Investigator:** Frances A. Campbell, Ph.D., Senior Scientist, University of North Carolina at Chapel Hill, Frank Porter Graham Child Development Center, Chapel Hill, North Carolina. Period of Support: 01/01/2006 – 12/31/2009.

8. **R40 MC 05488: School Competence of African American High School Youth**

This study examines how selected youth, peer, family, and school factors serve as risk and protective factors for African American youth's school competence during the transition to high school. Understanding the sociocultural factors that affect the school competence of African Americans during the high school years is critical for addressing the academic achievement gaps and differential opportunities as adults between African Americans and their non-minority peers in American society. The study objectives are to: a) identify mediators of the anticipated negative effects of exposure to multiple risks for the academic achievement and adjustment of African American youth during the transition to high school; b) determine the multiple youth (e.g., greater engagement in school, stronger racial identity), peer (e.g., higher quality friendships and less loneliness), family, (e.g., greater parental monitoring of activities and responsive and supportive parenting), and school (e.g., supportive teacher-student relationships and fewer low-income youth) characteristics that serve as protective factors for the school competence of African American youth during the transition to high school; and c) examine whether developmental trajectories across academic achievement, adjustment, and peer relationships during the transition to high school are linked for African American youth.
Study participants are 140 13 to 16 year old African American youth from low- and middle-income families, 70 of whom have been studied since infancy and their 70 friends who have been studied since 6th grade. The Maternal and Child Health Bureau has provided the funding since the youth began the study. Study youth's school engagement, racial beliefs and practices, peer relationships, adjustment, and academic achievement, and selected family, parenting, and school characteristics will be assessed in the summers after 9th and 10th grades. Standardized assessments will be used to measure the youth's academic achievement in reading, writing, and math. Questionnaires completed by the study youth and their teachers and families will examine the study youth's social and school adjustment, engagement in school, peer relationships, and racial beliefs/behavior. Characteristics of the school will be collected. Growth curve analyses will determine whether hypothesized youth, peer, family, and school factors serve as mediating or promotive/protective factors in the school competence of African American youth during the transition to and during the high school years. Study findings should have important implications for understanding the sociocultural factors that affect the school success of African American youth in their transition to high school and guide interventions to promote their school competence.

Understanding the sociocultural factors that affect the school competence of African Americans in high school is critical, given the demographic and ecological gaps between African American and White children in American society. Study findings should have important implications for the school success of African American youth in their transition to high school and guide interventions to promote school competence.


9. **R40 MC 05474: Aggregated Complication Measure for Neonatal Quality of Care**

Every year in the United States over 57,000 infants are delivered at least two months prematurely. Many of these infants are severely disabled, and their estimated cost for medical care to age 18 is between 4 and 5.4 billion dollars. A large part of these long-term costs result from complications developed after birth in the neonatal intensive care unit (NICU). While some outcomes are an unavoidable consequence of premature birth, increased cost and long-term disabilities may result from the quality of care these infants received in the NICU. However, there are no validated measures of the quality of neonatal care; currently available measures, such as mortality and individual complication rates, lack adequate power and validity and are confounded by influences outside the control of the NICU. This study will develop and validate a new quality measure, the aggregate complication measure (ACM), to evaluate hospitals according to the quality of care they provide after using direct standardization methods to control for differences in casemix. This study will use population data from Pennsylvania, New York, and California, with an estimated 95,000 premature births each year. Statistical modeling techniques will determine valid weights for each complication based on the impact of each complication on one of four outcomes of interest: death, length of stay,
cost, or 28-day readmissions. This project fulfills MCH Strategic Research Issues III, "Systems to assure quality of care for MCH populations" by giving policy makers a validated method of assessing and assuring the quality of neonatal care at individual hospitals. Additionally, this project fulfills MCH Strategic Research Issue I, "Public health service systems and infrastructures at the community, state, and/or national levels, as they apply to different maternal and child health populations based on demographic, epidemiological, and/or other factors" by determining the optimal location of care for different populations of high-risk infants. Completion of this project will produce a valid measure of neonatal quality to both evaluate hospitals and quantify the difference in quality between hospitals. Improved measures of neonatal quality will help facilitate initiatives to lower costs and improve the quality of neonatal care by reducing unnecessary morbidity and mortality in these infants.


**10. R40 MC 05470: Health Access for Children of Immigrants**

Migration will be a defining characteristic of the 21st century, yet little is known about the health of immigrants. Over the past 3 decades, the United States has experienced a wave of immigration that is both quantitatively and qualitatively unlike previous waves. The ethnic diversity that characterizes this wave of immigrants already has reshaped the demographic composition of the United States. Families with children are central to this demographic change, as children of immigrants are the fastest growing segment of the U.S. child population. Despite this growth, few studies examine health care access among children of immigrants. The majority of existing health access studies on children of immigrants lack national representation and lack inclusion of indicators of family migration. Given the inherent dependency of children upon adults, understanding of access to health care for children of immigrants may be improved by investigating the migration characteristics of their caretakers. The results of such analyses can advance the current knowledge pool regarding health access disparities among children of immigrants, as compared to those born to natives. Moreover, improved understanding of these relationships can be used to inform effective program and health policy development for this vulnerable and growing population of children. The proposed research provides a comprehensive examination of the association between caretaker immigration structure and access to health care among children of immigrants in the United States. Both potential access (barriers to care) and realized access (use of health care) will be examined. Univariate and bivariate analyses will be complemented by multivariate analyses using logistic regression, multinomial logistic regression, and 2-part econometric models. Moreover, subgroup analyses will test these adjusted models for variation of the associations among children of different racial, ethnic, and national origin categories. MCHB 2004 - 2009 Strategic Research Issues addressed include #II (elimination of health disparities and barriers to health care access) and #IV (promotion of healthy development of MCH populations). This proposal also addresses the Healthy People 2010 Leading Health Indicator of Access to Health Care.
11. R40 MC 05473: Wraparound Care Coordination for Part C Children
Care coordination is recognized as an essential component of services for children with special health care needs (CSHCN). CSHCN who participate in Part C early intervention services include children with families with complex health, developmental and family needs who would benefit from effective care coordination. This demonstration project will provide the Wraparound Care Coordination (WCC) to families with Part C eligible children, where families or children require high levels of care coordination. WCC uses a team-based planning and high intensity care coordination process that ensures children and their families receive individualized, community-based services and natural products. WCC facilitators will work with families to develop and implement service plans that address the priorities and needs of both parents and children. To make certain that the Wraparound services provided to families are faithful to WCC, facilitators will be trained in the Wraparound process through the use of manualized training and ongoing consultation. The evaluation of WCC will employ random assignment of families to intervention and comparison groups. Families in the intervention group will be provided WCC; families in the comparison group will receive standard Part C service coordination. The evaluation will assess child and family outcomes, including child developmental progress, family resources, parent stressors, satisfaction with services and service utilization.

12. R40 MC 05475: Family and Community Determinants of Childhood Injury Prevention
Safe environments are fundamental for successful and healthy children. Parental choices are the most important determinant of each child's risk of injury. This project seeks to develop new insights into the individual, household, and community determinants of parental safety behaviors in U.S. parents of children age 0 - 33 months.

We will analyze data collected in the National Evaluation of the Healthy Steps for Young Children Program. This dataset describes 5565 infants enrolled in 15 U.S. cities in 1996-1997 with follow-up until they were 30-33 months old. Parental reports of their own safety behaviors and their children's medically attended injuries and hospitalizations by age 2-4 months and by age 30-33 months will be supplemented by community level data from the 2000 Census and practice level data on each child's health care utilization.

The investigators will estimate the individual, household, and community determinants of safety behaviors using ANOVA, bivariate, and multivariate regression accounting for fixed effects and multilevel data structure. The investigators will test whether key life
events including parental relocation, mental health, alcohol use, and parental work force participation are associated with diminished safety behaviors and increased injuries. They will determine moderating factors which help to protect children from injury especially when they are growing up in higher risk communities and/or families.

**Principal Investigator:** David Bishai, M.D., Ph.D., Associate Professor, Department of Population and Family Health Sciences, Johns Hopkins University Bloomberg School of Public Health, Baltimore, Maryland. Period of Support: 9/1/2005 – 8/31/2007.

### 13. R40 MC 05501: Provider Payment and Dentistry for Poor Pregnant Women

Increasing recent evidence suggests that maternal oral infection is one factor in prematurity and growth restriction. At the same time, it has been known for at least two decades that untreated mothers are the source of oral infection in their children and that treating the mother greatly reduces the transmission of the disease to the child. Nevertheless the restriction of Medicaid dental benefits to pregnant women is increasing and Medicaid has failed to adapt to the "paradigm shift" that may be happening within dentistry - shifting from a focus on disease in the child to a medical model where the mother is treated to prevent problems with the offspring. Beyond the humanitarian and ethical issues, the State has an interest in this problem because low income women and children are more likely to have both of these conditions (caries and periodontal disease) and because low income children are legally entitled to medical and dental care for which the State must bear a major part of the cost. Research from four States (other than Oregon) shows that even among women with reported mouth symptoms, utilization of dental care is relatively low. Using analysis of Medicaid claims and a dental provider survey, the specific aims of this proposal are then: 1) To describe the utilization of dental care provided for pregnant and non-pregnant low-income women 18 - 35 years old in Oregon (N=3400 in 2003, Medicaid covered women in Oregon saw a dentist); 2) To ascertain the attitudes and knowledge of general dentists in Oregon (N=1700) regarding dental care for pregnant and non-pregnant women; and 3) To determine the impact of the method of provider payment (fee-for-service v. managed care/capitation) and provider knowledge and attitudes on access, use and cost of dental services. This research addresses MCHB Strategic Research Issue II: MCH services and systems of care efforts to eliminate health disparities and barriers to health care access for MCH populations, and III: Services and systems to assure quality of care for MCH populations.


Prenatal case management (PCM) is a community-based, health service provided to medically and socially high risk pregnant women. Twenty years of data from three longitudinal clinical trials show that PCM provided by registered nurses (RNs) has better outcomes for pregnant and parenting women than programs using lay para-professionals. Yet, the evidence based (EB) professional model is not universally implemented and
program structure varies. The purpose of this research is to understand barriers to the use of the EB professional model so that more effective adoption of interventions can be developed.

The aims of this study are to: (1) Characterize the types of existing PCM program models based on staff mix and extent to which it is an EB professional nursing PCM program model; (2) Identify the relationship of organizational and program internal environment to use of the EB professional nursing PCM model; (3) Identify the relationship of community, organizational, program internal environment, and program model to CM practice patterns; and (4) Identify the relationship of PCM program model and practice patterns to program outcomes, given community, organizational, and program internal environment. These aims are derived from four preliminary studies and a multi-level conceptual model. Study Aim 2 encompasses specific hypotheses predicting use of the EB program model.

A survey methodology is used with a multi-stage sample design with probabilities proportionate to number of PCM programs per state, yielding 10 states from which a random sample of 30 programs are selected per state. Survey data are collected from 250 PCM program directors and 1250 personnel involved in directly providing PCM to clients. Instruments include scales with demonstrated reliability with PCM personnel. Intervention data are also collected from case managers. Data are aggregated to the program level for analyses, and linked with community data from the Area Resource File and state vital statistics. Descriptive statistics are used to derive types of PCM program models and address hypotheses regarding contextual influences on the program model. Multiple regression, MANCOVA, and hierarchical linear modeling analyses are planned for Study Aims 3 and 4.

**Principal Investigator:** Michele Issel, Ph.D., Clinical Associate Professor, Department of Community Health Sciences, University of Illinois at Chicago School of Public Health, Chicago, Illinois. **Period of Support:** 9/1/2005 – 8/31/2007.

15. **R40 MC 05471: State-specific disparities in maternal and perinatal morbidity**
Scant data are available about maternal and perinatal morbidity. Such data are needed to shed light on racial and ethnic disparities in maternal, fetal and infant mortality within a state as well as disparities among states. These data answer the question of whether a racial disparity in mortality is due to a higher morbidity rate in one group, a higher case-fatality rate in that group, or both.

Numerous studies have shown that perinatal morbidity is under-reported on birth and fetal death certificates. In contrast, hospital discharge summaries provide reasonably accurate ascertainment of many perinatal morbidities. However, they lack information about important demographic and obstetric covariates, such as ethnicity, race, and parity. These covariates are reported on birth certificates. Linkage of hospital discharge summaries with birth certificates remedies the limitations of either source. Additionally, researchers using hospital chart abstraction as their "gold standard" have shown that, for an individual mother or child, joint consideration of birth certificates and hospital
discharge summaries provides more complete and accurate morbidity ascertainment than using either source alone.

In this project we will work with the nine states (CA, FL, GA, MA, MI, MO, NJ, SC, and WA) that have linked hospital discharge summaries with birth certificates and other vital records for 2000 and 2001. Our over-arching goal is to identify interventions that hold the promise of reducing disparities in maternal, fetal, and infant mortality through examining perinatal morbidity. Our objectives are: 1) to use linked birth certificate-hospital discharge data to describe the contribution of differences in morbidity and case-fatality rates to disparities within and among states for maternal, fetal, and infant mortality; 2) to prepare written reports of the results and consult with participating states on interpretation of the findings, particularly with regard to programmatic interventions; and 3) to disseminate the findings. Within each state, we will compare perinatal morbidity and case-fatality rates among groups defined by race and ethnicity. For each racial/ethnic group, we will also compare morbidity and case-fatality rates among states. These comparisons allow an individual state to see how it performs relative to other states. This project directly supports two strategic issues of the Maternal and Child Health Bureau, HRSA: 1) eliminating health disparities for MCH populations and 2) (supporting) systems and services to assure the quality of care for MCH populations.

**Principal Investigator:** Melissa Adams, Ph.D., Professor, Department of Maternal and Child Health, University of Alabama at Birmingham School of Public Health, Birmingham, Alabama. Period of Support: 9/1/2005 – 8/31/2008.

**16. R40 MC 04298: Dexamethasone For Bronchiolitis RCT: A PECARN Project.** Bronchiolitis is the most common lower respiratory infection of infants. It is associated with rapidly increasing hospital admission rates. Bronchiolitis is also one of the most common serious illnesses of childhood lacking evidence-based treatment. Despite previous negative trials, a recent small study suggested that oral dexamethasone in a single dose of 1mg/kg may markedly decrease the need for hospital admission. This project aims to continue such a trial, which has enrolled 200 infants thus far but requires 600 more to provide a definitive answer to this question. This study will assess the effectiveness of oral dexamethasone for acute moderate-to-severe outpatient infant bronchiolitis in a multi-center randomized controlled trial, taking as outcomes: (1) The need for hospital admission (primary outcome); (2) Clinical severity, measured by respiratory scores; (3) Duration of hospitalization (if admitted); (4) The safety of this treatment. Methodology: This project will continue a trial begun using existing resources at 16 medical centers in the EMSC/MCHB Pediatric Emergency Care Applied Research Network (PECARN). Results of the first year’s efforts show impressive parent acceptance of the study, nearly flawless randomization and blinding, complete and valid data collection, excellent follow-up rates, and apparent safety thus far. Study participation requires four hours of observation in the Emergency Department and a single, follow-up telephone call after 7 to 10 days. The study is designed to achieve 90% power to detect an effect size less than half that seen in the previously mentioned study, and will seek to enroll approximately 400 patients in each group.
Principal Investigator: Howard M. Corneli, M.D., Professor, Division of Pediatric Emergency Medicine, University of Utah, Salt Lake City, Utah. Period of Support: 01/01/2005-12/31/2006.

This is a Competing Extension of a randomized trial of a health promotion/overweight prevention program conducted among low-income, urban, African American adolescents. The existing project, entitled Challenge! Project, includes 248 adolescents randomized to intervention or control and followed for 18 months. The multi-level Intervention, based on developmental-ecological and social cognitive theory, includes a mentorship model in which the intervention adolescents receive a personal trainer/mentor who meets with them individually in home and community sites to administer the 12-session curriculum and to help the adolescents learn to establish challenges for themselves related to dietary and physical activity goals. The curriculum, based on extensive formative research, is action oriented – each session includes healthy food, physical activity, review of the adolescents' progress on the previous session's challenges, and new challenges for the subsequent week. Preliminary results from the 6-month evaluation are encouraging, suggesting that, in comparison with control adolescents, intervention adolescents eat more fruit, attain more dietary goals, are more physically active, and gain less weight. This application disseminates and extends the empirically supported nutritional and physical activity intervention further into the community by ensuring that the curriculum can be delivered in individual or group format, developing intervention and evaluation materials that can be disseminated, developing resources to conduct training, and conducting process evaluations in three community agencies.

Principal Investigator: Maureen Black, Ph.D., Professor, School of Medicine, University of Maryland Baltimore, Baltimore, Maryland. Period of Support: 01/01/2005-12/31/2006.

18. R40 MC 04294: Early Lactation Success in a Multi-Ethnic Population
Increasing the duration of exclusive breastfeeding is a health priority in the U.S., because of the many health benefits for mothers and infants. Campaigns to encourage mothers to attempt breastfeeding have resulted in increased rates of breastfeeding initiation, but the percentage predominantly breastfeeding at 10 wk postpartum has not improved. A major reason for this is that many mothers who initiate breastfeeding begin to supplement with formula or cease breastfeeding entirely within the first few weeks due to lactation difficulties. Thus, the most urgent need is to ensure that mothers who attempt breastfeeding are able to overcome these barriers. In a cohort of 280 predominantly Caucasian women who were highly motivated to breastfeed, the investigators found that more than 80% encountered problems during the first week postpartum such as delayed onset of milk production, sub-optimal infant breastfeeding behavior, or sore/cracked nipples. The investigators predict that these problems are at least as common in other ethnic groups, and that their effect on rates of exclusive breastfeeding are particularly
strong among women with lower motivation to breastfeed. The specific aims are to: 1) compare the incidence of early breastfeeding problems among primiparous African-American, Hispanic and non-Hispanic white women; 2) identify risk factors associated with delayed onset of milk production, sub-optimal infant breastfeeding behavior and sore nipples, with a focus on factors such as maternal and infant stress during labor and delivery, maternal overweight, infant characteristics and feeding patterns; and 3) assess factors associated with exclusive breastfeeding at one month postpartum within each of the three main ethnic groups, with a focus on the interaction between two key sets of potential predictors: a. prenatal breastfeeding intentions and self-efficacy, and b. breastfeeding problems during the first week postpartum. This will be a multi-ethnic prospective study of 660 urban mother-infant pairs in Sacramento, CA. Mothers will be recruited prenatally and interviewed within 24 hours of giving birth (considered "day 0") as well as on days 3, 7, 14, 30 and 60 postpartum. The long-term goal is to develop culturally appropriate, evidence-based strategies to reduce the incidence of breastfeeding problems and assist mothers to breastfeed exclusively.

Principal Investigator: Kathryn G. Dewey, Ph.D., Professor, Department of Nutrition, University of California, Davis, California. Period of Support: 01/01/2005-12/31/2008.

Tooth decay is the most common chronic childhood disease (Edelstein et al, 1995). Recent evidence indicates that nearly half of children aged 5 to 17 have decayed, missing, or filled tooth surfaces and teeth (Kaste, 1996). Low Income, minority children are disproportionately affected and are more likely to go untreated. Other evidence shows that few children covered by Medicaid receive the preventive dental care recommended under the Early and Periodic Screening, Diagnosis and Treatment program (DHHS, 1996). The reasons are complex. For dentists who operate independently, the access problems can be attributed to low fees, burdensome paperwork, reimbursement delays, aversion to managed care and unkept appointments. For low income families, preventive dental care may be a low priority, and they may not be aware of the importance of good dental hygiene. Access to dental care for low income children has become more acute due to the financial constraints linked to Medicaid managed care. Research examining children's use of and access to dental care under Medicaid managed care arrangements is sparse.

This proposed research will address this gap in knowledge. First, the investigators will analyze Medicaid eligibility, claims and encounter data for children with special health care needs enrolled in the DC Medicaid program to evaluate the effects of plan choice (managed care versus fee-for-service) on use of dental care services. Second, the investigators will evaluate the effect of plan choice on access to dental services. To evaluate access to dental care, recently conducted interviews with parents of 1,088 children with special health care needs enrolled in the DC Medicaid program will be used. The investigators will evaluate access to dental services over time.

From Neurons to Neighborhoods, the National Research Council's recent major report on factors that influence child development, articulates seven inter-related social, economic and political challenges facing those who care for children, whether at the level of families or the level of public policy. Among these is the "devolution of some important responsibilities for the implementation of child and family policies to the state and local levels." Title V of the Social Security Act (beginning with its predecessor, the Sheppard-Towner Act) represents the fundamental federal role in maternal and child health programs and through the years Title V has reflected the swinging of the pendulum between state and federal roles. While the MCH Services Block Grant provides core funding for infrastructure, population-based services, enabling services, and gap filling for clinical and other services that may not be readily available, the capacity of MCH agencies or programs to meet the needs of the population is a function of multiple political and economic characteristics of the states. In the political domain, the structure and capacity of governors' and the legislatures' roles may influence policy. In the economic domain, state domestic product, total taxable resources, per capita personal income, special education spending and other variables may have an impact on allocation decisions. Similarly, in the health domain state-level health insurance coverage, the supply of health care providers and other health system indicators may constrain or advance MCH programs.

Given the understandable, but nevertheless disproportionate, impact of services for Children and Youth with Special Health Care Needs on state resources, it is especially important to understand the relationship between state capacity and outcomes for these children and their families. The National Survey of CSHCN provides state level health status process measures to enable analysis of the relationship between state social, political and economic capacity and the health status of C/YSHCN. Using multivariable techniques, this research project will examine contextual factors that affect the capacity of MCH professionals and programs to assure the health of C/YSHCN.

**Principal Investigator:** Lewis H. Margolis, M.D., M.P.H., Associate Professor, Department of Maternal and Child Health, University of North Carolina at Chapel Hill, Chapel Hill, N.C.  Period of Support: 01/01/2005-12/31/2005.

Understanding the complex factors that influence maternal and child health and development requires a matching complexity and integration of methods at multiple levels. Advances in both quantitative and qualitative methods have enhanced our ability to measure developmental outcomes, describe patterns of change, and identify factors associated with change. However, the integration of both approaches in applied research has lagged behind their use individually. The methods provide complementary information, and, indeed, the weaknesses of one method can be offset by the strengths of the other. To oversimplify, qualitative data can provide in-depth information about developmental processes and their contexts, but usually include observations of only a
small number of individuals so generalizability of findings is suspect. Quantitative data can describe developmental trajectories and identify correlates of change in a manner that facilitates generalizability, but is less useful for describing process or the meanings that underlie health behaviors and attitudes. Integration of these methods should provide greater breadth and depth of understanding. However, there are many barriers to integrating methods at all levels (sampling, measurement development and/or selection, data collection, data analysis and interpretation), and few successful examples exist.

This study is expected to demonstrate the feasibility and utility of integrated analyses by extending the data collection and analysis in three large, recently funded, longitudinal studies of child development during the first five years of life. The investigators propose data collection and analysis that is not included in these ongoing projects and is not covered by current funding. They plan to integrate methods to optimize the appropriateness and cultural sensitivity of parenting and child outcome instruments by using traditional psychometric analyses, item response theory analyses using differential item function, and semi-structured interviews. Further, they will examine two research questions relating parenting beliefs and practices to child safety practices and to the development of self-regulation. Information about developmental processes collected in qualitative data through cultural models analysis and structural discovery approaches will be combined with information about developmental trajectories collected in the quantitative data through growth curve and latent profile analyses. The three projects involve longitudinal assessments of low and middle-income children in rural and urban settings, and include children from diverse ethnic backgrounds. One includes children with a specific genetic disorder, fragile X syndrome. This study extends those projects by providing additional methodological time and expertise to integrate methods within both measurement and analysis phases within and across projects, and to conduct an ethnographic study of the process of integrating methods across the three projects to identify characteristics of research designs and teams that facilitate integration.

Principal Investigator: Margaret R. Burchinal, Ph.D., Senior Scientist, Frank Porter Graham Child Development Institute, Chapel Hill, N.C. Period of Support: 01/01/2005-12/31/2007.

22. R40 MC 03600: Smoking During Pregnancy and Infantile GI Dysregulation. This project will investigate a physiologically plausible link between maternal smoking and infantile colic (IC). Intensely distressing to the infant, colic is also distressing for the caretaker. Caretakers of infants with colic have been reported as depressed, exhausted, and angry. Moreover, to the extent that caretakers of colicky infants provide fewer positive responses to their infants, colic may hinder attachment to the care-taker with serious long-term consequences. Presence of a colicky child can also adversely effect family functioning. Despite the high prevalence of colic, there is no consensus regarding its cause. Moreover, existing treatments for colic have, at best, limited efficacy in reducing infant distress. Therefore, it is important to conduct practical research to identify modifiable risk(s) for IC. Such research endeavors can be particularly beneficial to maternal and child health when they can also shed light on the pathophysiology of IC; thus, allowing development of potentially effective clinical interventions. Accumulating
Evidence suggests exposure to cigarette smoke or its metabolites may be linked with IC. Moreover, recent studies of the gastrointestinal system provide strong, but indirect, corroborating evidence by suggesting physiologic mechanisms by which maternal smoking can be linked with the offspring’s colic. This study will examine the chain of events within a single cohort of mothers and their infants. Findings from this research are expected to have significant public health and clinical implications in terms of preventing IC as well as maternal smoking, particularly during and immediately after pregnancy.

**Principal Investigator:** Edmond Shenassa, Sc.D., Assistant Professor of Community Health, Centers for Behavioral and Preventive Medicine at Brown Medical School and the Miriam Hospital, Providence, Rhode Island. Period of Support: 09/01/04-08/31/08.

23. **R40 MC 03602: Maternal Depressive Symptoms and Children’s Growth.**
This study aims to investigate whether maternal depressive symptoms adversely affect attained size and growth of young children, using an ecologic model that frames children’s and mother’s characteristics within the context of the family. Medical records and survey data are obtained from the national evaluation of the Healthy Steps (HS) for Young Children Program. Medical records data on weights and length from birth to 32 months are available for over 4,700 children whose mothers responded to a telephone survey at 2-4 months and who provided data about depressive symptoms based on a modified Center for Epidemiologic Studies Depression (CES-D) scale. Additional data about the mother and child include child’s sex, birth weight and general health status, maternal behaviors including infant feeding patterns and reported interactions with the infant, mother’s demographic characteristics and family composition, socioeconomic status, and the father’s help with the infant. Patterns of growth from birth to 24 months and upper and lower percentiles for weight, length and weight-for-length at 6, 12, and 24 months relative to the 2000 CDC growth charts for children 0 – 24 months will be compared for children whose mothers did and did not report depressive symptoms at 2 – 4 months. Findings from the study have potentially important implications regarding postpartum screening of mothers for depressive symptoms and for interventions to reduce deviations of children from expected growth trajectories.

**Principal Investigator:** Donna M. Strobino, Ph.D., Professor and Deputy Chair, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland. Period of Support: 09/01/04-08/31/06.

24. **R40 MC 03605: The Economic Impact of Health-e-Access.**
Inner city families, whose children are most burdened by morbidity and whose reliance on childcare is most important to their ability to improve economic circumstances, are those least equipped to deal with the challenge of illness in childcare. Using commercially-available information technology that enables clinicians to evaluate and treat ill children at a distant childcare site, Health-e-Access is a novel, yet logical and efficient, approach to a serious problem of national as well as local significance. The service has operated in 7 large inner-city childcare centers (and soon, the 8th) in Rochester. Evidence already firmly supports high levels of acceptance and satisfaction
with this innovation by parents and childcare programs. Demonstrated reduction in child absence due to illness has been dramatic and undoubtedly impacts parent work absence. It is anticipated that employers, too, will encourage expansion of Health-e-Access. Keys to expansion and sustainability of Health-e-Access are physician acceptance and insurance reimbursement. Physician acceptance can be anticipated if appropriate reimbursement is available and telehealth services can be integrated efficiently in the primary care medical home. Insurance reimbursement can be anticipated if telehealth services can be shown to reduce healthcare costs. Study 1 (office integration) will assess the feasibility and acceptability of integrating telehealth in 2 primary care practices serving inner city children, and it will assess impact on continuity of care. Study 2 (utilization and cost impact) will assess the hypothesis that health care use and costs associated with acute medical problems for children in childcare has been reduced, and it will quantify reduction. Cost impact will be assessed in before-and-after and concurrent comparisons. Costs incurred by childcare populations before telehealth (period 1) will be compared with costs incurred after telehealth startup (period 2). Control for secular trends will be achieved through comparisons to centers that did not have telehealth in either period 1 or period 2. Study 3 (parent and employer benefits) will estimate the economic benefits of Health-e-Access for parents and for employers, providing value estimates for events assessed in Study 2.

**Principal Investigator:** Kenneth McConnochie, M.D., M.P.H., Professor of Pediatrics, University of Rochester Medical Center, Rochester, New York. Period of Support: 09/01/04-08/31/07.

**25. R40 MC 03607: Do Medical Homes Improve Health Care Quality for CSHCN?**

Although it is commonly advocated that Children with Special Health Care Needs (CSHCN), should have a “medical home,” there is remarkably little empirical information in the literature about a) how, and to what degree, children with chronic diseases utilize medical homes and b) whether using a medical home is associated with improved quality of healthcare. A critical barrier to our understanding of “medical home” is that there are no clear data-based methods for identifying a “medical home” or for quantifying the degree to which medical homes are utilized by various groups of children. A major challenge continues to be the identification of the primary provider – or medical home – for children with chronic conditions. Furthermore, the most essential question, “Does having a medical home lead to improved quality of care?” remains unanswered. Specifically, this study seeks to answer the following questions:

1. What kinds of provider – and provider organizations – serve as the medical homes for CSHCN? This study will help identify two possible kinds of medical homes the “Overall Medical Home” (OMH) and the “Primary Care Medical Home” (PCMH).
2. To what extent do CSHCN have different OMHs and PCMHs and what factors are associated with having a single vs. a “divided” medical home?
3. What factors are related to the provider type/specialty of the medical homes utilized by CSHCN?
4. Is quality of healthcare related to the type of a medical home used by CSHCN?
26. **R40 MC 03619: Characterizing Children At Risk for Special Health Needs**

In 1998, the Maternal and Child Health Bureau published a new definition of children with special health care needs that included children with existing special needs and those “at increased risk” for developing a special health care need. The population “at-risk” was included to incorporate a preventive perspective in the definition. However, the population at increased risk has never been defined conceptually or described empirically. Consequently, almost all uses of the definition have been limited to children with existing special needs. Until progress is made in this area, no inroads can be made in designing and implementing primary and secondary prevention programs to reduce the number of children developing special needs. This project seeks to identify the factors that lead to an increased likelihood that children will develop special health care needs. The project will be conducted in two phases. Phase 1 includes the development of the conceptual framework for assessing risk factors for CSHCN. The conceptual model will incorporate major determinants of health identified in previous studies of population health but tailored to CSHCN. Phase 2 consists of empirical analyses, to identify the independent effects and contributions of the risk factors identified in Phase 1. The 2003 National Survey of Children’s Health, a population-based survey of approximately 100,000 children, will serve as the primary data source. Geo-coded contextual data will be merged to this data set. The project will be guided by an expert panel of respected practitioners, health service researchers, and epidemiologists. The resulting products will be helpful in informing health practitioners, families, health policymakers and health services researchers concerning risk factors for special health care needs. They will also be useful in establishing a literature on this topic and providing a foundation for additional conceptual and empirical work. Although subject to certain limitations, the results will be useful in providing a starting point for the development of prevention strategies.

**Principal Investigator:** Paul Newacheck, Dr.P.H., Professor, University of California San Francisco Institute for Health Policy Studies, San Francisco, California. Period of Support: 09/01/04-08/31/06.

27. **R40 MC 03620: Seasonal and Racial Variation in Vitamin D Deficiency**

Vitamin D deficiency appears to be widespread in the maternal and child health population, and our pilot data suggest that more urban infants and pregnant women are deficient than has previously been suggested. Goals: This cross sectional study will examine vitamin D status in an urban population of newborns and their mothers to determine 1) Differences in vitamin D status in Blacks, Whites, and Hispanics; 2) Impact of seasonality on vitamin D levels in African American and Hispanics; 3) The effect of maternal vitamin D status on infant vitamin D status; and 4) The impact of skin color on vitamin D status. Enrolled subjects will be 318 mother/newborn pairs from 3 racial/ethnic groups (Blacks/non Hispanic; Whites/non Hispanic; Hispanics) to determine vitamin D status of infants and mothers during the postpartum hospital stay. We will administer a survey to establish maternal diet history, use of prenatal vitamins, and other
factors affecting vitamin D levels. It is expected that many infants and their mothers will be deficient, that race/ethnicity and season will affect level of deficiency, and that maternal and infant deficiency will be correlated.

**Principal Investigator:** Barbara L. Philipp, M.D., Associate Professor of Pediatrics, Boston University School of Medicine, Boston, Massachusetts. Period of Support: 09/01/04-08/31/07.

28. **R40 MC 03621: Preventing Childhood Caries with Chlorhexidine Varnish**

Dental caries (tooth decay) is the single most prevalent chronic disease among U.S. children, occurring 5 – 8 times as frequently as asthma, the second most common chronic disease in children. Early childhood caries (ECC) is a particularly virulent form of caries that affects infants, toddlers and preschool children. The disease burden of ECC goes beyond the pain and infection. Severe ECC often affects a child’s ability to eat, speak, and communicate. In the U.S. the population group with one of the highest rates of ECC is American Indians and Alaska Natives (AI/AN). Nationwide, approximately 76 percent of AI/AN 2 – 4 year olds have decay, compared to 18% of non-AI/AN in the same age group. ECC results from an infectious disease, with the primary etiologic agent being mutans streptococci (MS). The major reservoir from which infants acquire MS is their mother or primary caregiver. If maternal levels of MS are low during the first two years of the child’s life, the child is less likely to acquire MS and to develop ECC. The antimicrobial chlorhexidine (CHX) is effective in reducing oral MS levels. This study is a randomized, double blind, placebo-controlled clinical trial designed to test the efficacy of a 10% CHX varnish for the prevention of ECC in a very high risk population of AI/AN children. Mothers with children less than 5 months of age will be recruited at four tribal community sites. When the child is 5 – 6 months old, mothers will receive four weekly applications of a CHX or placebo varnish, followed by additional applications when the child is 12 months and 18 months of age. The mother-child pair will receive calibrated dental examinations when the child is 5, 12, 18, and 24 months of age. The primary outcome variable will be the number of decayed, missing, and filled primary tooth surfaces (dmfs) when the child is 24 months of age. Six hundred mother-child pairs will be enrolled during the course of the study. If successful, this study could pave the way for an effective new primary prevention modality for ECC using chlorhexidine varnish applied to mothers’ teeth.

**Principal Investigator:** Lawrence Devall Robertson, M.D., M.P.H., Principal Investigator, Tuba City Regional Health Care Corporation, Tuba City, Arizona. Period of Support: 09/01/04-08/31/08.
29. R40 MC 03622: Xylitol for Acute Otitis Media & Early Childhood Caries
This community-based study addresses the prevention of Acute Otitis Media (AOM) and Early Childhood Caries (ECC) using xylitol syrup among disadvantaged children. AOM and ECC are two of the most common diseases in children costing billions of dollars annually and disproportionately affect those of low socio-economic status. Reductions in both diseases are objectives of Healthy People 2010. Xylitol is safe and approved by FDA for use as a sugar substitute since 1960s. This 12-month study will help evaluate the effect of xylitol on AOM and ECC in children in the first 2 years of life. The goal is to establish the feasibility of using xylitol syrup to reduce the incidence of AOM and ECC. The aims are to verify the protective effect of xylitol syrup in this age group and to determine the relationship between the frequency of xylitol application and the magnitude of protection against ECC and AOM. The secondary outcome measure will be the amount of antibiotics used to treat AOM. One hundred 9 – 15 month old children in the Republic of the Marshall Islands (in free association with the U.S. and qualified under Title V of the Social Security Act) will be recruited and randomized into the placebo control group or one of 3 xylitol groups, 1, 3, or 5 xylitol doses per day. During the 12-month follow-up, all cases of AOM will be recorded. Cases of ECC will be ascertained at 6 and 12 months. The sample size allows for adequate evaluation of the acceptability of the protocol. Power to detect a linear relationship between the number of xylitol applications and incidence of AOM or ECC is 88% - 99%. The use of xylitol will be viable for MCH program if effectiveness at 1 to 3 doses per day can be ascertained.


This is a 5th-year continuation to complete a trial testing a behavioral intervention designed to reduce environmental tobacco smoke exposure (ETS) and parents’ smoking among 150 low-income families recruited from WIC. The primary aims are: 1) to determine the effects of the counseling program on young children’s ETS exposure; 2) to determine the effects of participation on mothers’ level of smoking and proportion who quit smoking; 3) to validate parent-reported ETS exposure using urine cotinine assays and environmental nicotine monitors. The secondary aims are: 4) to determine the effects of participation on other parents’ and other smokers’ level of smoking and proportion of quitters; 5) to explore health outcome measures; 6) to identify possible determinants of ETS exposure and smoking cessation; 7) to examine patterns in repeated baseline children’s urine cotinine values; 8) to explore the cost effectiveness of the intervention. This study combines behavioral counseling for ETS reduction and smoking cessation with nicotine replacement therapy. After 3 baselines, families are assigned at random to the experimental counseling or “usual care” control condition. The experimental group receives 14 counseling sessions over 6 months. Primary participants are mothers, but other parents and other smokers living in the home are encouraged to participate. Counseling incorporates behavioral contracting, shaping, and problem-
solving negotiations. Measures are obtained at baselines, 3, 6, 12, and 18 months and include a detailed interview concerning smoking and exposure rates, key Social Learning Theory variables, and children’s health, children’s urine samples for cotinine analysis, and environmental nicotine. Self-reported smoking cessation is verified with saliva cotinine or anabasine/anatabine analysis. If effective, the intervention could be incorporated into standard care at WIC clinics nationwide as well as in other settings.

**Principal Investigator:** Melbourne F. Hovell, Ph.D., Professor, San Diego State University, San Diego, CA. Period of Support: 01/01/04-12/31/04.

**31. R40 MC 02495: State Managed Care Policies and Special Needs Children.** This project will assess the effects of state policy choices concerning managed care for publicly insured children with special health care needs (CSHCN). The project is organized around two phases. In the first phase, the investigators will assemble and summarize a unified set of information on state policies concerning the use of managed care in Medicaid and SCHIP for CSHCN. This information will be assembled from existing administrative sources, such as the Center for Medicare and Medicaid Services website, special surveys conducted by the Urban Institute, a database of Medicaid and SCHIP managed care contracts developed by the Center for Health Services Research and Policy at George Washington University, and supplemented with limited primary data collection where necessary. The information will be analyzed to create a typology of managed care program models at two levels of complexity. The typology would incorporate the general structure of the managed care program with respect to how services for CSHCN are organized and financed. For capitated programs, the investigators would create a sub-typology that would incorporate information on the extent to which statutory or regulatory requirements were designed to meet the special service use needs of CSHCN or provide economic incentives to health plans to provide appropriate levels of care for CSHCN. Information on individual state programs and policies, and the characterization of programs using this typology would provide a unique resource for policymakers and researchers. In the second phase of the project, the investigators will examine the relationship between the different models of managed care and access, use, care coordination, and satisfaction for Medicaid or SCHIP enrolled CSHCN, allowing for the identification of program characteristics associated with the best outcomes for CSHCN. Data on Medicaid and SCHIP managed care programs developed in Phase I of the project will be linked to the National Survey of CSHCN and to the National Health Interview Survey, both household surveys that include a variety of characteristics of children, as well as measures of access to care, satisfaction, coordination and use of services. Using descriptive and multivariate techniques, the investigators will determine whether various outcomes for CSHCN are associated with different managed care program designs.

**Principal Investigator:** Amy J. Davidoff, Ph.D., Senior Research Associate, Health Policy Center, The Urban Institute, Washington, D.C. Period of Support: 01/01/04-12/31/04.
32. **R40 MC 02497: Preventing postpartum depression in high-risk pregnant Latinas: Effects on maternal and infant health.** This is a four-year research project that develops, revises, and tests an intervention aimed at preventing the onset of maternal depression among high-risk, low-income, Spanish-speaking Latina immigrant women receiving prenatal care at Mary’s Center for Maternal and Child Care, a community-based prenatal clinic in Washington, D.C.. The Mothers and Babies course is a cognitive-behavioral intervention aimed at teaching women mood regulation skills to prevent the onset of major depressive episodes. This 12-week intervention has been shown to be effective in Spanish-speaking women in the San Francisco, CA area but has not yet been tested in the Washington, D.C. area and among the New Latina women, of predominantly Central American (El Salvadoran) backgrounds. This intervention will be shortened to 8-weeks and compared to an existing 8-week prenatal course currently offered as the standard of care by the Mary’s Center; their prenatal course provides content regarding emotional and physical changes during pregnancy, birth, and delivery, but with minimal emphasis on mood. In addition, 3 booster sessions will be provided for the intervention participants during the first postpartum year. Longitudinal data will be collected on all participating women for one year following the completion of the prenatal courses, including data on their psychological and physical health, maternal-infant interaction, and stress. This study will provide much needed data on the importance of the prenatal period as an opportunity to prevent postpartum depression in an under-represented, high-risk population as well as to examine the impact of these interventions on the mental health of these women and their infants.

**Principal Investigator:** Huynh-Nhu Le, Ph.D., Assistant Professor, Department of Psychology, George Washington University, Washington, D.C. Period of Support: 01/01/04-12/31/07.

33. **R40 MC 02502: Improving Medical Homes for Children with Chronic Conditions.** This is a three-year research project that will determine the effects of receiving care through a medical home with care coordination in community primary care settings on three main outcomes for families with children with special health care needs (CSHCN): access to care, satisfaction with care, and mental health of children and parents. A secondary aim is to describe how variations in care coordinators’ roles may affect these outcomes. The study population will consist of: (1) Five new primary care practices enrolling in the Massachusetts Medical Home Program (MMHP), an effort of the state health department to improve care for children with chronic conditions by placing state care coordinators in community pediatric practices; two comparison practices without coordinators; (2) 80 – 100 families with children with chronic conditions per intervention practice and 120 matched families from each of the 2 comparison practices. The researchers will use a quasi-experimental differences-in-differences examination of changes over one year in families newly enrolling in care coordination through the MMHP versus changes at same time in comparison practice families. Measures include: (1) access to care and met needs; (2) child and parent mental health measures; (3) satisfaction with care; (4) parent views of the care coordination
process; and (5) sociodemographic and child health status data. The Medical Home Index (MHI) will assess practice changes in methods to provide chronic care over time. This research project represents a collaboration with the Massachusetts Department of Public Health (MDPH) to study the effects of this new MDPH program, the Massachusetts Medical Home Project (MMHP), designed to improve care and outcomes for children with chronic health conditions and their families by placing state-employed care coordinators in community primary care practices. The project is designed to promote the health of children with chronic conditions and disabilities and tests out the medical home concept.

**Principal Investigator:** James M. Perrin, M.D., Professor of Pediatrics, Massachusetts General Hospital, Center for Child and Adolescent Health Policy, Boston, MA. **Period of Support:** 03/01/04-12/31/06.

### 34. R40 MC 02461: Childhood Head Trauma: A Neuroimaging Decision Rule.

The long-term objective of this study is to develop a highly accurate decision rule for the evaluation of children with blunt head trauma on which to base evidence-driven guidelines on this topic. This decision rule will identify all children with traumatic brain injury (TBI) in need of acute intervention, yet also will result in less frequent use of computerized tomography (CT) scans in children with blunt head trauma evaluated in emergency departments (EDs). The specific aims are to derive and internally validate a clinical decision rule with a high degree of confidence which accurately and reliably identifies children at high risk and those at near-zero risk of TBI after blunt head trauma. TBI is the leading cause of death and disability in children older than one year. Some children with TBIs are initially not identified, leading to preventable morbidity. Although CT scanning is the reference standard for diagnosing TBI in head-injured children, and failure to diagnose TBI increases morbidity and mortality, overuse of CT scanning has important drawbacks. The most important among these is radiation exposure which may result in death from malignancy, estimated as 1 radiation-induced fatality per 2000 – 5000 pediatric cranial CT scans. Fewer than 10% of CT scans currently performed on children with head injury reveal TBI, thus CT scans are used inefficiently. This is a prospective, multicenter observational study of children with blunt head trauma evaluated in the 25 hospitals of the Pediatric Emergency Care Applied Research Network (PECARN) of the Maternal and Child Health Bureau. These 25 hospitals evaluate more than 808,000 children of diverse geographic and racial/ethnic background in their EDs on an annual basis. Children with blunt head trauma at PECARN EDs will be enrolled into the study over two years, and will be followed prospectively to detect the outcomes of interest: 1) TBI on CT scan and, 2) TBI in need of acute intervention (defined by the need for neurosurgery, endotracheal intubation for 24 hours or more, or hospitalization for 2 or more nights). The clinical data from the time of ED presentation will be analyzed using binary recursive partitioning to generate a clinical decision rules for the identification of children at high risk, and near-zero risk of TBI. Once externally validated and disseminated widely, the decision rule will result in safer, more efficient, evidence-based evaluation of children with head trauma, a decrease in the frequency of unnecessary CT use, and improved child health.
**Principal Investigator:** Nathan Kuppermann, M.D., M.P.H., Associate Professor, University of California School of Medicine, Davis, CA. Period of Support: 01/01/04-12/31/06.

**35. R40 MC 00333: Early Intervention Collaborative Study: Late Adolescence.**
This four-year study is a continuation of the Early Intervention Collaborative Study (EICS) of children and families who participated in early intervention services because of a child’s special needs identified before 24 months of age. This phase of the longitudinal study will focus on the approximately 120 adolescents as they turn age 18, a critical transition point for them and their families. The general aims are to examine the social-emotional outcomes of adolescents with developmental disabilities and the well-being of their parents. Analyses will focus on modeling change and testing specific hypothesized predictors of change over multiple time periods in regards to behavior problems and peer acceptance of adolescents and child-related stress and depression reported by their mothers and fathers. Hypotheses specifying contemporaneous predictors of adolescent autonomy and maternal and paternal well-being will also be tested. The purpose of this project is to provide empirical information on healthy development in adolescents with special needs and their families, which will aid the construction of policies, programs, and practices for this important group of youth.

**Principal Investigator:** Penny Hauser-Cram, Ed.D., Professor, Lynch School of Education, Boston College, Chestnut Hill, MA. Period of Support: 01/01/03-12/31/06.

**36. R40 MC 00334: Psycho-Social Sequelae of BPD and VLBW: Phase (3) Three.**
Bronchopulmonary dysplasia (BPD), a chronic lung disease of prematurity, currently occurs in 25-40% of very low birthweight (VLBW) births and has been found to be significantly related to poorer developmental outcome in VLBW cohorts. The first waves of post-surfactant survivors are now approaching early adolescence, with little known about their long-term pulmonary outcomes, growth or functional abilities. Since 1990, incidence of BPD has increased more than 50% with >11,000 new cases annually. Further, there are few data regarding behavioral, psychosocial and family outcomes of VLBW cohorts in general, because VLBW infants are disproportionately minority (African-American) and of low SES, understanding the role of these factors in moderating outcomes is important. This study will investigate early adolescent outcomes with a focus on the influence of BPD, relative to other risk factors, on pulmonary, cognitive, language, neuropsychological and behavioral/emotional outcomes. Standardized measures of child outcomes, teacher and parental report of child behaviors, and parental report of psychological and parenting stress, coping mechanisms and social supports will be given. Delineation of specific relationships of early medical conditions, such as BPD, relative to other complications of prematurity, to adolescent outcomes may lead to early identification of those VLBW infants at highest risk for learning and behavior problems, and elucidate biologic and psychological mechanisms related to the negative sequelae of VLBW birth.
Principal Investigator:  Lynn T. Singer, Ph.D., Professor, School of Medicine, Pediatrics, Case Western Reserve University, Cleveland, OH.  Period of Support: 01/01/03-12/31/06.

37. R40 MC 00343: Predicting African American Adolescents’ School Success. Understanding the child, family, and school factors during early and middle childhood that affect the school success and adjustment of African American adolescents is critical, given the demographic and ecological gaps between African Americans and White children in American society. This study will follow a group of African American youth (primarily from low-income families, whose development, family, and school environments have been prospectively documented since infancy through funding from the MCHB) into early adolescence. Child measures will assess the youths’ Afrocultural beliefs and practices, peer relations, language and executive function skills, and school competence. Family measures will examine factors such as maternal education, parental involvement and monitoring, and Afrocultural beliefs and practices. School measures will assess factors such as teachers’ perceptions of relationships with students and school demographics. Study findings should have important implications for the sociocultural factors that affect the school success of African American adolescents and guide intervention efforts directed at reducing risk and promoting success in adolescents’ school competence.

Principal Investigator:  Joanne E. Roberts, Ph.D., Senior Scientist, Frank Porter Graham Child Development Institute, University of North Carolina @ Chapel Hill, Chapel Hill, NC.  Period of Support: 03/01/03-12/31/06.

38. R40 MC 00316: Infancy to Middle Childhood in Rural Appalachia. Large numbers of rural children experience chronic poverty, and the majority of poor rural children are White, but comparatively little is known about development in this group. Poverty and low family socioeconomic status (SES) increase the risk that children will have behavior problems, will have low academic achievement, and will use tobacco. Many rural Appalachian children are growing up in low-SES families, and thereby are at risk for these problems. This project will study normative development and the risk and protective factors which predict individual differences in social and academic competence and tobacco attitudes/use of 10-year-old, low-SES, rural Appalachian children. The research design incorporates multiple sources of data (child self-report, observation of the child, parent-report, teacher-report, and school achievement tests) and multiple methods of data collection (standardized measures, interviews, and semi-structured interactions).

This longitudinal study follows a cohort of children from birth through middle childhood and will investigate stability and change over time in social adjustment and academic competence, identify risk and protective factors, and examine developmental processes.
related to individual differences in middle childhood social adjustment, academic competence, and tobacco attitudes/use.

**Principal Investigator:** Margaret C. Fish, Ph.D., Clinical Professor, Marshall University Research Corporation, School of Medicine, Huntington, WV. Period of Support: 01/01/03-12/31/05.

39. **R40 MC 01214: Reducing Barriers to Care for Vulnerable Children with Asthma.** This four-year project will develop and test culturally and linguistically appropriate interventions to reduce barriers to health care for vulnerable children with persistent asthma. The research will adapt and test a tailored Problem Solving Therapy (tPST) intervention to address barriers to care. Children ages 5-12 years with persistent asthma and their families will be randomized to care coordination, a combination of care coordination and tailored problem solving therapy, or a wait-list control. Successful accomplishment of the specific aims could have substantial impact on the clinical management of children with asthma throughout the United States. Evidence for the efficacy of tailored Problem Solving Therapy and the availability of culturally and linguistically appropriate treatment manuals will be of value in the field for practitioners and programs seeking evidence-based optimal clinical management strategies.

**Principal Investigator:** Michael Seid, Ph.D., Principal Investigator, RAND Corporation, Santa Monica, CA. Period of Support: 09/01/03-08/31/07.

40. **R40 MC 01063: Drug-Abusing Mothers: Infant Massage-Parenting Enhancement.** With 4.6 million women of child-bearing age regularly using cocaine in the United States and 750,000 drug-exposed births annually, maternal substance abuse highlights the multigenerational impact of drug use in high-risk populations and its risks to our children. Interventions that build upon the natural components of early mother-infant interactions are critical to reversing these sequelae and breaking the cycle of addiction. However, despite the incorporation of educational, vocational, and social rehabilitation, as well as parenting classes and day care into drug treatment programs, child abuse, neglect, and physical, mental and emotional deficits remain pervasive in the children of substance-abusing mothers (SAMs). One intervention with documented developmental benefits on high-risk neonates is Infant Massage (IM). This study will determine the long-term value-added effects of blending Infant Massage (IM) into a systematic Parenting Enhancement Program (PEP) on health outcomes and interaction among SAMs and their babies. The impact of this low-cost intervention on family preservation and health enhancement in high-risk populations will facilitate maternal-child health practitioners, nurse educators, public health professionals, and substance abuse service providers to design client-tailored parenting programs, which utilize IM as both a health promotion and therapeutic intervention.

**Principal Investigator:** Luz Sobong Porter, Ph.D., Professor, Florida International University, North Miami, FL. Period of Support: 09/01/03-08/31/07.
41. R60 MC 00003: Pediatric Clinical Research Center (PCRC). Clinical research is the most successful and enduring means of improving the outcomes of sick children. No scientific discovery, and no new medication or medical device, can benefit ill children without first being subjected to rigorous, scientific, pediatric clinical research. Therefore, coordinating pediatric research discoveries, translational and applied research, and clinical trials is urgently needed to improve the treatment outcomes for chronically ill children. Thus, an infrastructure is needed to test efficacy of treatments and to coordinate the implementation of the processes involved in transferring research results to treatment settings. This Pediatric Clinical Research Center (PCRC) at All Children’s Hospital will coordinate pediatric research discoveries, translational and applied research, and clinical trials in St. Petersburg, Florida. This PCRC will provide a point of service for facilitating the pediatric clinical and observational research efforts from a comprehensive cancer research center, a school of public health, a college of nursing, a college of medicine, and a children’s hospital. The PCRC demonstration project will support the administrative infrastructure needed for clinical research efforts focused toward preventing and curing diseases of children and eventuate in better health outcomes for children.

Program Director: John Sleasman, M.D., All Children’s Research Institute, Inc, St. Petersburg, FL. Period of Support: 09/30/02-08/01/05.

42. R40 MC 00294: Reducing Injury Among High-Risk Preschool Children.
Although unintentional injury is the leading cause of death for all children, it exacts a disproportionately high toll among the economically disadvantaged. Low income and minority children are twice as likely to die in a car crash, four times more likely to die from drowning, and five times more likely to die in a fire. Usage rates of effective prevention devices such as safety seats and bicycle helmets are much lower among economically disadvantaged families. The purpose of this randomized controlled trial is to reduce risk of injury among economically disadvantaged preschool age children and families through a Head Start-based injury prevention program based on Social Learning Theory. The primary goals are to increase use of injury prevention devices and behaviors among Head Start children and their adult caregivers, identify barriers to use of these devices and behaviors, to increase awareness and knowledge of the risks of pediatric injury among preschool children, parents, and teachers. The results of this study may identify a unique, theory-based public health approach to pediatric injury in high-risk groups that can be integrated into the existing Head Start infrastructure. If the model is effective, it can be expanded to other preschool and daycare settings as well as to other health-related issues.

Principal Investigator: Victor F. Garcia, M.D., Director, Trauma Service, Pediatric Surgery, Children’s Hospital Medical Center, Cincinnati, OH. Period of Support: 01/01/02-12/31/04.
43. **R40 MC 00303: Neighborhood Conditions and Health Disparities.** This study investigates causes of class, ethnic, racial disparities in physical, mental health, and access to and use of services. Data collected from the Los Angeles Family and Neighborhood Survey (LAFANS), a study carried out in a representative sample of 65 neighborhoods in Los Angeles County will be used. In each neighborhood, LAFANS includes (1) a household survey, including interviews with adults and children, and (2) a neighborhood survey with key informants and social service providers and independent observations of neighborhood physical conditions. The dataset includes information from 3,491 families on health behaviors and utilization of health care services reported by parents, caregivers and children, and measures of “collective efficacy,” informal social controls and social cohesion. Focus will be on health problems that are of increasing importance to youth and adolescents: obesity, injury, asthma, and teen pregnancy. All of these disproportionately affect low-income populations of minority status and may, in part, be related to neighborhood level factors. Data from the US Census 2000, land use information including alcohol outlet locations and health department surveillance data on injury mortality and teen pregnancy at the census tract level will also be obtained. This study will be among the first to test whether neighborhood structural variables, defined and measured independently of the neighborhood residents, are associated with social processes, with individual level health risk behaviors, with health care utilization and with population level health outcomes.

**Principal Investigator:** Deborah Cohen, MD, MPH, Senior Natural Scientist, RAND Corporation, Santa Monica, CA. Period of Support: 09/01/02-08/31/04.

44. **R40 MC 00305: Assessing the Stress/Preterm-Low Birthweight Relationship.** Strenuous working conditions and occupational fatigue in pregnancy have been associated with pre-term delivery (PTD) and low birthweight (LBW) among working women. Associations have also been reported between adverse pregnancy outcomes and objective or perceived stressful life events, anxiety, depression and low levels of social support. While recent studies suggest that the effects of stress on preterm deliveries may be mediated by increases in placental secretion of corticotropin-releasing hormone (CRH), no studies have looked at this relationship among working women specifically. This study offers the unique opportunity to examine race/ethnicity, socioeconomic status (SES) and CRH levels.

Building on the infrastructure of a study conducted by the California Department of Health Services (DHS) in San Diego County, this study will test the extent to which occupational stressors vary by race/ethnicity or SES and how stressors (including racial discrimination) impact risk of PTD and/or LBW. It will further identify the role of CRH in mediating this effect, will weigh the contribution of antenatal leave in mediating birth outcomes, and will profile women with available antenatal leave. By investigating the relationships between stress during pregnancy, placental CRH and antenatal leave, this study will help identify the risks and protective factors that contribute to pregnancy outcomes among working women.
Principal Investigator: Sylvia Guendelman, Ph.D., Associate Professor, University of California at Berkeley, School of Public Health, Berkeley, CA. Period of Support: 09/01/02-08/31/05.

45. R40 MC 00307: Economic Impact of Breast-Feeding Promotion Interventions.
This supplemental proposal of a previous MCHB-funded project, is a randomized clinical trial that will test whether an individualized pre-post-natal Lactation Consultant intervention results in: 1) better breastfeeding practice (knowledge, initiation, duration); b) better infant (up to 12 months) health outcomes, specifically for “breast-feeding sensitive morbidities,” i.e., otitis media, GI, respiratory infections); and c) lower infant (up to 12 months) health care costs. The intervention consists of two (2) individualized pre-natal visits with a Study Lactation Consultant; immediate post-partum visits whenever feasible and possible (often in the hospital), and phone or home follow-up as needed. Women are recruited from two affiliated health clinics, one of which operates on a Family Medicine model, the other on an Ob-Gyn/Peds model. The supplemental funds allow for achievement of target sample size, allowing sufficient power to analyze site effects. The interventions consist of individualized face-to-face sessions with a trained lactation consultant during the pre-natal period, and intensive post-partum support up to weaning or 12 months. Cost, breast-feeding practice, and health outcomes will be tracked for 12 months through 8 research interviews, and analysis of health center billing and encounter records. Health care costs for the intervention and control groups will be analyzed, as will differences in breast-feeding practice and child health outcomes.

Principal Investigator: Karen Ann Bonuck, Ph.D., Assistant Professor, Montefiore Medical Center, Department of Social Medicine, Bronx, NY. Period of Support: 09/01/02-08/31/04.

46. R40 MC 00312: Preterm Functional Development and Outcome. This four-year proposal seeks to standardize and validate a unique inexpensive clinical tool to measure early central nervous system (CNS) function and determine developmental delay prior to term in high-risk preterm infants. Despite advances in neuroimaging techniques that visualize central nervous system injury, it is not possible to predict individual outcome for preterm infants discharged from a Neonatal Intensive Care Unit (NICU). Serial neurodevelopmental exams, requiring expertise but not technology, will be quantified by both degree of abnormality (Abnormality Score) and rate of neuromaturation (Maturity Score) and compared to neurodevelopmental disability and functional outcome at 18 months. Early assessment and prediction of CNS outcome may identify infants for future preventive and treatment strategies for CNS injury and target infants for more efficient and effective utilization of limited comprehensive follow-up and early intervention resources. The specific aims of this proposal are: To establish norms for CNS function and neuromaturation prior to term; To determine how infants with intrauterine growth restriction (IUGR), perinatal intraventricular hemorrhage (IVH) and neonatal chronic lung disease (CLD) differ from established norms for early CNS function; To evaluate
the efficacy of these measures in determining delay and predicting neurodevelopmental disability and functional outcome at 18 months.

**Principal Investigator:** Marilee C. Allen, M.D., Professor of Pediatrics, Johns Hopkins University, Pediatrics/Division of Neonatology, Baltimore, MD. Period of Support: 09/01/02-08/31/06.

47. **MC 00319: Project EAT II: A Longitudinal Study.** This project is an extension of a study previously funded by the MCHB: Project EAT I which was conducted between 1997 and 2001 and resulted in information regarding the patterns of teens and fast food, meals with families, attitudes about weight control, vegetarianism, and weight teasing. The current proposal will utilize the existing cohort and identify the trends of nutrition, exercise, and weight management in order to establish causality for dietary-related problems as the cohort enters middle adolescence to young adulthood. The study cohort represents a significant percentage of minority and lower socio-economic youth who will be surveyed to examine changes in their eating patterns and weight status as they progress from early adolescence (ages 11-14) to middle adolescence (ages 15-17), and from middle to late adolescence/young adulthood (ages 18-21). Socio-environmental, personal, and behavioral predictors of eating patterns and weight status will be identified in order to guide the development of more effective interventions.

**Principal Investigator:** Diane Neumark-Sztainer, Ph.D., Associate Professor, University of Minnesota, School of Public Health, Division of Epidemiology, Minneapolis, MN. Period of Support: 10/01/02-09/30/05.

48. **R40 MC 00195: Improved Prenatal Down Syndrome Screening: PAIRED Testing.** Down syndrome screening has technically evolved to the point that approximately 2.4 million pregnant women are now provided with prenatal screening for Down syndrome, annually. Nevertheless, despite the widespread screening, the false positive rate for Down syndrome remains high. This results in unnecessary morbidity and psychological stress. Pregnant women who are found to have positive screening test results (most of which are false positives) experience considerable anxiety and usually require invasive studies to identify whether or not Down syndrome is present in the fetus. It is therefore important to minimize screen positive test results to avoid raising anxiety and keep procedure related fetal losses to a minimum. This study is designed to test and validate a new approach to serum based prenatal screening for fetal Down syndrome that is expected to reduce dramatically the false positive rate as compared to the current standard of care: the triple test [alpha fetoprotein (AFP), unconjugated estriol (uE3), human chorionic gonadotrophin (hCG)]. The test identifies 69 per 1000 women as high risk. This prenatal Down Syndrome screening, initially referred to as the Practical Approach to Integrated Risk Evaluation for Down Syndrome (PAIRED) serum test in the earlier protocol and now renamed as the Integrated Serum Test (IST), will reduce the number of women with false positive test results to 21 per 1,000. The IST combines both first and second trimester maternal serum biochemical measurements with maternal age
to assign each pregnancy a Down syndrome risk. Those risks are then used to identify women at sufficient risk to warrant offering second trimester amniocentesis and fetal karyotyping. Compared to the current standard of care (the triple test), the IST serum test will maintain high Down syndrome detection (75%) but will reduce the false positive (and amniocentesis) rate by more than two-thirds (from 6.9 to 2.1%).

This IST for Down syndrome screening addresses the following questions: 1) will the predicted reduction in the false positive rate be achieved, 2) will women receiving prenatal care in the first trimester agree to IST screening, 3) will women agreeing in the first trimester to IST screening submit a second trimester serum sample, 4) will health care practices now providing second trimester prenatal screening for Down syndrome agree to offer the IST, 5) will a high percentage of screen positive women opt for diagnostic testing, 6) is the Down syndrome detection rate consistent with expectations based on modeling and 7) will IST screening be cost effective (in both financial and medical terms), when compared to the current standard of practice (triple test)? If successful, the IST will provide a high performance screening method that can be used in all types of primary care practices in rural and urban settings.

Principal Investigator: George Knight, Ph.D., Director, Prenatal Screening Laboratory, Foundation for Blood Research, Scarborough, Maine. Project period: 08/01/2001 – 07/31/2004.

49. R40 MC 00241: Growth and Development: Longitudinal Follow-up Phase 2: This is a Competing Continuation of a previously funded MCH grant that examined the longitudinal growth and development of children with and without a history of failure-to-thrive (FTT). Pediatric obesity is a serious public health problem that is increasing in prevalence, particularly among minority children from low-income families. The goals of the study are to prevent increasing rates of obesity by developing, implementing, and evaluating a health promotion program that targets diet and lifestyle activity appropriate for African American 13-15 year old youth from low-income, urban families. The project has two phases. In the “Formative Phase,” the study will (1) examine the ethnotheories of body size, diet, and activity and opportunities to engage in healthy diet and physical activity at home, in school, and in communities, and (2) based on gathered information, develop home-based intervention protocols. In the “Intervention Phase,” the study will use a randomized controlled trial to implement and evaluate the health promotion interventions. The outcome measures to be evaluated include amounts of food purchases, levels of support for healthy diet and physical activity at the individual levels, changes in body fat (Body Mass Index and Bioelectrical Impedance Assessment), diet (% fat and serving of fruits and vegetables), and physical activity. Using longitudinal analytical strategies such as hierarchical linear modeling, the study will also examine changes in outcome measures in relation to genetic factors (e.g., parental weight and height), and environmental and psychological factors from constructs proposed by the underlying theories and ethnographic research.
Principal Investigator: Maureen M. Black, Ph.D., Department of Pediatrics, Western Health Center, University of Maryland School of Medicine, Baltimore, MD. Project period: 08/01/01 – 07/31/05.

50. R40 MC 00236: Infant Functional Status and Discharge Management:
Discharge algorithms for premature infants are controversial, in part because they determine the allocation of significant resources, in part because discharge decisions often place families and physicians at odds with insurers, and in part because of a lack of information on the relationship between infant physiologic status at discharge and subsequent resource utilization and outcomes. This proposal seeks to develop a more optimal algorithm to support infant discharge decisions, based on the relationship between physiologic parameters reflecting infant functional status and total resource utilization associated with these discharge decisions. The main hypothesis to be tested is whether there exists a range of discharge algorithms in which longer hospital stays may result in reduced overall resource utilization. Using a unique database maintained by the Kaiser Permanente Medical Care Program (KPMCP) among 6 hospitals in Northern California, the study will (1) randomly select a cohort of 1400 premature infants; (2) abstract charts to extract key daily physiologic data on feeding, weight gain, temperature stability, respiratory status, and medical stability; (3) perform a cost accounting starting from a consistent point in each hospitalization -- defined as the point when a minimal level of maturity is achieved and discharge is first possible, and extending to 6 months after achieving such physiologic maturity; (4) construct models to predict total cost and readmission rate as a function of specific patterns of discharge defined by specifying physiologic parameters associated with functional status; and (5) determine optimal patterns of discharge using the data collected and the derived economic and outcomes model. Once models are developed and the cost accounting is complete, the study will formally test whether a specific discharge algorithm will be optimal in terms of minimizing cost and readmissions. Results from the study will ultimately provide important information relating physiologic status to outcomes and cost so that more rational discharge algorithms can be developed.

Principal Investigator: Jeffrey Silber, M.D., Ph.D., Associate Professor, Center for Outcomes Research (COR) at The Joseph Stokes, Jr., Research Institute, Children's Hospital of Philadelphia (CHOP), Philadelphia, PA. Project period: 09/01/01 – 08/31/04.

51. R40 MC 00252: Enhancing Breastfeeding Duration in Premature Infants:
Breastmilk is the optimal form of nutrition for all infants. Yet impoverished families who stand to gain most from the health benefits of breastfeeding practice it least. For premature infants, the health benefits of breastmilk are vital and include protection against infections including necrotizing enterocolitis, sepsis and meningitis, enhanced digestion, and improved visual function and neurocognitive development. Our preliminary findings suggest the NICU environment exacerbates all problems associated with low breastfeeding rates among underprivileged groups. A key problem is lack of
Research shows peer counselors increase breastfeeding duration in a population of low-income full-term infants, but counselors have not been used in the NICU setting. Research also shows hospital policies can have a negative impact on breastfeeding rates. The goal of this study is to increase breastfeeding duration rates among premature infants and to study determinants of breastfeeding in a population of low-income mothers. This is a randomized clinical trial, conducted at an inner-city hospital serving primarily minority and low-income families. 242 premature infant (26-37 weeks gestational age)/mother pairs in the NICU will be randomized to either the control group (standard of care consisting of breastfeeding assistance from hospital staff) or the intervention group (standard of care plus a peer counselor). Both groups will complete an extensive questionnaire on breastfeeding determinants. Outcome measures will include rates of breastfeeding at 4, 8, and 12 weeks post-birth, amount of time spent in kangaroo care and determinants of breastfeeding. This study will determine if peer counselors increase the duration of breastfeeding among impoverished women with premature infants.

**Principal Investigator:** Barbara Philipp, M.D., Assistant Professor of Pediatrics, Boston Medical Center, Boston, MA. Project period: 09/01/01-08/31/04.

**52. R40 MC 00270: Early Detection of Autism: Comparison of Three Screening Instruments.** Autism and other pervasive developmental disorders (PDD) are severe disorders of development, often leading to life-long disability. Early detection and intervention can substantially improve prognosis; however, with available screening instruments, early detection is difficult. Diagnosis and intervention often follow initial suspicion by as much as three years or more. This study involves the comparison of three parent checklist screening instruments for 24-month-olds: (1) The Checklist for Autism in Toddlers (CHAT)- Parent Report section (Baron-Cohen, Allen, & Gillberg, 1992; Baron-Cohen et al, 1996), (2) The Modified Checklist for Autism in Toddlers (M-CHAT, Robins, Fein, & Barton, in press), and (3) the Yale Autism/PDD Screener. The CHAT parent report has 9 items. To form the M-CHAT, items were added to the CHAT and after pilot testing, refined to a 23-item scale. Pilot data on 1293 two-year-olds from pediatric practices and early intervention sites, 58 of whom were evaluated and 39 of whom were diagnosed with autism or PDD, demonstrates excellent promise of effectiveness for both the CHAT and M-CHAT, with the M-CHAT showing slightly better screening properties. A follow-up study of the first 600 participants at the age of 42-48 months to ascertain true sensitivity, has been started. The Yale Autism/PDD Screener, a 14-item parent checklist, has been used to study young children referred for possible autism. All but 4 items have been found to discriminate children with autism/PDD from children with other developmental disorders or normal development. All pediatricians and early intervention sites in the State of Connecticut will be contacted; pilot data (see Preliminary Studies) have successfully included a representative demographic sample of SES and ethnicity and include urban, suburban and rural communities. Evaluations will include psychiatric diagnoses and assessment of cognitive, language, and adaptive functioning. Analyses at both time points will use signal detection and discriminant function analyses to assess and compare the sensitivity
and specificity of each instrument, and to determine the optimal set of items to detect PDD. This study should greatly advance the development of an effective early screening tool for autism and related disorders. Planned future studies include replication in other states, and cross-cultural comparisons in such countries as Japan.

**Principal Investigator:** Deborah Fein, Ph.D., Professor, University of Connecticut, Storrs, CT. Project period: 09/01/01-08/31/05.

**53. R40 MC 00262: Pediatric PHASE (PreHospital Arrest Survival Evaluation).**
The Center for Pediatric Emergency Medicine (CEPM) will perform a population based, prospective observational study of all children under 18 years of age requiring resuscitation (assisted ventilation or CPR) in New York City cared for by NYC Fire EMS over a 12-month period. The aim is to determine the incidence interventions, complications and outcome in these children. This information will better define the causes, process and outcome of pediatric resuscitation and allow for planning of interventions and new research to improve the outcome of pediatric resuscitation. Three hypotheses will be considered: (1) Ventricular fibrillation in children in cardiopulmonary arrest is a more frequent occurrence than previously has been thought; (2) After adjustment for initial rhythm, the outcome of cardiac arrest in children is different than that of adults; (3) Patients in respiratory arrest who are "adequately treated" demonstrate no difference in outcome if they are treated with bag-valve-mask vs. endotracheal intubation. CPEM's Pediatric PreHospital Arrest Survival Evaluation (PHASE) Project will utilize the standardized uniform data reporting elements from the "Pediatric Utstein Style." CPEM will collaborate with the American Heart Association (AHA) funded PHASE II study, which replicates a very successful study from 1990 that used an excellent prospective data collection methodology that captured 100% of the population. The PHASE II methodology used specially trained EMS paramedics, who provided 24 hours a day/7 days a week coverage, to track all out-of-hospital cardiac arrests in adults and interview all EMTs and paramedics who rendered care to a cardiac patient within 8 hours of the call. Without CPEM's Pediatric PHASE input, the AHA PHASE II study in its current form excludes children. Pediatric PHASE will include information gathering on all patients less than 18 years of age cared for by NYC Fire EMS who require assisted ventilation or CPR; track all pediatric patients into the hospital ED, hospital ward, through final disposition (hospital discharge to home, chronic care facility, or death); and analyze pediatric data collected. Pediatric PHASE will add a large, prospective, population-based cohort study with "the Pediatric Utstein" uniform data reporting style to the limited literature on resuscitation of children, an area in which there is a great need for investigation, and generate more hypotheses for further research.

**Principal Investigator:** George Foltin, M.D., Director, Center for Pediatric Emergency Medicine, NYU School of Medicine/Bellevue Hospital Center, New York, NY. Project period: 09/01/01-08/31/04.

**54. R40 MC 00248: Epidural and Intrapartum Fever.** The proposed project is a randomized trial to investigate the effects of epidural use on intrapartum temperature in
low risk women. The study will definitively determine whether epidural causes fever and whether epidural-related fever is due to infection. In addition, it will evaluate the physiologic correlates of epidural-related fever and explore the consequences of this fever for neonatal outcome. During term labor, most fever is associated with epidural use. Understanding this fever is essential since 50-55% of women receive epidural. While the association of epidural with fever has been reported in several studies, it remains controversial. This fever is generally believed to result from thermoregulatory alterations. But, a recent report of higher rates of histologic chorioamnionitis with epidural-related fever has led to the suggestion that it is infectious. Previous work suggests, that even if not due to infection, epidural-related fever may be harmful for the fetus. In a term, low risk population, epidural-related fever was associated with lower Apgar scores, bag and mask resuscitation, hypotonia, oxygen treatment and neonatal seizures. The researchers hypothesize that epidural-related fever is not due to infection but results from increased cell-mediated immune activity. Both fever and localized inflammation (chorioamnionitis) may be induced by noninfectious agents, producing manifestations similar to infection. This 4 year trial will randomize 1500 low risk, nulliparous women to epidural or no epidural groups. Women in the no-epidural group will be asked to avoid epidural use and provided with labor support to assist them. Cytokine concentrations in maternal admission and delivery and cord blood will be determined and used as correlates of immune activation. The presence of histologic chorioamnionitis and placental infection will be determined. The rate of fever, infection and cytokine levels will be compared across randomization groups in intention-to-treat analyses. Since epidural is such an integral part of practice and its benefits for pain relief so clear, it is critical that the etiology, physiologic correlates and clinical consequences of epidural-related fever be understood so that women can make informed decisions about pain relief. The findings may also suggest effective methods for prevention or treatment of epidural-related fever and its consequences.

**Principal Investigator:** Ellice Lieberman, M.D., Dr.P.H., Associate Professor, Brigham and Women’s Hospital, Boston, MA. Project period: 09/01/01 – 08/31/05.

**55. R40 MC 00254: Intergenerational Pathways to Competence in Minority Families.** This study examines longitudinal factors associated with the attainment of vocational success, supportive parenthood, and the adoption of a healthy lifestyle within a sample of predominantly minority adults born into low income families. The sample, of which 96% is African American, will include up to 170 individual adults who will be assessed between the ages of 26 and 30 years. The sample includes six cohorts from both the Abecedarian Project, as well as Project Care, two early intervention projects in which samples were initially collected in the late 1970's through the 1980's. One goal of the proposed study will be to learn the extent to which early childhood intervention is associated with better adult adaptation for those individuals who participated in either of the two intervention projects. Predictors of successful adult outcomes will include early family of origin factors, early intervention, cognitive development, academic success, educational attainment, and avoidance of problem behaviors. A second goal is to explore intergenerational effects in relation to children born to those individuals who participated
in the early intervention programs. Children of these adults who are aged three and above will be assessed in relation to their cognitive and socioemotional competencies. The proposed data collection at age 26-30 is considered to offer assessment at an age when these individuals will have completed formal education and are establishing careers and families of their own.

The CARE participants have only been assessed through age 12 to this point. However, the investigators note that including the CARE participants in the proposed research will expand the number of available adult cases, and allow for more sophisticated analytic strategies. In addition to the 26-30 years data collection, telephone survey data will be collected on CARE adults at age 21-22, providing an equivalent data source to match the Abecedarian Project data collection protocol.

**Principal Investigator:** Frances Campbell, Ph.D., Senior Scientist, Frank Porter Graham Child Development Center, Chapel Hill, NC. Project Period: 09/30/01 – 08/31/05.

56. **R40 MC 00325:** Community-based Violence Prevention for High-Risk Youth. Youth violence and resulting injury is a major public health concern that increasingly threatens the health of American children and adolescents. While much is known about general risk factors for adolescent injury, less is known about repeat injury among youth presenting to emergency departments (EDs) for intentional injuries. This investigation extends injury prevention and control to further identify causes and risk factors and develop interventions. A group of 196 high risk youth age 9—12 years living in the District of Columbia, who show to ED with interpersonal intentional injuries (excluding child abuse and sexual abuse) will be identified. Intervention will be initiated during the ED visit, the time immediately after an injury when the victim may be more open to preventive messages. The study will: 1) assess violence prevention services provided to assault victims in the ED and after discharge; 2) assess the receptiveness of injured youth presenting to the ED and their families to violence prevention interventions; and 3) determine the feasibility and effectiveness of an individualized home-based youth and family intervention with community involvement.

**Principal Investigator:** Tina Cheng, M.D., M.P.H., Associate Professor, The Johns Hopkins University School of Medicine, Baltimore, MD. Period of Support: 01/01/00 – 12/31/04.

57. **R40 MC 00198:** Economic Impact of Breast-Feeding Promotion Intervention. This investigation will evaluate the economic benefits of pre- and post-natal breast-feeding promotion interventions by measuring total health care costs, in addition to providing an estimation of potential intervention-related savings associated with 3 “breast-feeding sensitive” morbidities, otitis media, gastrointestinal, and respiratory infections. It will also measure the impact of these interventions on breast-feeding practices and child health outcomes. Low-income women and their children who are at
high risk for not initiating, or early cessation of breast-feeding will be recruited from 2 Montefiore Medical Center community health centers in the Bronx, New York. An estimated 80-90% of these women participate in WIC and less than 10% are exclusively breast-feeding at hospital discharge. Most health insurance plans do not cover lactation support services, yet it is precisely the type of preventive activity that managed care plans might cover if the economic costs and benefits were known.

**Principal Investigator:** Karen Bonuck, Ph.D., Assistant Professor, Department of Social Medicine, Montefiore Medical Center, Bronx, NY. Period of Support: 09/01/00 – 08/31/04.

**58. R40 MC 00187: The Epidemiology of Abruptio Placentae.** Abruptio placentae (AP), the premature separation of the normally implanted placenta before delivery of the infant, is a life threatening obstetric complication for both mother and fetus. Low maternal intake of folate and other B vitamins and maternal iron deficiency anemia may be associated with an increased risk of AP. However, the etiology of AP is unknown. This investigation seeks to study the epidemiology of AP by utilizing an existing maternal second trimester serum repository, state vital records data, and a hospital discharge diagnosis database. The study will assess the relation between risk of AP and biological markers of low folate, vitamin B6, vitamin B12, and iron. Metabolic consequences of low folate and other B vitamins in relation to risk of AP will also be evaluated. Results of this study may increase the ability to identify pregnant women at increased risk of experiencing AP, to further understand the mechanisms by which AP occurs, and to develop alternative, preventative interventions for AP.

**Principal Investigator:** Michelle Williams, Sc. D., Professor of Epidemiology, Center for Perinatal Studies, Swedish Medical Center, Seattle, WA. Period of Support: 09/01/00 – 08/31/04.

**59. R40 MC00203: Doula Support for Young Mothers: A Randomized Trial.** This four-year investigation seeks to determine the efficacy of a paraprofessional doula intervention program for young, low-income African American mothers and their infants. The doulas are to provide guidance and support to mothers during the prenatal, intrapartum, and postpartum periods in order to promote good obstetrical outcomes, breast feeding, responsive parenting, parenting efficacy, maternal well-being, and child health and development. This study is expected to extend knowledge by: 1) examining a model of doula intervention that expands into the prenatal and postnatal periods; 2) following families longitudinally to examine the long-term benefits of doula support on mothers and infants; and 3) elucidating biological mechanisms, as well as personal, programmatic, and contextual factors, through which doula support has an effect on mothers and children. Two-hundred forty-eight (248) mothers under 21 years of age who are receiving prenatal care at clinics associated with a major urban medical center will be randomly assigned to receive either doula support or regular clinic services for young mothers.
**Principal Investigator:** Sydney L. Hans, Ph.D., Associate Professor, Department of Psychiatry, University of Chicago, Chicago, IL. Period of Support: 09/01/00 – 08/31/04.

**MCHB-Funded Network Programs**

**60. R60 MC 00107: National Practice Based Network to Improve Child Health.**
This project is carried out by the Pediatric Research in Office Settings (PROS), a program of the Center for Child Health Research of the American Academy of Pediatrics (AAP). PROS, a national practice-based research network of primary care practitioners, is intended to: generate new knowledge about the effectiveness of pediatric primary services; elucidate information about the obstacles that practitioners face in providing effective pediatric primary care services; and help practitioners overcome those obstacles to improve the services that they deliver. The problems addressed by this project are as follows: 1) There remains a relative paucity of knowledge derived from research in primary care settings on which to base guidelines for pediatric primary care services; 2) the insufficient knowledge base decreases the credibility of guidelines for the practitioners who deliver pediatric primary care; 3) pediatric practitioners are often not adhering to guidelines; 4) sub-optimal adherence to guidelines by primary care practitioners could adversely affect the health of the children for whom they provide care; 5) increased knowledge about what services are effective in primary care settings, insights as to why practitioners fail to adhere to guidelines, and explicit efforts to improve primary care practice are needed. The goals are to: 1) improve the management of chronic asthma in pediatric practice; 2) improve the pediatric practice management of newborns after discharge from the hospital; 3) improve the use of antibiotics for respiratory illnesses in pediatric practice; 4) improve the management of ADHD in pediatric practice; and 5) implement research findings from practice-based research into pediatric care. These goals will be achieved through the development of information on the knowledge base related to the issue; measurement of effectiveness or outcomes; feedback of information to a group of interested pediatricians who may use it to change their practices in appropriate ways; and feedback of information to those who set standards and develop educational materials for physicians and other pediatric caregivers.

**Principal Investigator:** Richard C. Wasserman, M.D., M.P.H., Director, PROS Network, The American Academy of Pediatrics, Elk Grove Village, IL. Period of Support: 09/01/90 – 08/31/04.

**61. R60 MC 00105: The Collaborative Ambulatory Research Network.** Existing research used in the development of standards and guidelines for perinatal health care, has typically been oriented towards hospital-based populations rather than ambulatory care settings. The Collaborative Ambulatory Research Network (CARN) comprises a group of Fellows of the American College of Obstetricians and Gynecologists who
voluntarily participate in research on various health care issues that affect their ambulatory care practices and patients. Obstetrician-gynecologists are the principal health care providers for women during the perinatal period. Moreover, they are the de facto primary care providers for many American women. Through the use of written questionnaire surveys, the CARN provides a mechanism for conducting research on obstetrician-gynecologists’ clinical practice patterns, knowledge base and educational needs with respect to a range of topics. A key aspect of improving healthcare for patients is providing educational opportunities and up-to-date information for practicing physicians. Information gathered by way of the Network has been used to develop well-informed educational materials and strategies. Additionally, the CARN provides a structure for collecting normative data that can be used to inform the development of standards and guidelines to improve patient health outcomes.

**Principal Investigator:** Jay Schulkin, Ph.D., Director, Department of Research, The American Academy of Obstetricians and Gynecologists, Washington, D.C. Period of Support: 07/01/90 – 06/30/05.

### 62. Pediatric Emergency Care Applied Research Network (PECARN). The PECARN was created by the Maternal and Child Health Bureau through a partnership between the Emergency Medical Services for Children (EMSC) Program and the MCH Research Program. The goal of this network is to conduct high priority multi-institutional research into the prevention and management of acute illnesses and injuries in children and youth of all ages. PECARN, comprised of four regional multi-institutional nodes (University of California, Davis; University of Michigan; Children’s National Medical Center; and Columbia University) and a central data management and coordinating center (University of Utah), is the first federally-funded pediatric emergency medicine research network. Each node works collaboratively with the others and with MCHB to initiate, implement, and administer network research. The four Regional Node Centers (RNCs) and their 25 Hospital Emergency Department Affiliates (HEDAs) in the PECARN network serve approximately 808,000 acutely ill and injured children every year. PECARN performs meaningful and rigorous multi-institutional research across the continuum of emergency medicine health care delivery for children and youth. To accomplish these tasks PECARN provides the leadership and infrastructure needed to promote multicenter studies, support research collaboration among EMSC investigators, and encourage informational exchanges between EMSC investigators and providers.

**Principal Investigators:**
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