Maternal and Child Health
RESEARCH PROGRAM

1994–96

Completed Projects
Maternal and Child Health RESEARCH PROGRAM

Completed Projects 1994-96
Maternal and Child Health RESEARCH PROGRAM

Completed Projects 1994-96

Supported by
Maternal and Child Health Bureau
Health Resources and Services Administration
Public Health Service
U.S. Department of Health and Human Services

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Safeguarding and improving the health of mothers and children is a demanding national responsibility. It requires significant expenditures of funds, highly trained and dedicated professionals, private and State-supported professional schools to educate new practitioners and update seasoned clinicians, systems of vital statistics, and laboratory and hospital data to monitor morbidity and mortality when and where they happen. Above all, safeguarding and improving the health of mothers and children requires an expanding scientific knowledge base and the means for scientists and practitioners to draw upon this knowledge quickly and accurately.

Research is the mechanism that expands our scientific knowledge base. Our knowledge base is expanded when new knowledge is generated or existing scientific information is validated or rejected. These activities do not materialize overnight, and at the research project level, they often do not produce more than modest gains in knowledge.

Quality research requires more than the application of the scientific method to data collection and careful monitoring of research in the laboratory or the field. With few exceptions, it is essential that each research proposal be peer reviewed and assessed at the planning stage for originality, importance, and technical quality. Only research proposals that can pass this scrutiny should be approved and funded, since they involve a significant commitment of national resources. When completed, the research project should again meet the standards of peer review before the findings are published in professional journals—a prerequisite for acceptance by the scientific community.

After being accepted by the scientific community and incorporated into the knowledge base, research findings need to advance to the application stage. As with formulating and executing research, translating research findings into clinical application calls for careful planning, imaginative thinking, and hard work. Publishing findings in scientific journals does not automatically lead to clinical application. Sometimes, professional inertia may delay application of new findings; at other times, the potential for clinical application may not be fully realized. Not infrequently, an additional piece of knowledge may be needed in order to apply a body of findings to clinical settings. Often, research findings are not applied in health care delivery settings simply because prospective users are not aware of new findings—a problem addressed through this continuing series of MCH research publications.
About This Publication

This edition of completed research abstracts, the fifth in the series, is a companion volume to Maternal and Child Health Research Program: Active Projects. The volume of completed abstracts informs MCH practitioners and scientists of the availability of findings from the MCHB-supported research projects whose principal investigators submitted a final report to the Research Program during 1994–96.

The research projects in this book are listed according to grant number. The first two digits of the grant number represent the State where the grantee institution is located (e.g., MCJ-01 = Alabama). Thus, the projects are also arranged alphabetically by State.

This edition also features a project classification system to help readers understand the nature of each research project at a glance. Each study is classified according to the Healthy People 2000 objectives addressed, study design, time design, care emphasis, population focus, and racial/ethnic focus (if applicable). The completed projects are also indexed by title and by research topic at the back of this book.

In addition, this volume contains a cumulative list of publications generated from all MCHB research projects that submitted a final report in 1992 or later. Principal investigators who submitted a final report in 1992 or 1993 were asked to provide an updated list of products relating to their grant.

This publication also contains a section listing all final reports received by the Maternal and Child Health Bureau for completed research projects since 1980. The final reports of these projects are available through the National Technical Information Service (NTIS); price and ordering information is included at the end of the book. In addition to presenting substantive findings in great detail, these final reports include technical information on how the investigators approached their research projects. This should be instructive for both new and experienced investigators. Frequently, the final reports include extensive critical reviews of the pertinent literature and sometimes include reports of “no findings.” Reports of “no findings” are seldom published in peer-reviewed journals, yet they can be as important as positive findings in advancing our knowledge.

We believe this publication will promote increased knowledge as well as enlightened discussion of state-of-the-art research in the field of maternal and child health.

Gontran Lamberty, Dr.P.H.
Director, Maternal and Child Health Bureau Research Program
April 1998
Introduction

Assessing the performance of health and medical care research at the project or program level can be approached in different ways. One approach involves comparing the cost of conducting the research to the benefits produced, measured by indicators such as number of lives saved, number of years of life added, amount and types of disabilities prevented, quality of life achieved, and health care dollars saved. A second approach is to determine the clinical importance of the findings produced and their direct and indirect contributions to the scientific knowledge base. This analysis can be made by expert panels or through criteria such as number of scientific awards received, spin-off investigations generated, articles and books published, formal citations received in refereed journals, and other measures. The method chosen depends on the goals for the assessment as well as on the amount and types of resources available. By analyzing the products of MCHB-supported research projects, this publication provides valuable information for assessing the performance of the Maternal and Child Health Bureau Research Program.

As part of its routine program monitoring activities, the MCHB Research Program asks principal investigators to report, for each research project completed, the number and types of products generated (e.g., presentations at professional meetings, articles published in peer-reviewed journals, books or chapters published, abstracts published, doctoral dissertations). The first reporting is part of the final report, a requirement for receiving Federal research grant awards. Since a period of 1–5 years is needed to fully analyze the data collected in an investigation, a special followup query takes place 5 years after the study’s completion to capture any additional products. For peer-reviewed articles, the principal investigators are also asked to provide the titles and publication dates of the journals that published their articles. The review process includes locating a sample of the reported publications, then reading the articles to determine whether the content corresponds to the research questions on record for the project. Although imperfect, such indicators as the number and types of products generated and the types of journals that published the research findings provide valuable clues to the quantity and quality of the products generated by the MCHB Research Program.
Table 1 shows that the projects in the completed portfolio are producing many products. The products were generated by the MCHB completed research projects that submitted final reports during the past 5 years (34 projects whose abstracts are included in this publication, and 18 projects that submitted final reports in 1992–93). In total, these research projects generated 839 products. Of the products reported, 43.4 percent were presentations at professional meetings and conferences, 25.0 percent were articles published in peer-reviewed journals, and 17.6 percent represented abstracts. Notably, 210 articles on MCHB-supported research were published in peer-reviewed journals, averaging slightly more than 4 journal articles per project; 148 abstracts were published by the projects submitting final reports in the last 5 years, an average of 2.8 abstracts per project. The principal investigators delivered 364 presentations on their research, averaging 7 presentations per project. In addition, 16 books and reports and 51 book chapters were developed as a result of the MCHB-

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funded research. Four dissertations and 46 other products such as newsletters and editorials were also produced. These data indicate that the products of MCHB-funded research are being disseminated in a variety of ways, including publication in peer-reviewed journals, indicating a high degree of scientific rigor and quality.

The types of journals in which MCHB research findings are published are also important. Table 2 depicts the number and percentage of articles published by type of journal. Of the 210 peer-reviewed articles included among the products in the last 5 years, 81 articles (38.6 percent of the peer-reviewed publications) appeared in medical journals. Of these 81 articles, 10 were published in general medical journals, 66 in pediatric medical journals, and 5 in obstetric/gynecologic journals. In addition, 51 articles were published in journals with a behavioral focus—24 in general behavioral journals and 27 in pediatric behavioral journals. The remaining 39 articles were published in basic, laboratory, and clinical sciences journals representing a broad spectrum of disciplines and focuses.

Table 3 shows that grantees published their results in highly acclaimed journals with rigorous peer-review procedures. The largest number of MCHB research articles (25) were published in the journal Pediatrics. The Journal of Pediatrics also published 13 articles by grantees.
### TABLE 3

**Articles Published from MCHB-Funded Research, by Title of Journal, 1992-96**

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<td>American Journal of Pediatric Hematology/Oncology</td>
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<td>Archives of Pediatrics and Adolescent Medicine</td>
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TABLE 3

Articles Published from MCHB-Funded Research, by Title of Journal, 1992-96
While all of the projects included in this publication provide important information about selected aspects of maternal and child health, six are of particular interest. Pollack’s study on reducing pediatric intensive care mortality showed that risk-adjusted mortality is influenced by the hospital’s teaching status and presence of a pediatric intensivist. This study also showed that the characteristics indicative of overall hospital quality may not be associated, or may be negatively associated, with quality of care in specialized care areas, including the pediatric intensive care unit.

Murphy’s study of an educational intervention for rural children with asthma showed that a structured self-management education program can help decrease asthma morbidity and health care utilization. The telephone followup intervention did not show any significant advantages compared with the educational program alone, offering valuable data for hospitals, communities, and States considering intervention programs in this area.

Lederman’s study on body composition in pregnancy included sufficient numbers of subjects to be able to relate weight gain and fat gain to the outcome of pregnancy as reflected in birthweight. Lederman was also able to show that the recommended amounts of gain were not disadvantageous to her research subjects. This provides strong support for the current weight gain guidelines. This project also included data on African-American and Hispanic women; pregnancy weight gain data for these racial/ethnic groups has been scarce.

Roberts determined that there was a direct association between otitis media with effusion and associated hearing loss and measures of children’s language and cognition at 1 and 2 years of age. However, these relationships were no longer significant when the quality of home and child care environments were taken into account. Further analyses examined how other factors, including the quality of child care and the level of stimulation within the home environment, influenced children’s cognitive and language development during early childhood.

Watterberg’s study of early cortisol deficiency and bronchopulmonary dysplasia strongly supported the hypothesis that decreased cortisol effect during the first week of life is causally linked with adverse respiratory outcome. This study provides a theoretical basis to support a clinical trial to evaluate the effectiveness of low-dose replacement therapy.
Fish was successful in identifying infant, mother, and caregiving environment factors that significantly discriminated between infants of stable and changing temperament, secure and insecure attachment relationships, and high and low verbal communication skills. This study also provides valuable information about parent-child interaction in an understudied population: Appalachian families of low socioeconomic status.
Each project in this book is classified according to the Healthy People 2000 objectives addressed, study design, time design, care emphasis, population focus, and racial/ethnic focus (if applicable). These categories are described below.

**Healthy People 2000 Objectives**

This category lists the Healthy People 2000 objective(s) addressed by each project. The number of the objective(s) is listed for each abstract and a complete listing of the objectives corresponding to these numbers is provided in the appendices of this book. An asterisk (*) next to the number indicates duplicate objectives that appear in two or more priority areas.

**Study Design**

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

**Time Design**

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

**Care Emphasis**

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

**Population Focus**

This category describes the investigation’s primary population group in terms of age, sex, family role, pregnancy status, or other dimensions or characteristics. Within these stated dimensions, particular subgroups (e.g., neonates, preschool children, pregnant women) have specific relevance to maternal and child health program issues and concerns.

**Racial/Ethnic Focus**

This category classifies projects according to whether they describe or elucidate issues related to racial and/or ethnic status by using either a within-group or between-group study format. Studies that do not meet this definition are classified as having no racial/ethnic focus.
Adolescent Mothering and Preschool Behavior Problems

Summary

Statement of the Problem

This study followed a sample of adolescent mothers and their infants in the preschool years to examine the role of parenting behaviors in the development of behavior problems. Research suggests that serious school-age conduct problems typically have their roots in parent-child interactions during the preschool period, but parent-child interactions at this age have not been studied extensively in populations of adolescent mothers and their children.

Research Questions or Hypotheses

This study addressed the following hypotheses:

1. Quality of parenting at each age point will be related to concurrent measures of child compliance, inappropriate behavior, and behavior problems.

2. From time 1 to time 2, changes in parenting quality are influenced by the presence of vulnerability or protective mechanisms in the mothers.

3. Severity of behavior problems will be stable from time 1 to time 2, except as influenced by changes in parenting quality.

4. Adolescent mothers who have not completed important life transitions to young adulthood will demonstrate more inappropriate parenting than adolescent mothers who have completed these transitions successfully; similarly, the children of mothers who have not completed these transitions will demonstrate more behavior problems than
the children whose mothers have successfully completed the transitions;
5. Children with stable attachments from infancy through time 1 will have fewer behavior problems at time 2, compared with children with insecure attachments from infancy.
6. Boys will exhibit more externalizing behavior problems (including conduct problems) than girls. Boys who have insecure attachments in infancy followed by poor parenting or additional vulnerability factors during the preschool years will be more vulnerable than girls to developing conduct problems.

Study Design and Methods

This project used a modified sequential longitudinal study that was quasi-experimental in nature. The study population consisted of two cohorts of preschool children drawn from a sample of 209 children who participated in an earlier study of adolescent parenting and infant attachment at 1 year of age. These cohorts were followed concurrently across a 1-year period and were assessed at two preschool ages on the outcome variables of behavior problems, compliance, and inappropriate behavior. Cohort 1 was assessed at ages 3 1/2 years (time 1) and 4 1/2 years (time 2), and cohort 2 was assessed at ages 4 1/2 years (time 1) and 5 1/2 years (time 2). The major independent and dependent variables were assessed at time 1 and time 2, permitting comparisons of developmental processes at three different ages across the preschool period. The six sets of independent variables included measures of infant attachment security, parenting, maternal vulnerability, maternal protective mechanisms, child vulnerability mechanisms, and child protective mechanisms. Additional analyses were conducted on the longitudinal data from time 1 to time 2 for each cohort and for the combined sample in order to examine influences on developmental pathways. Thus, some of the study’s hypotheses reflected cross-sectional issues, and some reflected longitudinal issues.

1. Home Visit (time 1 and 2): The home visit began with the interviewer explaining the study’s purpose and procedures to the mother. The interviewer administered five interview instruments: Interview and Demographics; Child Vignettes; Mother’s Social Network, Part I and Part II; Child’s Social Network Interview; and Difficult Life Circumstances. The interviewer asked mothers with children who were in child care, nursery school, or kindergarten settings at least half-time to sign a letter of consent authorizing the provider to complete the Preschool Behavior Questionnaire. This measure was mailed to the provider with a self-addressed postage-paid envelope. The home visit concluded with the interviewer paying the mother $20 and obtaining the names of three people who could help the research personnel locate the mother if she relocated before completing the study. After leaving the subject’s home, the interviewer completed two observation-based questionnaires: The Home Observation for Measurement of the Environment and the Adult Conversation Skills Scale.

2. Laboratory visit (time 1 and 2). The laboratory visit was scheduled to occur within 1 week following the home visit. Transportation was provided to and from the university. When the mother and child arrived at the laboratory playroom, research personnel administered the Test for Auditory Comprehension–Revised to the child, while the mother completed the Parent Opinion Questionnaire in a different room. The mother was brought into the playroom for the first of two videotaped sessions involving mother-child interactions (child’s game/parent’s game/clean-up). During this session, the mother wore a “bug-in-the-ear” radio
receiver to allow the experimenter to communicate unobtrusively from the adjoining observation room.

At the conclusion of the child’s game/parent’s game/clean-up assessment, the mother and child had a break and a snack. They walked to a second playroom in the next building; after entering the playroom, the mother left the child in the company of the examiner. The mother was taken to an interview room where she completed a questionnaire packet containing the Life Experiences Survey, Child Behavior Checklist, Beck Depression Inventory, Parenting Sense of Competence Scale, O’Leary Porter Scale, and the Parent Aptitudes Tests. Mothers of children age 5 1/2 also completed the Disruptive Behavior Disorders section of the revised Parent Form of the Diagnostic Interview for Children and Adolescents.

While the mother was answering the questionnaires, other tests were being administered to the child. The Pictorial Scale of Perceived Competence and Social Acceptance for Young Children was administered to children age 4 1/2. The Separation Anxiety Test was administered to children ages 4 1/2 and 5 1/2. Only those age 5 1/2 were asked to draw their family and complete three subscales of the Peabody Individual Achievement Test-Revised. The mother returned to the playroom after completing the questionnaires. The reunion was videotaped and later coded for attachment security. The mother received $20 for the laboratory visit and $20 for the questionnaire packet. If she completed time 1 and time 2 assessments, she received an additional $60.

**Study Sample and/or Population**

The sample was originally recruited in an earlier study on psychosocial and environmental factors related to infant attachment security (Mothering in Adolescence: Factors Related to Infant Security, MCJ-530535, 1986–89). The original sample consisted primarily of adolescent women who were white (79 percent) and unmarried (80 percent), and who had at least a high school education (61 percent). The average age of the mothers in the original sample was 17.1 years at time of delivery; 43 percent of the children born to these mothers were male.

Of the original study sample, 114 were recruited into the followup study. Subjects were originally recruited from clinics, schools, and adolescent parent programs in the greater Seattle area. Subjects were included if the target child was born before the mother’s 20th birthday, and if the mother chose to parent her child.

**Findings**

The findings confirm that the children of adolescent mothers are at greater risk for developing externalizing behavior problems than the children from the general population. More than twice as many children as expected exceeded the clinical cutoff scores on the two narrow band scales, Aggressive Behavior and Delinquent Behavior, that constitute the Externalizing Scale of the Child Behavior Checklist. Nearly one-third of the sample exceeded the cutoff for inappropriate behavior in the parent-child interaction task. In all, 20 percent of the children aged 5 1/2 received at least one DSM III–R diagnosis for Disruptive Behavior Disorders (based on the Diagnostic and Statistical Manual of Mental Disorders, third edition, revised). In contrast, these children did not show elevated levels of internalizing problems, compared with normative samples.

The results suggest that the daughters of adolescent mothers may be at particularly high risk for the development of conduct problems, as the girls in this sample were more consistently above the clinical cutoffs on the Child Behavior Checklist than were the...
boys. Furthermore, mothers of girls had more punitive child-rearing attitudes than did mothers of boys.

Regression analyses revealed that infant attachment security and maternal negative affect measured in preschool, and preschool attachment security all significantly predicted externalizing problems and conduct problems in preschool. When these analyses were conducted separately by gender, somewhat different results were found. For boys, mother’s negative affect in preschool predicted externalizing problems, and both maternal negative affect and preschool attachment predicted conduct problems. For girls, only infancy attachment predicted externalizing problems and conduct problems. Thus, there may be different factors that predict risk status for boys and girls of adolescent mothers.

Publications

Articles, Books, and Chapters


Abstracts

None to date.

Presentations


**Collaborative Study of the Effects of HIV on Development of Hemophilic Children**

**Grantee**
Children’s Hospital of Los Angeles

**Investigator**
Edward D. Gomperts, M.D., M.Sc.
4650 Sunset Boulevard
Mailstop #54
Los Angeles, CA 90027
(213) 669-5699
(213) 660-7128 fax

**Project Number** 060570

**NTIS Number**

**Project Period** 10/01/88-03/31/95

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**Year 2000 Objectives**
6.14, 17.2

**Study Design**
Quasi-experimental

**Time Design**
Longitudinal

**Care Emphasis**
Noninterventional

**Population Focus**
School-aged children, Adolescents
(not pregnancy related)

**Racial/ Ethnic Focus**
None

**Summary**

**Statement of the Problem**

Between 1979 and 1984, persons with hemophilia were at risk for human immunodeficiency virus (HIV) infection through infusion with contaminated clotting-factor concentrate derived from pooled human blood plasma. During that period, approximately 60 percent of hemophilic persons in the United States, many of them children, became HIV seropositive.

Hemophilia also may have an effect on the growth and maturation of the affected child. The disease may result in morbidity from intracranial hemorrhage, for example, as well as from the substantial behavioral effects of this chronic inherited disorder.

The Hemophilia Growth and Development Study (HGDS) research project evaluated the progressive and time-dependent effects of HIV infection on key growth issues of childhood, namely, physical growth, sexual maturation, and mental development in hemophilic children. This research effort was considered important because of (1) the unique group under study, (2) the longitudinal nature of the research program, and (3) the study objectives, which encompassed the major developmental issues of childhood.

In this study, HIV-negative hemophilic children acted as a control group for the HIV-infected cohort. However, the subjects in this group were also compared with their nonhemophilic siblings to determine the effects of hemophilia itself on the developing child.
Research Questions or Hypotheses

Specific aims of the research project were as follows:

1. Measure longitudinally the physical growth and development in a cohort of HIV-positive and HIV-negative hemophilic children;
2. Measure longitudinally the changes in central nervous system (CNS) structure and function in the HIV-positive and HIV-negative groups, using neuropsychological assessment, neurological examination, magnetic resonance imaging, and electroencephalograms (EEGs);
3. Measure longitudinally the immunologic status of subjects in HIV-positive and HIV-negative groups, and in the HIV-positive group correlate changes in immune status with host viral interactions over time;
4. Compare and relate effects of HIV on immune status, CNS structure and function, and physical growth and development in HIV-positive individuals over time to determine developmental relationships among these systems as affected by HIV;
5. Distinguish the effects of HIV disease from the effects of hemophilia on growth and development; and
6. Adjust for the effect, on HIV-positive and HIV-negative groups, of new therapeutic interventions (i.e., the effect of antiviral agents and immunomodulators on HIV-positive subjects and the effect of clotting factor concentrates of varying purity on both HIV-positive and HIV-negative subjects).

Study Design and Methods

This study had three broad components: Neurology and neuropsychology; immune functioning; and growth, development, and endocrine functioning. The type and intensity of the study procedures were based on the assigned study groups. Patients were divided by study center into two groups: Those receiving a standard core battery of examinations, and those receiving the same core battery plus an additional more intensive set of neurological and neuropsychological examinations. The latter group was termed the intensive neuropsychological followup (INF) group.

At entry into the study and at each subsequent annual examination, the patient could have an abnormality detected, indicating the need for more intensive examination (“Trigger”). Trigger criteria were established for the three major areas of investigation, specifically growth/maturation, immune function, and neuropsychologic function.

Subjects were studied at 6-month intervals with basic growth markers and immunologic, serologic, neurologic, neuroradiologic, endocrinologic, and neuropsychologic measures.

Population Description and Sampling Plan

The study population, drawn from 333 hemophilia study subjects, comprised 69.2 percent of the eligible population across 14 hemophilia treatment centers and was representative of the ethnic diversity of the populations at these centers. The study sample consisted of 207 HIV-infected and 126 noninfected children and an additional 45 nonhemophilic male siblings. The size of this population was predetermined for statistical power considerations.

Findings

The data generated were analyzed and reported centrally, with the inquiry guided by the study’s scientific committees. The research team’s approach to the analyses of these data was based on a strong collaboration among the physicians, data coordinators,
and statisticians to produce analyses that were statistically valid and helped describe the nature of the disease.

The major accomplishments of this collaborative research effort may be summarized as follows:
1. There was a high rate of retention of study subjects; after 4 years, only 8 percent of the originally enrolled cohort had dropped out. Of the participants still enrolled, 90 percent or more participated in each followup exam.
2. There was a high rate of compliance with the exam windows.
3. There was a comprehensive data bank and cells/serum bank.
4. Overhead costs were kept to 10 percent.
5. There was a high degree of productivity and collegiality among the research centers.
6. Unique scientific observations have been made despite the incomplete status of the data set.

Based on a set of predefined criteria for detecting deficits in growth, development, immune function, and neuropsychological performance, HIV-positive children and adolescents were three times as likely as HIV-negative participants to show deficits in attained height for age, twice as likely to have delays in sexual maturation, and more than three times as likely to exhibit certain defects in immune function. Following evaluations at three time points (baseline, first annual, and second annual exams), rates of overall performance on neuropsychological test batteries indicated a greater-than-expected number of individuals in both HIV groups meeting predetermined trigger criteria.

Almost two-thirds of the HIV-positive group with deficits in growth also had abnormalities on brain magnetic resonance imaging (MRI) results, whereas only 25.9 percent of those with normal growth had abnormalities (p < .001). Despite the fact that an abnormal MRI in HIV-positive participants correlated with deficits in growth, neuropsychological and neurological abnormalities did not. Poor consistency between these relationships may have resulted from host differences or differences in viral tropism, but clearly these early correlative efforts emphasized the importance of longitudinal followup for the development of new abnormalities in the HIV-positive cohort.

In comparisons of height, weight, rate of growth over time, skeletal maturation, and triceps skinfold thickness, the research team found that compared with HIV-negative participants, HIV-positive participants were shorter (p < .05), lighter, and slower growing (p < .05). Simple nutritional causes were unlikely to be responsible since HIV-positive subjects were not underweight for height (except in the subgroup of HIV-positive participants with advanced impairment in immune function), and triceps skinfold thickness (adjusted for age and weight) was similar in the two groups (p = .8).

Evaluation of baseline MRI scans showed that HIV-infected hemophilic patients more frequently had abnormalities on their baseline MRI scan than seronegative hemophilic patients, with most of the excess in abnormalities accounted for by the subgroup of participants whose immune systems were significantly compromised. The major abnormality seen in this subgroup was generalized atrophy. Atrophy on MRI was associated with decreased muscle bulk on neurological examination, but not with other neurological abnormalities such as hyperreflexia. Other lesions, including single or multifocal white matter lesions, could not be attributed to HIV infection in this population. While it was expected that hemophilic patients would have an excess of old hemorrhagic lesions, the more frequent finding of old infarctions and small focal high-signal intensity white matter lesions was surprising.

These results support the fact that the effects of HIV on the infected hemophilic youth are severe, broad, and not necessarily all secondary to infec-
tion of CD4+ lymphocytes. The research team found a lack of correlation between most nonspecific T-lymphocyte and nonspecific/specific B-lymphocyte–related parameters, consistent with the hypothesis that HIV’s immunologic effects were not due solely to infection of T helper cells or T lymphocytes in general. The results support additional, independent effects on B-lymphocytes, antigen-presenting cells, and/or cytokine production.

The results of the neuropsychological test battery showed that, at baseline, a greater-than-expected number of individuals in both HIV groups showed below-average performance, and the groups as a whole had lowered performance in adaptive behavior and academic achievement measures (p < .01, Bonferroni adjusted for multiple comparisons) relative to IQ.

In this group, after an estimated 4 to 7 years following seroconversion, the results suggest that the progression of HIV brain disease in children and adolescents seroconverting past infancy may more closely resemble the lengthy course seen in adults rather than the relatively rapid course seen in many (though not all) cases with vertically transmitted HIV infection.

This longitudinal study has focused on key components of childhood and adolescence and highlighted certain disease manifestations in this group. The data generated by this research clearly documented that HIV-infected children show impaired growth and physical development that is distinct from a nutritional defect. This knowledge is important to other HIV-infected pediatric groups, especially with the knowledge that a substantial component of vertically infected children are surviving well beyond infancy. While this research project has not elucidated the mechanism of this delay, an impaired link between HIV infection and neuroimmunologic development seems likely. On the basis of these observations, an understanding of the neuroendocrine abnormalities impacting the physical growth of the HIV-infected child should be undertaken.

The data and analyses have substantial implications for the approach to immunization of the HIV-infected child and for public health and the control of infectious diseases. The research data clearly demonstrated that titers of antibodies to common immunogens tend to be lower in the immunized infected child and were not correlated with the CD4 absolute numbers. In addition, while recall response to immunogens did occur, the response was less vigorous.

Knowledge of the response to primary immunization and extent of response to boosting was needed in order to make rational decisions as to basic public health issues and the continued protection of the population as a whole from preventable serious infectious diseases. This was of growing importance as the population of HIV-infected persons grows and extends across our Nation.

One key finding was that these children are under-achieving neuropsychologically relative to their mental potential, despite the fact that all are receiving modern hemophilia comprehensive care and thus optimizing their potential. This observation was of particular interest as our society focuses on the child, the need for appropriate schooling, and the impact on our society in the future.

Careful studies of educational intervention practice should be carried out to determine the most feasible and optimal avenues to close the functional/potential gap in these children’s achievements. Such studies are likely to benefit all children and ultimately our population as a whole.
Publications

Articles, Books, and Chapters


Abstracts

None to date.

Presentations


Summary

Statement of the Problem

The research team pursued this investigation in order to better understand the pathogenesis of high-risk infants. These infants are usually categorized by extremes of birthweight. Infants weighing less than 2,500 grams are generally considered low birthweight, whereas those weighing more than 4,000 grams are generally thought to have elevated birthweight. Many investigators have shown that these extremes in weight are usually associated with increased morbidity and mortality. It is interesting that in a heterogeneous society such as the United States, little research has focused on the relationship of ethnicity to the occurrence of high-risk infancy. In this study, the research team concentrated on infants of elevated birthweight.

Research Questions or Hypotheses

Six hypotheses were developed for this study:
1. The physiologic factors responsible for infantile macrosomia can be defined;
2. Overweight women will give birth to infants with macrosomia;
3. Macrosomia is more frequent in infants who are born to mothers with gestational diabetes;
4. There is a relationship between ethnic group and macrosomia, based on some of the factors listed above;
5. Infants with macrosomia have higher levels of body fat; and
It is possible to diagnose gestational diabetes with the use of a hand glucometer.

Study Design and Methods

All pregnant women who entered San Francisco General Hospital were initially included in this study. A glucose tolerance test was performed at 26–28 weeks’ gestation. Glucose was determined simultaneously from blood drawn through venipuncture in the laboratory as well as from a fingerstick.

Each mother was asked to respond to a questionnaire primarily seeking to determine age, ethnic group, and gestational period as well as drug, alcohol, and tobacco abuse. Prepregnancy weight, weight at first prenatal visit, and weight after parturition were obtained. Each infant was weighed on an electronic scale at birth and blood was drawn primarily to measure insulin, other hormones, and glucose.

The body composition of the infants was measured with skinfolds and a prototype of the Total Body Electrical Conductivity (TOBEC) machine. This relatively new method has been used with a great deal of success with adults; at the time of this study, it had been used for only a short time to determine body composition in infants. TOBEC is a noninvasive technique that can obtain a reading in less than 1 minute. The accuracy of the reading was determined by measuring the body composition of miniature pigs and comparing the results obtained through TOBEC with direct analysis of the pigs.

Study Sample and/or Population

The study sample consisted of 2,120 pregnant women at 26–28 weeks’ gestation. Only those women who delivered term live infants were included in the study. More than 40 percent of the study population was Hispanic, 19 percent Chinese, and 10 percent African American. Other ethnic groups represented in the study included Caucasians, Filipinos, non-Chinese Asians, Pacific Islanders, and Native Americans.

Findings

For each ethnic group, the research team analyzed the relationship between the body mass index (BMI) of the mother and the correlated BMI of the infant. Pregnant women with an elevated BMI were more likely to give birth to an infant with macrosomia. The screening glucose was also significantly associated with the BMI of the infant. These relationships were statistically significant only for the Chinese and Hispanic ethnic groups. Infants born to mothers with glucose values greater than 200 mg/dl had the largest increase in infant BMI.

Although the study showed that the weight of the mother was directly related to the appearance of macrosomia in the infant, the study did not find that elevated maternal glucose had substantial effects on the weight of the infant. Consequently, the research team concluded that maternal glucose is not a reliable indicator of risk for macrosomia.

The study also found a remarkable variation in the incidence of abnormal glucose load tests. A particularly high incidence was observed among Chinese and Filipino women, and an intermediate incidence among Hispanic women. African-American and non-Hispanic white women had the lowest incidence of abnormal glucose load tests.

As expected, the level of serum glucose increased as maternal BMI increased. This effect was more apparent in Chinese and Hispanic women. Hormonal assays, primarily insulin, were measured in the blood of pregnant women. In general, the women who were classified as obese had a higher concentration of insulin than did those who were of ideal weight or underweight.
The results obtained through the use of the hand glucometer were as accurate as those obtained from venipuncture. The hand glucometer was simpler to use, the results were obtained immediately, and the measurement could be made in the clinic.

Publications

Articles, Books, and Chapters


Abstracts

Presentations
Physiologic Risk Assessments to Predict Preterm Birth

Summary

Statement of the Problem

Preterm birth is the primary cause of perinatal morbidity and mortality in the United States. Most preterm births result from either unsuccessfully treated preterm labor or preterm premature rupture of the membranes (PPROM). Unfortunately, most women who experience these pregnancy complications do not have classic medical risk factors such as multiple-gestation pregnancy, cervical or uterine malformation, or history of preterm labor or delivery. The purpose of this investigation was to determine whether three physiologic measures (uterine contractility, cervical examination, and vaginal pH) that have been shown to have some predictive value in patients at high risk for preterm birth would be valuable predictors in a low-risk population.

Research Questions or Hypotheses

This study tested the following three hypotheses:

1. Intermittent assessment of uterine contractility for 30 minutes at standard prenatal visits during the late second and early third trimesters is an effective means to identify women without major medical risks who will develop preterm labor.

2. Periodic examination of the cervix will improve the identification of women who subsequently develop preterm labor.

3. Abnormally elevated vaginal pH will correspond to a higher risk of subsequent PPROM.
Study Design and Methods

The study design was a prospective, blinded evaluation of intermittent contraction frequency, cervical examination findings, and vaginal pH determinations to identify women destined to develop preterm labor or PPROM. The predictor variables and outcome variables were carefully defined. The choice of monitoring intervals and duration was based on both preliminary data and practical considerations so that monitoring could occur at times of routinely scheduled prenatal visits. Because new clinical prediction rules or diagnostic tests often perform less well when replicated in the same or a new setting, the study was designed to be conducted in two consecutive samples of women.

Prenatal charts of women receiving obstetric services through San Francisco Kaiser-Permanente were reviewed to identify patients who met the study design criteria for gestational age and risk status. Exclusion criteria included multiple gestation, history of preterm delivery, preterm labor in current pregnancy or before 34 weeks in previous pregnancy, uterine malformation (including large myomas), clinical obesity (>140 percent ideal body weight for height), and gestational age at 24 weeks' gestation. The research nurses invited eligible women before 22 weeks' gestation to participate in the study. Patients were enrolled until an initial “training” sample of 500 women had completed the study and pregnancy outcome on this sample was known.

Monitoring data were read by one of three nurse investigators who were blinded to patient identity and pregnancy outcome. The plan was to then apply the thresholds determined to be most predictive in the training sample and test them in a replication sample of women. Unfortunately, when the data from the first sample were analyzed, no clinically useful predictors were revealed. Therefore, the study was stopped before the planned completion time.

Study Sample and/or Population

Women from a racially and ethnically mixed group of clients receiving onsite prenatal care from Kaiser-Permanente Hospital provided the sample for this study. The population was approximately 54 percent white, 20 percent African American, 17 percent Asian, and 8 percent Hispanic. Virtually all of the women received prenatal care well before 24 weeks' gestation. The extremes of socioeconomic class are underrepresented in the Kaiser population, since paid health care membership is a prerequisite. The overall preterm delivery rate for women who receive prenatal care at Kaiser Hospital is currently 7–8 percent. Racial differences in the prevalence of preterm and low birth-weight infants are apparent and reflect the relative risks seen in the United States population as a whole. The individual racial and ethnic preterm rates in the Kaiser program are lower than the national rates. In total, 738 low-risk women (500 from the first sample and 238 from the second sample) completed the contraction monitoring portion of the study.

Findings

Of the 738 women who completed the study, only 32 women (4.3 percent) experienced preterm labor and/or delivery; 17 had preterm labor (15 of whom delivered < 37 weeks’ gestation), 6 had PPROM, and 9 had medical complications. Only 5 women (0.7 percent) delivered before 34 weeks’ gestation and only 3 (0.2 percent) before 32 weeks’ gestation. Three babies weighed less than 1,500 grams at birth. There were no neonatal deaths or stillbirths in the study. None of the patients who completed the study were
excluded from analysis. Two hundred and forty-three women in the study agreed to participate regularly in the cervical examination and vaginal pH part of the study. Twelve of these women (4.9 percent) delivered before term.

The mean number of contractions was significantly higher at 30, 32, and 34 weeks’ gestation among the women who experienced preterm labor compared with those who delivered at term. However, at no threshold were there good sensitivity, specificity, and positive predictive value for uterine contraction frequency. For example, the “best” predictor (> 3 contractions per 30-minute period) had a sensitivity of 0.771 and a specificity 0.52, \( p = 0.10 \). Test performance was not improved by subgroup analysis of more confined gestational ages. Cervical dilation and effacement and vaginal pH had no significant value, in large part because of the high frequency of “abnormal” findings in the term delivery group.

Other cervical examination findings, including fetal station, position of cervix, and consistency of cervix, also were not useful discriminators. Because of the lack of any statistically or clinically significant predictors, the study did not pursue more complex statistical modeling to define predictor thresholds.

In this large sample of pregnant women at very low risk for preterm delivery, evaluation of uterine contractility, cervical status, and vaginal pH failed to differentiate the few women destined to deliver prior to term. This suggests that these approaches are not useful in populations at very low risk, despite their possible value in populations of women at high risk for preterm labor or PPROM.

The failure to demonstrate benefit may in part relate to the very-low-risk nature of the population studied, with respect to both total preterm delivery rates and clinically significant (< 34 weeks’ gestation) preterm delivery rates. Monitoring for only 30-minute intervals may be an inadequate length of time to identify those destined to deliver preterm because of preterm labor or PPROM.

**Publications**

**Articles, Books, and Chapters**

None to date.

**Abstracts**


**Presentations**

Risk Taking Behavior in Adolescents: Impact of Puberty

Summary

Statement of the Problem

Adolescence is generally viewed as a period of optimal physical health. In reality, adolescence represents the only age group in the United States in which mortality continued to increase during the 1980s. Approximately 75 percent of the deaths in this age group are due to fatal injuries, homicide, and suicide. The major causes of morbidity in youth include the consequences of sexual activity, substance abuse, motor/recreational vehicle crashes, and attempted homicide with resultant injury and disability. The behaviors associated with these negative outcomes account for more than 50 percent of adolescent morbidity/mortality (including the largest number of hospitalizations), and have a profound impact on the short-term and long-term physical and mental health of youth. These problems, which have their onset early in adolescence, are widespread, behavioral in nature, and prevalent in all socioeconomic groups.

The behaviors associated with the major mortalities and morbidities of adolescents share a common theme: Risk taking. Young people engage in potentially destructive behaviors with or without understanding the immediate or long-term consequences of their actions. Although some risk taking is necessary in the developmental process, too often the results are disastrous.

Preliminary data on covariation among these risky behaviors in youth supported taking a generic approach to the problem of adolescent risk-taking behavior. Substance abuse, behaviors associated with injuries,
and sexual activity have high prevalence rates during adolescence and demonstrate covariation. Although the relationships among these behaviors have been partially documented in late adolescence, the mediating factors underlying these interrelationships remain unclear.

The lack of knowledge about the underlying mechanisms is reflected by the meager progress in affecting adolescent risk-taking behavior. Research focused on examining single behaviors has been used to develop intervention programs that fail to address the underlying issues and consequently have minimal impact on the behaviors or on the resultant negative health outcomes.

Research on adolescent risk taking has also been hampered by an almost exclusive focus on psychosocial phenomena. Physiological maturation during adolescence may be an important contributor to the onset of risky behaviors. Timing of physiological maturation has been shown to be associated with risk taking. Even though there are marked differences in the timing of pubertal development (both within and between the sexes), little attention has been given to the role that variations in timing of pubertal onset or completion may have on risky behaviors.

A better understanding of how adolescents perceive risk and of the biopsychosocial factors associated with those perceptions will assist in the development of prevention programs targeting those perceptions and associated behaviors. If timing of physiological change is one of the primary mechanisms that drives these behaviors, then a careful explanation of how physiology interacts with the other aspects of psychosocial development in adolescence will enable health professionals to develop more effective prevention and delivery programs. Clearly, the changes in puberty are more easily documented than the major psychosocial and cognitive changes.

Research Questions or Hypotheses

The objective of this research study was to examine the relationship between the timing of physiological development in adolescence and three risk-taking behaviors: Sexual activity, substance use, and injury-related behavior.

The underlying hypothesis was that the timing of physiological maturation predisposes adolescents to engage in certain risk-taking behaviors that fulfill critical developmental needs (both psychosocial and psychological) during the second decade of life. Specific psychosocial changes occur along with biological maturation and are associated with adolescent risk-taking behaviors. Timing of biological maturation was expected to directly influence a set of four psychosocial factors: Cognitive scope, self-perceptions, perceptions of the social environment, and personal values. These four factors were expected to influence two mediating factors, peer group selection and perceptions of risk, which in turn were hypothesized to predict adolescent risk-taking behaviors.

Self-perceptions, perceptions of the social environment, and personal values were expected to influence the adolescent's choice of peer group, which in turn was expected to influence risk-taking behaviors and was hypothesized to be affected primarily by characteristics of the peer group, cognitive scope, and self-perceptions. The influence of personal values on risk-taking behaviors was expected to occur as a function of its effects on peer group choice, although some direct effects of personal values were also expected.

Specifically, the following hypotheses, together with related subhypotheses, were tested:
1. Timing of adolescents’ pubertal maturation is associated with differences in adolescents’ perceptions of their early social environment;
2. Timing of adolescents’ pubertal maturation is asso-
associated with differences in adolescents’ self-perception;
3. Timing of adolescents’ pubertal maturation is associated with differences in personal values, psychosocial maturity, and cognitive capacity;
4. Timing of adolescents’ pubertal maturation is associated with differences in risk-taking behavior;
5. Adolescents’ environmental perceptions are associated with risk-taking behavior; and
6. Self-esteem is negatively correlated with risk-taking behavior.

Study Design and Methods

The study involved a cohort, sequential, longitudinal design, with data collected at three points in time. During phase 1 of this study, a large cross-sectional sample of adolescents was assessed. In phase 2, a cross-sectional subsample of 592 adolescents was assessed extensively. Phase 3 involved the 1-year followup of phase 2 subjects.

The adolescents and their parents were asked to give consent to participate in the screening (phase 1) portion of the study. During phase 1, pubertal development measures and sexual maturation scales were administered to the students. Sociodemographic data and height and weight measures were also collected. On the basis of data collected during phase 1, subjects were selected for phase 2 of the study. During phase 2, a physical examination, the Marlowe-Crowne Social Desirability Scale, the Jessor and Jessor Scales, and measures of egocentrism, future orientation, body image, risk perception, risk-taking behavior, and environmental perception were administered. Six months after the phase 2 assessments were completed, the phase 3 followup occurred, and all of the phase 2 assessments were repeated for the phase 2 subjects only.

Phase 1 assessments were conducted during one class period. Two other class periods were used for a subject orientation and for a feedback session in which the students were given a computer printout of their individual pubertal status and an overview of developmental changes they should expect over the next 1 to 2 years. Phase 2 and phase 3 assessments were conducted at the University of California at San Francisco. Subjects in these last two assessments were paid $10 for each assessment.

Study Sample and/or Population

The study sample consisted of 1,760 subjects selected from 3 San Francisco public schools. Two middle schools (subjects in grades 6–8) and one senior high school (subjects in grade 9) were selected and agreed to participate in the study. Approximately 2,100 adolescents were attending those grades in the target schools. Student participation was solicited during required classes to ensure that all students at each grade level were offered the opportunity to participate in the research. The majority of the students were of middle and lower-middle class status and represented approximately equal numbers of white, black, Asian, and Hispanic backgrounds. This racial/ethnic diversity allowed for greater generalizability of study findings. Limiting the sample to no more than four primary ethnic groups allowed for sufficient statistical power to detect differences that could emerge. The wide range of ages allowed examination of the effects of both early and late physiological maturation, as well as risk-taking behaviors that occur in early or late adolescence.
Findings

A majority of the adolescents ages 11–14 had tried alcohol and tobacco, and almost one-third had used marijuana; 21 percent were sexually active. Prevalence rates varied by social class, race/ethnicity, gender, and age. White adolescents were more likely than minority adolescents to have initiated substance use earlier. Black and Hispanic-American adolescents were more likely than white and Asian-American adolescents to have initiated sexual behavior. Males reported higher frequencies of engaging in all types of risk-taking behaviors, especially injury-related behaviors. Despite the negative aspect of the males’ risky behaviors, the males reported themselves to be physically, emotionally, and socially healthier than did the females. Compared with the males, the females reported lower self-esteem, more interpersonal problems, and a higher frequency of negative emotional states such as depression, anger, and nervousness. Covariation of behaviors is already established in this early adolescent cohort. Adolescents engaging in any given risky behavior (sexual intercourse, illicit substance use, tobacco/alcohol use, or dangerous vehicle-use) were more likely to engage in other risky behaviors as well. More than 75 percent of the sample had visited a health professional at least once in the previous year. Use of health services was highly related to race and social class, with white adolescents having the highest utilization rates and Asian-Americans having the lowest.

The study findings indicated that adolescents are capable of making judgments on risk. Adolescents in this study were capable of evaluating risk and its consequences. Their judgments were rational. They tended to assign lower risk to dangerous behaviors as they grew older; this finding may be associated with the tendency to diminish the level of risk as one engages in the risky behavior. The adolescents were also able to anticipate their intended behaviors and to assign positive and negative balances to the behaviors that were predictive of initiation of risky behaviors.

Puberty was a critical factor in the onset of risky behaviors. Early pubertal maturation was highly correlated with the initiation of certain risky behaviors in both sexes. The effects were stronger for females than for males. In females, late pubertal maturation was protective of initiation of risky behaviors. The females who had late pubertal maturation tended not to engage in risky behaviors. For the males, the effects of late pubertal maturation were not statistically significant, but the direction of the effects was similar to that of the females. Within the longitudinal sample, adolescent females who matured earlier were more likely to engage in substance use than were those whose maturation was either “on time” or later.

Family processes and structure also played a significant role in the initiation of risky behaviors. Family structure was highly correlated with initiation of risky behaviors: Adolescents from single-parent families were more likely to engage in risky behaviors than adolescents from intact families. Older males (ages 16–17) from single-parent families were most likely to experiment with different substances. Emotional detachment from parents (independent of family structure) was associated with experimentation with different substances. Parental support of autonomy, such as encouraging the expression of opinions and avoiding overprotection, was inversely related to sexual behavior. Relatedness (i.e., parental acceptance and family cohesion) and emotional detachment were associated with fighting and substance use.

Based on the results of this study, the research team developed seven recommendations:

1. Young adolescents are already engaging in risky behaviors. These behaviors begin in the peripubertal period. Screening for these risky behaviors and their consequences needs to begin at
11–12 years of age, when the adolescent is most likely to be experimenting with the behaviors. Anticipatory guidance needs to be offered to the parent and the adolescent before the onset of adolescence.

2. Covariation of risky behaviors is already present in early adolescence. Health care settings that address one issue (e.g., sexual behavior, trauma) need to be aware of the co-occurrence of other risky behaviors (e.g., substance use).

3. Since pubertal maturation is a well-demarcated event, clinicians should be informed about the correlation between the onset of risky behaviors and early maturation.

4. Health care providers need to be educated about the early onset of risky behaviors in adolescence, through graduate education programs and continuing health education programs.

5. Since most of the sample reported a visit to a clinical setting in the previous year, screening, anticipatory guidance, and physical examinations need to be directed toward identifying those adolescents at risk and providing preventive services to all adolescents.

6. Emotional detachment is a strong predictor of engagement in risky behaviors. Many families assume that once a young person reaches adolescence, he or she can function independently. The study data indicate that those adolescents who are monitored, receive appropriate supervision, and are given graduated autonomy are less likely to engage in risky behaviors. Parental education programs that address the issues and needs of normal adolescence should be incorporated into health care delivery and educational systems.

7. Young adolescents already have knowledge about the dangers of risky behaviors. Health education programs need to emphasize self-assessment of risk and skill development.

Publications

Articles, Books, and Chapters


Abstracts


Kegeles SM, Adler NE, Irwin CE. 1988. Adolescents’ beliefs about and intentions to use condoms. Abstract published for the American Psychological Association meeting, Atlanta, GA.


Presentations

Irwin CE. 1993. Risk-taking during adolescence: What the research tells us about interventions. Presented at Children’s Hospital, Harvard Medical School, Boston, MA.

Irwin CE. 1993. Risky behavior during the teenage years: Can we intervene? Presented at Eastern Virginia Medical School, Norfolk, VA.


Irwin CE. 1991. Risk taking: Opportunities for intervention for the pediatrician and internist. Presented at Baystate Medical Center, Tufts University Western Campus, Springfield, MA.

Irwin CE. 1990. Predictors of risk taking behaviors in adolescents. Presented at the Eighth Texas Tech University Symposium on Interfaces in Psychology, Adolescent and Adult Risk Taking, Texas Tech University, Lubbock, TX.

Irwin CE. 1990. Risk taking during adolescence. Presented to the Department of Pediatrics, Columbus Children’s Hospital, Ohio State University, Columbus, Ohio.


Summary

Statement of the Problem

The problem of physical abuse reportedly involves as many as 11 to 30 percent of pregnant women. Studies have addressed the relationship between physical abuse and pregnancy outcomes such as low birthweight. Yet these studies tend to be incomplete, since they fail to account for the multiple biomedical and psychosocial variables that may influence pregnancy outcome.

Biomedical and lifestyle risks in pregnancy have been delineated and interventions have been devised to address many of these risks. Less well developed are schemes for the identification and management of a pregnant woman’s psychosocial risk. This is especially true for women who have experienced psychosocial risk as a result of emotional trauma from physical abuse inflicted during pregnancy.

Pregnancy outcome complications have been identified as consequences of psychosocial risk. To account for possible confounders, biopsychosocial studies of pregnancy outcome have controlled for demographic, lifestyle, and biomedical variables. In these studies, social and psychological risks have been significantly related to maternal and infant complications of pregnancy.

As a life stressor, physical abuse may represent a psychosocial risk that will adversely influence pregnancy outcome. Thus, pregnancy outcomes such as low birthweight, prematurity, and low Apgar scores for newborns may be expected with physical abuse during pregnancy. Prematurity and low birthweight
Research Questions or Hypotheses

This 3-year prospective study tested the following hypotheses:
1. Abuse of women during pregnancy would result in an increased incidence of maternal complications and poorer infant outcomes;
2. Delivery complications would be related to biomedical risk, impaired social support, lower self-esteem, and external locus of control; and
3. Abused gravidas who perceive that high-quality support is available from family and/or friends would have more favorable outcomes of pregnancy.

Study Design and Methods

This study involved a prospective cohort design that used matched samples of gravidas who were using the services of the University of Louisville prenatal clinic. Between 1991 and 1994, these women were screened with a questionnaire to obtain basic demographics and to identify abuse. A total of 100 abused women were matched with individuals from a control group. Components of the match were race, parity, gravidity, smoking, alcohol consumption, and drug use. Subjects were given a battery of psychosocial tests and a medical history survey at 32 weeks. A postdelivery questionnaire was used to gather information on prenatal health status and abuse during pregnancy.

Information on prenatal health status and delivery complications was obtained from a postpartum chart survey. Variables recorded for the study included birthweight, delivery method, prematurity, pediatric Apgar score, lifestyle and demographic factors, biomedical risk, anxiety, life stressors, depression, social and personal resources, family function, self-esteem, locus of control, socioeconomic factors, and spouse abuse. Each variable was identified as an outcome, control, or predictor, and used in data analyses.
a final patient interview after delivery, the subjects were asked whether they had experienced abuse during the study period.

**Findings**

This study of abused women and their controls did not find significant differences in any of the more than 30 pregnancy outcome variables. Since the univariate tests were not significant, no further analyses of the outcome variables were warranted. Thus, the first two hypotheses regarding spouse abuse as a contributor to poor outcomes of pregnancy were not supported by these data.

However, with respect to the third hypothesis, the two groups differed significantly on all of the psychosocial dimensions in the hypothesized direction. Abused women who had strong social support in the form of a confidant differed from those who did not have a confidant on 6 of the 10 psychosocial instruments. However, when compared on outcome variables, abused women who had a confidant did not differ significantly on any of the outcome variables except weight gain: Abused women who had a confidant gained significantly more weight than did those without a confidant.

This study has raised additional questions surrounding spouse abuse and pregnancy outcomes. Previous research has shown the effects of stress on pregnancy outcomes. Given the violent and debilitating nature of spouse/partner abuse, it seems likely that this additional stressor should have resulted in poorer outcomes of pregnancy. It is possible that this population of urban low-income women already experience such significant levels of stress due to poverty and unstable family life that the additional stressor of spouse abuse is not sufficient to influence pregnancy outcomes differentially.

It is also possible that this group of women had sufficient prenatal care to offset the effects of a stressful life. Only those women who came for prenatal care were identified for the study. Although there was obvious variability in the number of prenatal visits, the groups did not differ significantly on this dimension.

Another explanation for these findings is the presence of a confidant. Most of these women reported having someone with whom they could share their problems and difficulties. The literature has previously shown the protective effect of a confidant during pregnancy.

This research project recommends continued study of the phenomenon of spouse abuse in pregnancy. The potential morbidity associated with partner abuse has been demonstrated. Although this group of women did not report high levels of violence, the potential remains for violence to escalate once it has been introduced as a conflict response tactic. Any study of an embarrassing or potentially deadly event may result in less than total truthfulness on the part of the victims, due to fear of reprisal. Overcoming this added dimension will be the challenge of future studies.

**Publications**

**Articles, Books, and Chapters**


**Abstracts**

Smilkstein G. 1995. Family violence. Abstracts of presentations given at the 14th World Congress of National Colleges and Academies of Family Medicine, Hong Kong.

**Presentations**


Smilkstein G. 1994. Violence: What we can do as health care providers. FAP 195 Course: Health Care to the Medically Underserved, School of Medicine, University of California, Davis, CA.

Reducing the Nation’s Pediatric Intensive Care Mortality

Summary

Statement of the Problem

Pediatric intensive care units (PICUs) have proliferated in all types of hospitals, but little is known about which characteristics of intensive care are associated with good outcomes. Current data indicate that quality of care may differ substantially among PICUs. This study was designed to ascertain which of four characteristics (size, medical-school teaching status, intensivist status, and coordination of care among multiple teams) determine the quality of care.

Research Questions or Hypotheses

Recent data indicate that the quality of pediatric intensive care is not uniform, resulting in the unnecessary deaths of numerous infants and children each year. This project investigated four primary intensive care characteristics using an objective, quantitative methodology that can be applied to future studies. This methodology, validated in a national study, indicated that there is a precise relationship between severity of illness (i.e., physiologic instability as assessed by the Pediatric Risk of Mortality [PRISM] score) and intensive care outcome (i.e., survival or death) in university pediatric intensive care units with intensivist directors. The research team hypothesized that the precise relationship between severity of illness and outcome would not hold consistently in all pediatric intensive care units, resulting in underestimation of mortality.
Study Design and Methods

The specific primary quality characteristics to be studied were as follows: Size of the unit, medical school affiliation, presence of a pediatric intensivist, and coordination of care with multidisciplinary health care teams. Sixteen pediatric intensive care units were recruited to represent the unique combinations of these quality factors. Each unit collected four time-interval PRISM scores, demographic data, and frequency of variable measurement data on consecutive admissions until 15 deaths had accumulated. A stepwise logistic regression determined the shortest time interval required for observation. A stepwise logistic regression model predicting intensive care unit outcome from the PRISM scores and the quality factors was established. A similar logistic regression model for intensive care unit outcome was obtained with the PRISM scores and a factor identifying each institution as covariants. Results were confirmed with goodness-of-fit tests and other methods based on the z statistic.

Study Sample and/or Population

A total of 5,415 PICU admissions from 16 PICUs were studied. Mortality rates ranged from 2.2 percent to 16.4 percent. Other PICU variables differed significantly, including volume (13–63 admissions/month), hospital pediatric beds (20–173 beds), and readmissions (2–31 patients).

Findings

Analysis of the risk-adjusted mortality indicated that the hospital’s teaching status and the presence of a pediatric intensivist were significantly associated with a patient’s chance of survival. The probability of patient survival after hospitalization in a PICU located in a teaching hospital decreased (relative odds of dying 1.79; 95 percent confidence interval 1.23–2.61; p = .002). In contrast, the probability of patient survival after hospitalization in a PICU with a pediatric intensivist improved (relative odds of dying .65; 95 percent confidence interval .44–.95; p = .027). Post hoc analysis indicated that the higher seventy adjusted mortality in teaching hospitals may be explained by the presence of residents caring for the patients.

Characteristics indicative of overall hospital quality may not be associated, or may be negatively associated, with quality of care in specialized care areas, including the PICU. Study of care factors associated with measures of quality other than mortality should be expanded to better identify regional referral centers.

Publications

Articles, Books, and Chapters


Abstracts


Presentations


Summary

Statement of the Problem

Two sets of factors encouraged the Institute of Medicine to study the problem of unintended pregnancy. First, data published in 1990 showed that 57 percent of all pregnancies in the United States are unintended at conception, a proportion higher than that found in several other Western democracies. Second, there is evidence from the 1988 National Survey of Family Growth that the decline in births from unintended pregnancies during the 1970s had reversed in the 1980s, with particular increases noted among low-income women. These figures indicate that progress in one of the most basic measures of women’s autonomy (determining whether and when to bear children) has eroded, a development that obviously undermines efforts to improve women’s capacity for self-determination and full participation in their communities. Moreover, the increases in the number of births from unintended pregnancies were not confined to adolescents. This suggests that the Nation’s continuing focus on adolescent pregnancy might well be missing a larger issue, namely, that adults as well as adolescents are having difficulty in planning and preventing pregnancy.

The Institute of Medicine also noted with concern that little attention has been given to the relationship between the “intendedness” of pregnancy and the health and well-being of children. Throughout the late 1980s and early 1990s, an appreciable amount of advocacy on behalf of children centered on reducing...
infant mortality, increasing rates of immunization, expanding the Head Start program, and similar initiatives. But the world of education, counseling, and care that supports careful contraceptive use—often called family planning—has been starkly absent from the “children’s agenda” as articulated over the past 10 to 15 years. In fact, pregnancy prevention and family planning have generally been treated as marginal or controversial activities, rarely discussed in a broad, comprehensive way that recognizes the important role that fertility control plays in men’s and women’s lives, in children’s well-being, and in the overall tenor of communities. As evidence of this neglect, public investment in family planning services declined during the 1980s, perhaps by as much as one-third. Federal outlays for family planning through the Title X program dropped precipitously during the 1980s, although increased commitments from other public and private sources helped to fill a portion of the gap.

Research Questions or Hypotheses

With such concerns in mind, the Institute of Medicine’s Committee on Unintended Pregnancy was asked to explore the relationship of unintended pregnancy in the United States to the health and well-being of children and families, and to make recommendations for policy, practice, and research. In so doing, the committee was asked to (1) define what is meant by unintended pregnancy and related terms used in the relevant data and research; (2) summarize evidence on the effects of unintended pregnancy, both mistimed and unwanted, on the health and well-being of children, youth, and adults (to include commentary on the role of abortion in resolving unintended pregnancies); (3) analyze patterns and trends in unintended pregnancy in the United States, including data on the populations in whom unintended pregnancy is concentrated; (4) outline the various reasons that might help to explain the observed patterns; (5) describe the range of programs that have been organized in the last 10 years or so to reduce the incidence of unintended pregnancy and, to the extent possible, comment on the effectiveness of various approaches; and (6) draw conclusions and make recommendations for policy, practice, and research, based on the data assembled and reviewed.

The study was jointly supported by the Maternal and Child Health Bureau and other agencies of the U.S. Public Health Service, the Carnegie Corporation of New York, and the Robert Wood Johnson Foundation. The investigation culminated in completion of the final report The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families, which was published in book form. The report was formally released to the public in April 1995; a separate summary of the full report was also produced.

Study Design and Methods

In meeting its charge, the committee and staff reviewed published data and analyses pertinent to unintended pregnancy; studied more than 21 commissioned and contributed papers on a variety of topics related to pregnancy planning; talked informally with experts on the various topics of study; requested one original piece of analytic work by the Alan Guttmacher Institute on the 1988 National Maternal and Infant Health Survey; conducted an analysis of what the childbearing population in the United States would look like if unintended pregnancies were eliminated; and held five meetings of the full committee over a 13-month period (September 1993 through October 1994). The committee members and the staff participated in drafting the report. In addition, a careful effort was made to identify programs in this country that address unintended pregnancy, with a special emphasis on programs whose effects on unintended
pregnancy, broadly defined, had been evaluated and published in a peer-reviewed journal.

Findings

The study committee concluded that the consequences of unintended pregnancy are serious, imposing appreciable burdens on children, women, men, and families. These consequences are not confined to the unintended pregnancies that occur among adolescents or unmarried couples; in fact, unintended pregnancy can carry serious consequences at all ages and life stages. Five sets of data are available to assess the nature and extent of these consequences.

First, a complex and extensive group of studies has attempted to measure the impact of the intendedness of pregnancy on a wide variety of child and parental outcomes. These studies show that unintendedness itself (especially unwantedness) poses an added burden independent of the presence of any other factors, including the social and economic attributes of the mother in particular. With an unwanted pregnancy especially, the mother is more likely either to seek prenatal care after the first trimester or not to obtain care at all. She is more likely to expose the fetus to harmful substances by smoking tobacco or drinking alcohol. The child of an unwanted conception is at greater risk for low birthweight (weighing less than 2,500 grams at birth), of dying in the first year of life, of being abused, and of receiving insufficient resources for healthy development. The mother herself may be at greater risk for physical abuse, and her relationship with her partner is at greater risk for dissolution. Both mother and father may suffer economic hardship and fail to achieve their educational and career goals. The health and social risks associated with a mistimed conception are similar to those associated with an unwanted conception, although not as great. For some risks, such as low birthweight, an independent effect of planning status cannot be established (that is, the milieu in which the mistimed conception occurs may be the causal link to the adverse outcome). For other risks, such as child abuse and neglect, assisting families in having children when they are ready for them may attenuate the effects of resource deficits.

Second, a disproportionate share of the women bearing children who were unintended at conception are unmarried and/or at either end of the reproductive age span. These demographic attributes themselves carry increased medical and social burdens for children and their parents. At the same time, it is important to state that, although women who are unmarried and/or at either end of the reproductive age span are disproportionately represented among those having births that were unintended at conception, the majority of such births are to women without these demographic attributes.

Third, a pregnancy begun without some degree of planning and intent often precludes the opportunity to participate in preconception risk identification and management or to take full advantage of the rapidly expanding knowledge base regarding human genetics.

Fourth, unintended pregnancy leads to approximately 1.5 million abortions in the United States annually, a ratio of about 1 abortion to every 3 live births. This ratio is two to four times higher than that in many other Western democracies, in spite of the fact that access to abortion in those countries is often easier than in the United States. Although abortion has few long-term negative consequences for women’s health, resolving an unintended pregnancy by abortion can often be a sobering and emotionally difficult experience that no woman welcomes. In addition, the political and social tensions surrounding abortion in the United States continue to be a divisive force at the national, State, and local level. In recent years,
these tensions have taken a violent turn, as exemplified by the murder of several individuals associated with clinics that perform abortions.

Finally, a statistical recalculation of what the childbearing population in the United States would look like if unintended pregnancy did not occur (unwanted conceptions eliminated and mistimed ones redistributed) shows dramatic decreases in the proportion of children born to unmarried women. Specifically, the proportion of all births in 1994 that were to unmarried women or that were the result of an unwanted pregnancy would decrease from 38 to 21 percent, a 45-percent reduction overall. The percentage of all births to adolescent mothers would also decrease, given the disproportionate representation of adolescents in the pool of unmarried women giving birth. Although the complete elimination of all unintended fertility is an unrealistic goal, this statistical exercise adds to the evidence that an appreciable reduction in the number of unintended pregnancies would improve the well-being of future generations. The fact that other industrialized countries report fewer unintended pregnancies than the United States suggests that progress in the desired direction is a realistic, feasible goal.

Many factors help to explain the Nation’s high level of unintended pregnancy. Most obvious is the failure to use contraceptive methods carefully and consistently or to use them at all, as well as the actual technical failures of the methods themselves. Women and their partners who rely on reversible means of contraception (about 21 million women) and those who use no contraceptive at all without any clear intent to become pregnant (about 4 million women) contribute roughly equally to the pool of unintended pregnancies. Many women and couples who are not seeking pregnancy move between these two groups, sometimes using contraceptives, sometimes not. These patterns of contraceptive use and nonuse are in turn influenced by various attributes of the health care system and its providers, a wide variety of social and cultural phenomena, and numerous personal and motivational factors that are not well understood.

The committee concluded that the extent of unintended pregnancy and its serious consequences are poorly appreciated throughout the United States, and that a reduction in unintended pregnancies will require a new national understanding of this problem and a new consensus that pregnancy should be undertaken only with clear intent. Accordingly, the committee recommended that the Nation adopt a new social norm: All pregnancies should be intended—that is, they should be consciously and clearly desired at the time of conception.

To begin the long process of building national consensus around this norm, the committee recommended a multifaceted, long-term campaign to (1) educate the public about the major social and public health burdens of unintended pregnancy, and (2) stimulate a comprehensive set of activities at the national, State, and local level to reduce such pregnancies. This campaign should stress five core goals:
1. Improve knowledge about contraception and reproductive health;
2. Increase access to contraception;
3. Explicitly address the major roles that feelings, attitudes, and motivation play in using contraception and avoiding unintended pregnancy;
4. Develop and scrupulously evaluate a variety of local programs to reduce unintended pregnancy; and
5. Stimulate research to (a) develop new contraceptive methods for both women and men, (b) answer important questions about how best to organize contraceptive services, and (c) understand more fully the determinants and antecedents of unintended pregnancy.
Publications

**Articles, Books, and Chapters**


**Abstracts**

None to date.

**Presentations**

None to date.
An Educational Behavioral Program for PKU

Summary

Statement of the Problem

It is now recognized that long-term dietary treatment of patients with phenylketonuria (PKU) is essential for optimal development and maintenance of intellectual ability. In addition, females with PKU face a high risk of congenital disabilities in their offspring if blood phenylalanine levels are not reduced by dietary treatment during pregnancy. It is now necessary to consider PKU as a chronic disease that requires complex management beyond early childhood. Experience with diabetes, a chronic disease that requires adherence to a dietary regimen, indicates that children need to be educated and adequately prepared to assume self-management of their treatment as they undergo the process of physiologic and psychosocial maturation.

This study evaluated the effectiveness of a program that uses an educational and behavioral approach that is developmentally appropriate for three different age groups of PKU patients. The program was designed to increase participants' knowledge of PKU, its treatment, and its implications for pregnancy and birth outcomes, and to foster self-reliance in the management of PKU. All participants were on a phenylalanine-restricted diet, but their metabolic control may not have been optimal.

Research Questions or Hypotheses

The objectives of this study were to (1) determine whether participation in the educational program
resulted in increased knowledge of PKU and improved metabolic control, and (2) identify parameters that predict success with the program.

**Study Design and Methods**

The study followed a two-period crossover design, each period lasting 1 year. Subjects received the experimental treatment for 1 year (treatment group) and routine care for 1 year (control group), with the order decided randomly by using a permuted block design. This gave all subjects the opportunity to participate in the program. To guard against possible carry-over effect, only data from the first study period were used to make between-group comparisons. Data from the second period were used to determine the extent of the long-term effect of the program (for those who received the treatment program in the first period) and to compare within-group differences (i.e., subjects’ success or lack of success with the program).

Routine care consisted of two to three clinic visits per year and collection of diet diaries and blood samples during visits and between visits. The frequency for submitting blood samples and diet diaries during the year of routine care was specified by the physician.

The experimental group received the educational program, which consisted of three individual teaching sessions with the dietitian, during which time various concepts were taught and skills practiced. Between educational sessions, subjects were expected to submit a blood sample, diet diary, and completed homework sheet biweekly, and a point system was used as a reward for submitting each of the three items. Each participant received a phone call, followed by a postcard, stating the blood phenylalanine level, points earned, and feedback on the homework and diet diaries. Points earned were subtotaled at each clinic visit and rewards given to those who earned at least 60 percent of the possible points. Participants who did not send in the expected items received a postcard as both reminder and encouragement. At the end of the first study period, the experimental subjects crossed over and became control subjects, and the control subjects from the first study period became participants in the experimental portion in the second study period.

For both the treatment and control groups, the following measures were obtained at the first clinic visit, at the end of the first year, and at the end of the second year: Blood phenylalanine, knowledge of PKU, IQ, school achievement, psychopathology, cognitive maturity, locus of control, family environment, social maturity, and socioeconomic status.

**Study Sample and/or Population**

Individuals with PKU who were on a phenylalanine-restricted diet were recruited from the two PKU clinics in Illinois. One clinic was located at Children’s Memorial Hospital, the other at the University of Illinois Hospital. The two clinics were unique in that they were in close proximity and both had a long history of affiliation with the National Collaborative PKU study. Males and females ages 6–18 were enrolled in the study. Sixty-eight subjects with PKU who received dietary treatment at one of the two PKU clinics constituted the population for the study.

**Findings**

The study was designed to determine the impact on knowledge and metabolic control of a behaviorally based education program for school-age children with PKU and to determine whether there was a means of predicting which subjects would have the greatest success with the program.

The treatment and control subjects could be compared directly only for the first year of the study, before
subjects crossed over to the other group. It was surprising that there was no significant difference in change in knowledge or change in blood phenylalanine level between the two groups.

When data from experimental treatment subjects from both study periods were combined, a positive impact of the study was seen. Treatment subjects significantly increased their knowledge of PKU ($p < 0.001$) and realized no significant change (increase or decrease) in their blood phenylalanine levels. The lack of significant change in blood phenylalanine levels was not disappointing, considering that the mean baseline phenylalanine level of 9.7 mg/dl for the 68 subjects was within the recommended range of less than 10 mg/dl. When data from control subjects from both study periods were combined, there was a smaller, but still significant, increase in knowledge ($p < 0.05$) and no change in blood phenylalanine levels. Subjects’ scores indicated that when the participants were in the treatment group, their locus of control became significantly more internal, whereas no significant change in locus of control was seen when they were in the control group. This indicates that, while in the treatment group, subjects perceived to a greater extent that they had control over their own health. This may be an important step in assuming greater responsibility for the future management of their diet.

The first-year treatment group received routine care during the second year of the study; data were collected at the end of the second year to determine the long-term impact of the program on participants. For the younger grade group, there was a significant increase in the full-scale IQ score and a significant change in the Conflict subscore from the Family Environment Scale.

Thirty-seven of the 68 study participants followed through with the protocol of the program by earning points for completing the behavioral goals (sending blood samples, diet diaries, and completed work-sheets) and were labeled “successful” by earning at least 60 percent of the possible points. The significant predictors of success were blood phenylalanine (inversely related to success), verbal IQ, socioeconomic status, and age (inversely related). Therefore, younger children with better metabolic control and higher verbal IQ scores from families with higher socioeconomic status can be expected to be more successful by earning more points in the program.

Maintaining or achieving optimal metabolic control was another method of defining success (i.e., clinical success) with the program. Thirty-one of the 68 subjects finished the program with blood phenylalanine levels at or below 10 mg/dl. Predictors of clinical success included the score from the Achenbach Behavioral Checklist, the Conflict subscore from the Family Environment Scale, and the age of the subject.

It is recommended that the educational program be implemented in clinics treating subjects with PKU. The program should be presented longitudinally when possible so children can continue to build on the skills and knowledge gained at an earlier age. To achieve the greatest benefit for the amount of professional time expended, the program (which was designed for three different developmental levels) should be presented during first grade, fourth grade, and seventh grade for children of normal intelligence. This study showed that the program would be of limited benefit to patients who are in junior high school or older, who did not participate in the program when they were younger, and who have poor metabolic control.

For future study, it would be of great interest to follow the youngest patients who received the educational program in order to administer the remaining two programs as these patients matured, and to monitor knowledge, metabolic control, and degree of dietary self-management. Future programs may be more effective if a component for parents is included.
Publications

Articles, Books, and Chapters

None to date.

Abstracts


Presentations

Summary

Statement of the Problem

This study examined the prevalence and etiology of parental distress during the transition to parenthood; this has been identified as an important public health issue. Becoming a parent is a major event in the life cycle, with consequent changes in personal demands and social status. Adaptation to parenthood is important, as research findings indicate that parental distress or dysfunction can be associated with child maltreatment and maladaptive child development.

Specific prevalence rates have not been established for the varied adaptive problems during the transition to parenthood. Research on the transition to parenthood has focused primarily on women’s adaptation in the postpartum phase, particularly on postpartum depression in women. Although maternal rates of postpartum depressive symptomatology are generally estimated to be between 10 and 15 percent, rates as high as 50 percent have been reported. Considerably less attention has been given to the effect of new parenthood on men, but recent findings indicate that they may be equally affected. In addition, there is a need to document the prevalence of the varied manifestations of distress among new mothers and fathers, including anxiety, substance abuse, and marital distress.

Much of the literature on the transition to parenthood draws upon a psychoanalytic approach that excludes social factors. Some studies have taken into account the enormous transition in family roles associated with the increasing participation of women
in the labor force. However, such studies have failed to address role demands and preferences and most have excluded men. Since more than 50 percent of women with infants are currently in the labor force and 68.8 percent of first births occur to married couples, the effect of changing work and family roles on the emotional health of men and women during transition to parenthood is a salient issue that remains largely unexplored.

**Research Questions or Hypotheses**

This study focused on estimating the magnitude and distribution of distress and identifying risk and protective factors for parental distress in an ethnically diverse sample of new mothers and fathers. A theoretical framework of gender-role distress was tested during the stage of family formation. Based on study findings, approaches for primary prevention were identified for the preconception and postpartum stages of family development.

The study had six goals:
1. Test a theory of gender-role distress in men and women in the transition to parenthood and identify risk and protective factors for such distress;
2. Estimate prevalence rates of parental distress in men and women;
3. Examine the changes in the manifestation and magnitude of distress over time in men and women during the transition to parenthood;
4. Examine the effect of the partner on parental distress;
5. Examine the contribution of infant characteristics (health status, temperament) to parental distress; and
6. Suggest approaches for primary prevention (e.g., anticipatory guidance, social marketing, and social support).

**Study Design and Methods**

The conceptual basis of this study was derived from the work of Ross, Mirowsky, and Huber on marital gender-role arrangements and mental health. Within a gender-role context, the research team identified risk and protective factors for distress during the transition to parenthood. An epidemiological cohort design was used, allowing the research team to examine the influence of preparenthood factors on parental well-being. Two unique features of the study were the inclusion of the male spouse or partner and the racial and ethnic diversity of the sample.

Women and their cohabiting spouses or partners were followed prospectively for 9 months with two periods of observation: The first at the beginning of the third trimester of pregnancy, and the second at 4 months postpartum. Women and their partners were interviewed separately by telephone. The telephone interview method was selected because of the geographic dispersion of the study population, the sensitivity of some of the questions, and the need to minimize contamination from the spouse. In addition to the telephone interviews, a supplemental mail survey was used to collect parental perceptions of infant temperament, since the items regarding the infant’s behavior might require some time for reflection and/or observation. Additionally, data on maternal and neonatal health were abstracted from the birth certificate medical data base of the Illinois Department of Public Health.

Women and their partners received an incentive of $10.00 after completing the first interview and $15.00 after completing the second. The infant temperament questionnaire was included with the incentive at time 2.
Study Sample and/or Population

Women were recruited from large health maintenance organizations (HMOs) in the Chicago metropolitan area. Women were offered the opportunity to sign up for information about the study during a prenatal visit, generally during the first trimester. Nurses or nurse midwives asked all primiparous women initiating prenatal care to fill out a form requesting information about the study. All of the women who were found eligible and agreed to participate were then mailed a written consent form to be signed by each partner, a brief form with information about scheduling the telephone interview with the subject and her husband or partner, and more detailed information about the study and its objectives.

To be eligible for the study, women had to be (1) 18 years of age or older, (2) cohabiting with spouse or partner, (3) nulliparous, and (4) in the second trimester of pregnancy. Women who could not read or write English or who had previous parenting experience (adoptive, foster, or stepfamily) were excluded from the study. To be included in the study, males had to be at least 18 years of age and the spouse/partner of a female subject. Men who could not read or write English or who had previous parenting experience were excluded from the study.

Two of the HMOs were federally qualified, had large corporate contracts, and served a population diverse in social class and ethnicity. Additionally, the study recruited a smaller proportion of subjects (9.2 percent) from another large staff model HMO in the Chicago metropolitan area.

The sample population, drawn from a total of 14 different sites, was insured, and ethnically and geographically diverse. The final sample comprised 126 couples, of whom 59.1 percent were white, 24.6 percent African American, 7.9 percent Asian, 7.5 percent Hispanic, and 0.8 percent other ethnic origin.

Findings

This study supported the findings of previous research indicating that women experience significantly more depression and anxiety than men both during the pregnancy and in the postpartum period. It was also found that men experience a greater number of problems associated with alcohol consumption than do women during the postpartum period. Using a cutoff score of 16, the study found that 31.0 percent of the women and 7.1 percent of the men experienced some depressive symptomatology during the pregnancy. Using the more conservative cutoff score of 22, the study found that 14.3 percent of the women and 2.4 percent of the men could be classified as depressed. In addition, 12.7 percent of the women and 5.6 percent of the men were considered to be experiencing moderate levels of anxiety during the pregnancy.

Among both the men and the women, a reduction in the level of self-reported depression was observed from late in the second trimester to 16 weeks postpartum. Using a cutoff score of 16, 11.9 percent of the women and 6.3 percent of the men were considered to be experiencing depressive symptomatology after the birth. Using the more conservative score of 22, 1.6 percent of the women and 3.2 percent of the men could be classified as depressed. However, a significant proportion (18 percent) of the women also retrospectively reported that in the early postpartum period they had experienced five or more symptoms of major depression during 1 week or more, suggesting that depression after birth is common but generally transient.

These results suggest that while family work arrangements and gender-role attitudes may influence the men’s adjustment at 16 weeks postpartum, the women’s adjustment was not similarly influenced. Instead, the variables found to predict women’s distress were neg-
ative perceptions of the experience of parenting, quality of the couple’s relationship, and the infant’s temperament. One protective factor in women’s postpartum distress was part-time work.

Additionally, for women, anxiety was influenced by having an infant with a health condition or congenital disability, whereas depression was influenced by her partner’s feeling that the pregnancy was not intended. Although men involved with women who reported an unintended pregnancy were not significantly more likely to report postpartum distress, women involved with men who reported an unintended pregnancy had significantly higher levels of postpartum depression, state anxiety, and somatic complaints.

For women, the single largest predictor of both depression and anxiety was the level of parenting satisfaction, which not only mediated the relationships observed between the quality of the couple’s relationship, part-time work, and infant characteristics, but also exerted a strong direct effect on the level of distress. In contrast, parenting satisfaction was not a significant predictor of men’s distress. For men, distress was more likely to be influenced by a negative change in their perception of their primary relationship, liberal gender-role attitudes, and levels of distress experienced during pregnancy.

The framework presented in this study should be used to examine adaptation in the context of the birth of subsequent children. Qualitative research is needed to examine the processes underlying these findings. This is particularly important for understanding issues such as support and relationship characteristics, which typically do not have uniform methods of measurement in studies or agreed-upon causal mechanisms. There is a need for improved measures of distress and adaptation that are robust when applied in cross-cultural research. The current framework can also be used to address issues concerning children with special health needs, which may involve increased economic pressures and time demands for child care. Additionally, the mental health consequences of job characteristics and conditions need to be fully considered across social classes, with demographically diverse populations of new mothers and fathers. Finally, it is important to continue to focus on the couple or family rather than solely on the woman. A combination of theoretical approaches from family systems theory and lifespan development would provide a more informed understanding of distress and resilience among new parents.

The findings presented in this study add to the body of evidence on distress and resilience during the transition to parenthood in a relatively low-risk population. The fact that during this new stage of the life cycle a significant proportion of couples experienced at least moderate levels of distress, including relationship distress, warrants adoption of a preventive, family-centered approach (drawn from family systems theory) in prenatal and pediatric care. This approach goes beyond the focus on the developing fetus and infant, to the well-being of the woman, her partner, and their relationship to each other and to the infant. Furthermore, this approach extends to preconceptional care and male involvement in family planning, given the identified mental health consequences of unintended pregnancy found in this study.

Waiting until after the infant is born may be too late for primary prevention, given the finding that pregnancy itself may be more stressful than the initial postpartum period. The structure of such primary prevention programs would likely differ from typical office-based models of primary care. While it is important to draw men and other family members into prenatal and infant medical care services, it is not likely that current office-based settings can address the scope of primary prevention in relation to the findings of this study. The content of such programs would need to be individualized for both men and women, pop-
ulation based, and tailored for local communities to ensure acceptability and accessibility. Services such as universal home visiting and community-based programs, with the presence of male role models, would offer support and cognitive guidance to parents and would recognize the role of extended family. Media-based health promotion campaigns jointly sponsored with community-based organizations, MCH services, and managed care entities could target health service networks, religious institutions, and employers regarding the needs of new parents, including fathers.

Publications

Articles, Books, and Chapters


Abstracts

None to date.

Presentations

Effect of Breast Pumps on the Duration of Breastfeeding

Summary

Statement of the Problem

The purpose of this study targeting women and their newborn infants was to determine the effect of the content of the hospital discharge package on the duration of breastfeeding. Also evaluated was the effect of maternal attitudes toward infant feeding on the duration of breastfeeding. The project is consistent with maternal and child health goals to decrease infant morbidity and mortality, optimize conditions for survival, and improve cognitive and physical development. Under scoring the health benefits derived from breastfeeding, Healthy People 2000, published by the U.S. Department of Health and Human Services, includes objectives to increase the rate and duration of breastfeeding. At the time these objectives were established, the rate of breastfeeding had declined from a high of 62 percent in 1982 to 52 percent in 1989. Additionally, most women who initiated breastfeeding exclusively breastfed for a considerably shorter period of time than the 5–6 months recommended by the American Academy of Pediatrics and public health officials. The distribution of infant formula samples free of charge at the time mothers are discharged from the postpartum unit has frequently been cited as a contributing factor in decreased breastfeeding duration. Despite these assertions, studies of the effect of these samples on the duration of breastfeeding have been inconclusive. However, there are very few controlled studies of breastfeeding duration among women who received samples of infant formula compared
with those who received items of potential breastfeeding benefit (such as a breast pump).

Research Questions or Hypotheses

This project addresses two research hypotheses:
1. Women who receive a manual breast pump in their hospital discharge package will breastfeed for a longer period of time than will women who receive a commercial discharge package containing infant formula; and
2. Women’s attitudes concerning infant feeding can be used to predict those women most likely to be influenced by the inclusion of a breast pump in the hospital discharge package.

Study Design and Methods

The study included two components: The first was a hospital-based interview, and the second involved a series of telephone interviews. The hospital component was a randomized trial of women who elected to breastfeed their newborn infants. Women were interviewed within 48 hours postpartum. Hospital interviews addressed three content areas: Maternal infant feeding preferences, sociodemographic characteristics, and maternal attitudes concerning infant feeding. The 763 participants were randomly assigned to 1 of 3 groups. Group 1 received a specially prepared package containing a manual breast pump and breast pads. Group 2 received a commercially prepared package containing infant formula. Group 3, which served as the control, received both the breast pump package and the infant formula package. A multivariate analysis of variance (MANOVA) of the sociodemographic and attitudinal variables assessed during the hospital interview was used to test for overall differences between respondents who agreed to participate and those who decided not to participate.

The initial analyses evaluated possible biases in the sample created by loss of subjects to followup.

The second component of the study consisted of computer-assisted telephone interviews conducted at 2-week intervals until the infant was 16 weeks of age. At each 2-week telephone interview, the mothers were asked about their current method of infant feeding. The women were also asked to respond to questions addressing attitudes about infant feeding. All interviews (in the hospital setting and via computer-assisted telephone) were conducted by female interviewers specially selected and trained for this study. The dropout rates between the three groups were compared with a chi-square test of independence to determine any differences.

A one-way analysis of variance (ANOVA) was used to determine whether the inclusion of a manual breast pump in the hospital discharge package influenced the duration of exclusive breastfeeding or the duration of mixed breastfeeding and formula-feeding. Analyses concerning the effect of manual breast pumps on breastfeeding behavior involved survival analyses of changes in feeding over time. Survival analyses were conducted on the relationship between the experimental condition and changes in breastfeeding status over time. Product limit estimates of the survival curves for each dependent measure were used to graphically depict the role of the experimental condition in distinguishing time to change in breastfeeding behavior.

Survival analyses were also conducted for demographic or attitudinal variables found to predict breastfeeding duration. For the categorical predictor variables, survival curves were developed for the different groups, and comparisons were conducted with log-rank tests. For the continuous predictor variables, survival analyses were conducted with the continuous form to maximize the statistical power of the analyses. These survival curves indicated the point in time during the

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16-week period when differences in breastfeeding behavior between the groups began to emerge.

Study Sample and/or Population

All women who gave birth at a private community hospital in Cedar Rapids, IA, and who during their hospital stay elected to breastfeed were eligible to participate. Each year, approximately 2,400 infants are born at this hospital, which numbers 456 beds and 25 bassinets. Cedar Rapids, a city of 120,000, is a predominantly Caucasian community whose minority population is less than 10 percent of the total population. It is not possible to find an Iowa community with a percentage of underrepresented minority groups that reflects the demographics of the country as a whole. Therefore, African-American, Asian-American, Hispanic-American, and Native American women were underrepresented in the study. Secondary analysis of racial and ethnic considerations were unproductive because of the small numbers of subjects involved.

Findings

The first specific aim concerned the impact of the discharge package on (1) the duration of exclusive breastfeeding and (2) the duration of mixed breastfeeding and formula-feeding. Over the entire 16-week period, 17 percent of the women reported exclusive breastfeeding and 35 percent reported at least partial breastfeeding. Results of the analyses for women who reported exclusive breastfeeding did not support the hypothesis. Giving women a manual breast pump in their discharge package did not lead to a significant increase in the rate or duration of breastfeeding. The one statistically significant difference that emerged among the three treatment groups indicated that giving women infant formula samples only served to increase the duration of exclusive breastfeeding, compared with giving a manual breast pump or both a breast pump and formula. However, after sociodemographic and attitudinal variables predictive of the duration of exclusive breastfeeding were controlled for, the differences among the treatment groups disappeared.

The second specific aim of the study pertained to the effect of maternal attitudes about infant feeding on the rate and duration of breastfeeding over the 16-week followup period. Specifically, the study sought to answer the following question: After the effects of sociodemographic characteristics of the mother are accounted for, are maternal attitudes predictive of infant feeding behavior? After controlling for the influence of demographic variables, maternal attitudes assessed in the hospital were related to duration of both exclusive and partial breastfeeding. Women with more positive attitudes toward breastfeeding were more likely to breastfeed over the 16-week followup period. In addition, women who maintained positive attitudes toward breastfeeding over the followup period were less likely to change their feeding methods from breastfeeding to either partial breastfeeding or to formula-feeding.

The results of this study differ from the common perception that infant formula discharge packages have a negative effect on the duration of breastfeeding. However, it must be emphasized that significant changes have occurred in hospital discharge practices and marketing of infant formulas in the last 10 years. Most published studies on the effect of discharge packages on duration of breastfeeding were conducted at a time when mothers remained in the hospital for 3 to 4 days after the birth of the baby. Similarly, marketing of infant formulas was restricted to health professionals. In the current climate, mothers and healthy newborn infants rarely remain in the hospital longer than 36 hours. Today, most infant for-
Formula companies conduct direct consumer marketing. In addition to distributing infant formula literature and samples to obstetricians and family practitioners, many infant formula manufacturers also use direct mailing strategies to target pregnant women. Because of these changes in hospital practices and marketing strategies, it is possible that the contents of the hospital discharge packages have less influence on breastfeeding duration now than 10 years ago.

Efforts to increase the duration of breastfeeding should target those factors that influence a woman's breastfeeding attitudes both before conception and during the prenatal period. This strategy has merit because the study data confirm other published reports indicating that the vast majority of women have decided upon the initial method of infant feeding before the birth of the baby. The study also supports previous research reports that a woman's attitudes toward infant feeding are the strongest predictor of breastfeeding intent and duration. The study also showed that the stronger a woman’s attitudes toward breastfeeding, the longer the duration of breastfeeding. Because of the critical role of maternal attitudes in the initiation and duration of breastfeeding, it is important that all maternal–fetal units in health settings maintain an environment that is supportive of breastfeeding. However, simply withholding infant formula discharge packages may not be sufficient to increase the duration of breastfeeding. To achieve the Healthy People 2000 breastfeeding objectives, efforts to influence positive attitudes toward breastfeeding must be introduced as early as possible.

Publications

Articles, Books, and Chapters

Dungy CI, Losch ME, Russell D, Romitti P, Dusdieker LB. 1994. Iowa Infant Feeding Attitude Scale. [Copyright pending].


Abstracts


Presentations


Iron Absorption in Infants

Summary

Statement of the Problem

Iron deficiency is the leading nutritional deficiency disorder of infants and preschool children in the United States and in most other countries. This problem is particularly important because individuals with iron deficiency are at risk for developing iron deficiency anemia, a condition associated with at least temporary (and perhaps permanent) interference with cognitive development. Iron deficiency is most prevalent among low-income individuals, and its prevention is therefore directly relevant to the goals of the Title V MCH Program.

Research Questions or Hypotheses

This research was designed to address three questions that are important to the development of strategies for prevention of iron deficiency:

Question 1: Is there a significant difference in the absorption of iron (mg/day) from infant formulas fortified at levels of 12 mg per liter (mg/L) compared to those fortified at 8 mg/L? The single most reliable way of preventing iron deficiency in infancy is the feeding of iron-fortified formulas. Currently, such formulas are fortified at a level of 12 mg/L (standard formula concentration of 667 kcal/L) in the United States and at 6 to 8 mg/L in western Europe. Adverse effects of iron on other minerals are most likely to occur at high levels of iron intake. The upper limit for iron in infant formulas as currently stipulated by the U.S. Food and Drug Administration is 3 mg/100 kcal...
(19 mg/L at standard dilution), a value set to accommodate some “overage” by the manufacturers, especially in formulas based on soy protein. If the extent of iron absorption is not significantly greater from a formula with iron content of 12 mg/L than from a similar formula with iron content of 8 mg/L, it would seem desirable to decrease the level of iron fortification of infant formulas in the United States to 8 mg/L, and the allowable upper limit might be decreased appreciably.

Question 2: What is the extent of non-heme iron absorption from selected iron-fortified items: (a) Rice cereal fortified with ferrous fumarate, (b) iron-fortified strained beef and vegetables, and (c) iron-fortified strained beef? For breastfed infants and for formula-fed infants receiving formulas with low iron content (preferred by some physicians), iron can be supplied as a medicinal iron supplement or as an iron-rich food. With the exception of iron-fortified infant cereals, nearly all foods commonly fed to infants are low in iron content. Infant cereals have traditionally been fortified with iron, and such fortification has great appeal. However, the electrolytic iron of intermediate particle size that is the most common source of added iron in infant cereals is probably of low bioavailability, and a field study using a cereal fortified with this iron source did not demonstrate that regular feeding of the cereal was a reliable means of preventing iron deficiency in infants.

Thus, it would be desirable to find another source of iron that does not produce oxidative rancidity in the cereal (an important attribute of the currently used electrolytic iron powder) but that is of higher bioavailability. Ferrous fumarate, a product that is insoluble in water (and therefore unlikely to produce oxidative rancidity) but soluble in dilute acid (as in the stomach) seemed an attractive choice for study. Because meat, fish, and poultry are known to contain a factor (“meat factor”) that enhances absorption of non-heme iron, iron fortification of meat-containing products seemed logical.

Question 3: What is the extent of iron absorption from an iron-fortified vegetable product with a greater concentration of meat protein than any commercially available meat and vegetable combination? Although a high level of erythrocyte incorporation of iron from iron-fortified strained beef was demonstrated, strained meats have never been popular as infant foods. Meat and vegetable combinations have much higher levels of acceptance. Iron absorption was studied from two vegetable-beef mixtures in which the beef was provided as a beef protein concentrate. The beef protein content of these products was greater than that of commercially available products.

Study Design and Methods

Erythrocyte incorporation of the stable isotope $^{58}\text{Fe}$ was used as a surrogate for iron absorption. On 3 consecutive days, the iron-fortified food to be investigated was fed to normal infants under tightly standardized conditions. Each test feeding included a small amount of added $^{58}\text{Fe}$ as a label. It was assumed that the percentage of erythrocyte incorporation of the $^{58}\text{Fe}$ label was the same as that of the non-heme iron of the feeding (as is traditional in studies using isotopes, whether radioisotopes or stable isotopes).

Three samples of capillary blood were obtained from each infant: The first sample was obtained before the feeding of the $^{58}\text{Fe}$-labeled test meals; the second, 14 days after consumption of the first of the test meals; and the third, 28 days after consumption of the first of the test meals. Hemoglobin, serum ferritin, and the $^{58}\text{Fe}/^{57}\text{Fe}$ ratio were determined. To decrease variability, data were not included in the case of an infant whose serum ferritin concentration in the first two blood samples averaged less than 20 µg/L.

Question 1: From 112 to 196 days of age, one group
was fed a formula whose iron content (actual analysis) was approximately 12 mg/L and the other group was fed a similar formula whose iron content was 8 mg/L. At age 154 days, a precisely weighed amount (about 1 mg) of a solution of $^{58}$Fe-enriched ferrous sulfate (providing approximately 0.4 mg of iron and 0.3 mg of $^{58}$Fe) was added to 0.8 liters of formula and consumed by the infant during the first two or three feedings of the day. The quantity of additional formula consumed during the day was determined by weighing the containers. This regimen was repeated at 155 and 156 days of age, thus providing a total of 0.9 mg of $^{58}$Fe during the 3 test days. Multiplying the percentage of absorption of the $^{58}$Fe label for each infant by the total quantity of iron consumed during the 3 days on which the test feedings were given, the quantity of iron incorporated into erythrocytes was calculated. Successive cohorts of 10 infants were enrolled; the first cohort was fed formula whose iron content was approximately 12 mg/L (formula 12), the second was fed formula whose iron content was approximately 8 mg/L (formula 8), and the iron content of the feeding was alternated in subsequent cohorts.

Question 2: Three iron-fortified foods were studied: (a) Rice cereal fortified with ferrous fumarate, (b) iron-fortified strained beef with vegetables, and (c) iron-fortified strained beef. From age 112 days until 4 days after the day on which the first test meal was fed, the infants were fed a milk-based formula whose iron content was approximately 2 mg/L. At 140 days of age, a food similar to that of the test meal was introduced and fed at least once daily. At ages 154, 155, and 156 days, each infant was admitted to the Lora N. Thomas Metabolic Unit and was fed the test meal enriched with $^{58}$Fe under direct supervision. The quantity of iron incorporated into erythrocytes from the three test meals was calculated by multiplying the percentage of incorporation of administered $^{58}$Fe from the test meals by the total iron content of the three test meals. Results were expressed as mean erythrocyte incorporation per test meal.

Rice cereal fortified with ferrous fumarate was prepared by an infant food manufacturer and was fed to the infants daily for 2 weeks before feeding the test meals. To each test meal was added a small amount of $^{58}$Fe-enriched ferrous fumarate. A strained beef and vegetable product fortified with ferrous sulfate was prepared by an infant food manufacturer and was fed to the infants daily for 2 weeks before feeding the test meals. To each test meal was added a small amount of $^{58}$Fe-enriched ferrous sulfate. A commercially available product containing strained beef not fortified with iron was fed for 2 weeks before feeding the test meals. To each test meal was added approximately 2.7 mg of iron from ferrous sulfate, including approximately 0.8 mg of $^{58}$Fe.

Question 3: To determine the extent of iron absorption from an iron-fortified vegetable product with a greater concentration of meat protein than any commercially available meat and vegetable combination, the research team mixed strained vegetables with AMP 1200, a beef muscle protein concentrate (90 percent protein). Two levels of beef protein concentrate were studied. A commercially available vegetable mixture (the same mixture included in the strained beef and vegetable mixture used in the study designed to answer question 2) was fed for 2 weeks before feeding the test meals. In the first study, the test meals consisted of 5 grams of AMP 1200, 35 grams of strained vegetables, and approximately 3 mg of $^{58}$Fe-enriched ferrous sulfate in the 40-gram test meal (meat protein concentration of more than 11 grams per 100-gram product). In the second study, the test meals consisted of 7 grams of AMP 1200, 33 grams of strained vegetables and approximately 3 mg of $^{58}$Fe-enriched ferrous sulfate (meat protein concentration of nearly 16 grams per 100-gram product).
For the first 20 infants studied in question 1 and for all of the infants studied in questions 2 and 3, the $^{58}\text{Fe}/^{57}\text{Fe}$ ratio was determined by inductively coupled mass spectrometry (ICP/MS) that used the Elan 250 ICP/MS system. These results were calculated as mass isotope ratios ($\text{MIR} \frac{^{58}\text{Fe}}{^{57}\text{Fe}}$). The $^{58}\text{Fe}/^{57}\text{Fe}$ ratio in blood samples from the remaining infants studied in question 1 were also determined by ICP/MS but with the use of different instrumentation and some refinements in sample processing. The results of these determinations are reported as atom isotope ratios (IR) rather than as mass isotope ratios.

**Study Sample and/or Population**

Normal term infants were recruited at 112 days of age; all infants had been fed an iron-fortified formula (label claim for iron: 12 mg/L) from 8 to 112 days of age. Equal numbers of male and female infants were included.

**Findings**

In interpreting the results of the first study component (question 1), it is important to emphasize that erythrocyte incorporation of iron from test meals is a surrogate for but not a direct measure of iron absorption. The quantity of iron incorporated into erythrocytes 14 and 42 days after consumption of the test meals is equal to or less than (never more than) the quantity absorbed. Is there a significant difference in the absorption of iron (mg/day) from infant formulas providing 12 mg of iron per liter and formulas providing 8 mg of iron per liter was nonexistent or minimal, and that fortification of infant formulas with iron to a level of 8 mg/L is adequate.

The research team concluded that the difference in absorption of iron (as reflected by erythrocyte incorporation of iron) from formulas providing 12 mg of iron per liter and formulas providing 8 mg of iron per liter was nonexistent or minimal, and that fortification of infant formulas with iron to a level of 8 mg/L is adequate.

The second study component (question 2) examined the extent of non-heme iron absorption from three selected iron-fortified items: (a) Rice cereal fortified with ferrous fumarate, (b) iron-fortified strained beef and vegetables, and (c) iron-fortified strained beef. Twelve infants completed the study ingesting rice cereal fortified with ferrous fumarate. The mean iron intake from a test feeding was 3.36 mg. (A baseline serum value for $\text{MIR} \frac{^{58}\text{Fe}}{^{57}\text{Fe}}$ was not obtained for two infants, and results for these infants were calculated with the assumed baseline value of 0.1469, the mean baseline value for the other infants). The arithmetic mean incorporation of iron at 168 days (N = 10) was 3.2 percent of intake (geometric mean, 2.7 percent of intake), and the arithmetic mean incorporation of iron at 196 days (N = 11) was 2.8 percent (geometric mean, 2.4 percent of intake). At the current level of fortification of dry infant cereals (47.5 mg/100 g), a 70-gram feeding would provide slightly more than 3 mg of iron, and absorption of 3 percent would
be less than 0.1 mg/feeding. The research team concluded that this is too small a proportion of the estimated requirement for absorbed iron (0.55 to 0.77 mg/d) to merit promotion of ferrous fumarate as a fortifier for dry infant cereal.

In the third study component (question 3), 11 infants were fed with the iron-fortified strained beef and vegetables, but data from two were excluded because of low serum concentrations of ferritin. (A baseline value for MIR58/57 was not obtained for one subject, and results for this infant were calculated with the mean baseline for the other infants.) Arithmetic mean incorporation of iron at 168 days of age (N = 7) was 3.8 percent of intake, and at 196 days of age (N = 7) was 5.4 percent of intake. If a similar strained beef and vegetable product were fortified with ferrous sulfate at the level of 6 mg of iron per 100 grams of product (i.e., the level currently used in fortification of wet-pack cereal and fruit products), erythrocyte incorporation of 4 percent of a 70-gram serving would amount to 0.17 mg of iron (approximately 25 to 30 percent of the estimated requirement for absorbed iron) and erythrocyte incorporation of 5 percent would amount to 0.21 mg (approximately 0.28 to 0.38 percent of the estimated requirement for absorbed iron). The research team concluded that iron fortification of a commercially produced beef and vegetable product is worth considering.

Nine infants were studied by using the iron-fortified strained beef. The protein concentration of the product was 14.4 grams per 100 grams of product. Arithmetic mean erythrocyte incorporation of non-heme iron at 168 days of age (N = 8) was 10.0 percent of intake, and at 196 days of age (N = 8) was 14.6 percent of intake. Although commercially available strained meats have never been popular, it is evident that consumption of even 50 grams per day of a product fortified at a level of 6 mg of iron per 100 grams would result in erythrocyte incorporation of about 0.3 mg/day (approximately 40 to 55 percent of the estimated requirement for absorbed iron). The research team concluded that iron fortification of a strained beef product should be considered.

The extent of iron absorption from two iron-fortified vegetable products with a relatively high concentration of meat protein was tested in 10 infants. Test meals that included 5 grams of AMP 1200 with 35 grams of strained vegetables were fed to the infants. Data were excluded for one infant because of low serum ferritin concentration. Arithmetic mean erythrocyte incorporation of iron at 168 days of age (N = 8) was 3.1 percent of intake, and at 196 days of age (N = 8) was 3.1 percent of intake. Eleven infants were fed test meals that included 7 grams of AMP 1200 with 33 grams of strained vegetables. Arithmetic mean erythrocyte incorporation of iron at 168 days of age (N = 11) was 4.2 percent of intake, and at 196 days of age (N = 11) was 4.1 percent of intake.

The results of these two studies are surprising. Although the concentration of meat protein in the test meal with 5 grams of AMP 1200 and 33 grams of strained vegetables was greater than that of the strained beef and vegetable product, erythrocyte incorporation of iron was not greater from the product containing AMP 1200. The concentration of meat protein in the test meal with 7 grams of AMP 1200 was greater than that of the strained beef product, but erythrocyte incorporation of iron from the product containing AMP 1200 was much less than from the strained beef product. Because the beef protein concentrate failed to enhance iron absorption to the same extent as the beef protein, it seems possible that the “meat factor” either was inactivated during the course of processing the beef protein concentrate or does not reside in the protein fraction.
Publications

Articles, Books, and Chapters


Abstracts

None to date.

Presentations

None to date.
Breastfeeding Promotion Strategies for Urban WIC Women

Summary

Statement of the Problem

Breastfeeding promotion programs have emphasized the delivery of a consistent educational message and effective peer counseling. Although studies of populations receiving services through the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) have evaluated the effects of prenatal and postnatal breastfeeding programs on the decision to breastfeed, few have evaluated the effects of these programs on intention, initiation, and duration or variation in breastfeeding practice. Little was known about the effects of promotional programs among the WIC population and WIC’s influence on breastfeeding decisions or compliance with recommended practices. Moreover, studies about the effects of breastfeeding promotion on actual practice rarely controlled for demographic characteristics. Testing these factors would (1) lead to more precise estimates of the effects of breastfeeding promotion on practice, and (2) improve understanding of the effect of these interventions in populations of interest.

At the beginning of this study, the breastfeeding rate among Baltimore City WIC enrollees was 4.1 percent. The breastfeeding rate in the remainder of the State averaged 14.9 percent. The estimated national rate at hospital discharge was approximately 39 percent. A variety of efforts had been initiated to improve the low rates of breastfeeding initiation, with limited or no success. The use of peer counselors and/or the use of videotapes emphasizing the impor-
Importance of breastfeeding within a clinic setting were considered potentially useful in influencing a woman’s intention to initiate and continue breastfeeding.

**Research Questions or Hypotheses**

The objective of this study was to test the effectiveness of peer counseling and promotional videotapes singly or in combination in increasing breastfeeding rates among inner-city, African-American women enrolled in the Baltimore City WIC program. The research team hypothesized that the effects of the interventions would be additive so that the largest difference in breastfeeding rates would occur in the WIC clinic population receiving both interventions, when compared with the control group.

Specifically, the research team hypothesized the following:

1. A 10-percent difference would be seen in the rate of breastfeeding initiation between WIC participants exposed to the prenatal videotape and similar WIC controls;
2. A 10-percent difference would be seen in the rates of breastfeeding initiation between WIC participants receiving peer counseling (PC) and similar WIC controls;
3. For a combined effect of videotape and peer counseling interventions, a 20-percent difference would be seen in rates of breastfeeding initiation between WIC women receiving both interventions and similar WIC controls; and
4. A 10-percent difference in breastfeeding continuation would be seen between WIC women receiving peer counseling and those receiving either videotape or routine WIC health education (controls) at 16 weeks’ postpartum.

**Study Design and Methods**

This study examined whether differences in attitudes toward the behavior of breastfeeding, subjective norms, and attitude toward breastfeeding resulted in differences in breastfeeding rates between the WIC participants receiving the prenatal videotape and WIC counseling and the WIC controls. Differences in breastfeeding initiation rates between WIC participants receiving the peer counseling and similar WIC controls were examined to see whether identified differences, if any, were associated with social learning and behavioral control, and, to a lesser extent, with attitudes and behaviors toward breastfeeding. Also tested were differences in rates of breastfeeding continuation between WIC women receiving the peer counseling and similar WIC controls, and the differences (if any) in social learning and behavioral control.

The model assumed that behavioral intention is the immediate determinant of behavior and that all other factors that influence behavior are mediated through intention. The strength of a person’s intention to perform a specific behavior is a function of two factors: Attitude toward the behavior, and the influence of the social environment or general objective norms on the behavior. Social norms are determined by a person’s normative belief about what salient others think they should do and by the individual’s motivation to comply with those persons’ wishes.

The study took place within the Baltimore City WIC clinics administered by The Johns Hopkins University. The four WIC clinic study sites were matched for ethnicity and previous rates of breastfeeding, based on data from WIC certification records. The implementation of the intervention by clinic minimized
crossover and contamination between groups that would be likely to occur if interventions were randomized by individual.

Following is a brief description of the four WIC clinic sites selected:

1. Videotape intervention: A breastfeeding motivational videotape consisting of a series of eight trigger vignettes, 2–5 minutes in length, addressed the benefits and major barriers to breastfeeding. The tape was formatted to play so that it could be used in a waiting area without staff supervision. Posters corresponding with the video were displayed in the clinic areas and at other relevant sites. A discussion with the service provider following the videotape was encouraged, and printed information reinforcing the video message was distributed.

2. Peer counseling intervention: The peer counselor met with every client, assessed each woman’s attitudes toward breastfeeding and formula feeding, corrected any misconceptions about breastfeeding or formula feeding, distributed/reviewed handouts and pamphlets, and informed each woman about discussion sessions with other pregnant mothers who were thinking about breastfeeding. The counselor was also available at contact sites and for home visiting. Study personnel visited the assigned delivery suites, reviewed delivery logs, and documented infant feeding selection. Personnel visited breastfeeding women and delivered a breastfeeding promotional gift package, confirmed followup plans, and gave the mother a contact number to call if the mother had any problems or questions.

3. Combined peer counseling and videotape intervention: This intervention combined all of the components of each of the two interventions described above. The WIC provider and peer counselor coordinated their efforts through the use of the breastfeeding promotion record so that one could reinforce and extend areas not covered by the other.

4. Control: The control clinic provided all ongoing WIC services, all nutrition education, and breastfeeding promotion activities as required by Federal and State regulations. Services provided in the control clinic were indistinguishable from any other WIC clinic, but did not include any peer counseling or breastfeeding videotapes.

The formative component of the project investigated the knowledge, beliefs, and reported practices of WIC providers and clients in Baltimore on issues of breastfeeding and infant feeding. During individual interviews that used a photo projection technique, the respondents discussed advantages and disadvantages of various infant feeding choices. Topics raised and discussed by the respondents included the mother’s age; the mother’s nutrition; the influence of tobacco, alcohol, and drugs on her choice; career or work issues; time elements; self-concept; myths about breastfeeding in public; male influences; and others’ influences on the woman’s decision. In addition, focus group discussions were held with clients and providers after they had viewed the Best Start breastfeeding promotion videotape. Issues that emerged from these discussions included conversations about which segments were appealing and why; which segments the viewers did not like or felt skeptical about; and suggestions for improving the video and its use with WIC clients in promoting breastfeeding. The formative component not only provided information on knowledge, attitudes, beliefs, and behavior but also provided data to develop and modify the study instruments to more closely parallel perceptions within the community.

This study employed a two-by-two factorial design to assess the single and combined effects of the two different clinic-based breastfeeding promotion programs designed for use in the WIC population. The
research team prospectively followed a cohort of 548 mother-infant pairs from their entry into prenatal care before the 24th week of pregnancy until their 16th week postpartum. If the woman was eligible and consented to participate, the demographics questionnaire and the Knowledge, Attitudes, and Beliefs Questionnaire were administered. Study exclusions were (1) contraindications to breastfeeding (e.g., women with tuberculosis, HIV infection, or dependent use of illicit drugs); (2) delivery of a preterm or low birthweight singleton infant, twins, or an infant with major congenital disabilities.

Each woman received a modest payment of $5.00 for participating in the study and was instructed about future interviews. Followup telephone interviews were carried out. The telephone interviewer was an experienced individual who has worked on similar research projects in this community for almost 20 years. She was empathetic, nonjudgmental, and very supportive. She maintained a rapport with each client by being available at any hour of any day to answer questions, provide additional information, and refer the client if appropriate. Recruitment of study subjects was monitored by the research team very closely on a weekly basis. Adjustments were made with respect to deployment of personnel, interviewers, and study clinic staff to assure scheduled enrollment.

Women were followed from the time they entered prenatal care and enrolled in WIC (at or before 24 weeks’ gestation) through 16 weeks postpartum. At enrollment and at 34 weeks’ gestation, women were interviewed concerning their infant feeding intentions; at 7–10 days postpartum, they were reinterviewed to determine whether they had ever put the baby to the breast (initiation), whether they continued to breastfeed at 7–10 days (adoption), and whether they were still breastfeeding at 8–16 weeks (duration).

Study Sample and/or Population

Women were recruited into the study from the four WIC clinic sites in Baltimore City that were matched on breastfeeding rates and ethnicity. The clinics were administered through The Johns Hopkins University WIC Program. At the inception of the study, the clinics had rates of breastfeeding comparable to those of Baltimore City (4.1 percent). Although the WIC clinic populations in Baltimore City do vary, the clinics sites selected were similar in ethnicity, with the African-American population ranging from 90.4 to 96.1 percent, and the breastfeeding rates ranging from 2.0 to 5.9 percent.

Both primiparous and multiparous women ages 15–45 were included in the study. Verbal informed consent was obtained prior to each interview, eligibility determined, and signed consent obtained consistent with the approved materials from The Johns Hopkins University Committee on Human Volunteers.

Findings

Maternal intention to breastfeed at the time of enrollment in WIC had a powerful influence on breastfeeding initiation and adoption. Enrollment in the study did not influence the decision to breastfeed during the prenatal period as measured at 34 weeks prenatally and upon hospital admission. Peer counseling in the WIC clinic positively influenced the initiation rate. Video intervention alone and in combination with peer counseling had a weak effect, and after adjustment for intention to breastfeed, showed no significant effect. Thus, peer counseling activities in WIC may have limited ability to influence breastfeeding; motivational videotapes showed no significant influence primarily because decisions on how to feed an infant in this study population were formed prior to
enrollment in WIC and were strongly held throughout the prenatal period.

Specific hospital practices such as providing formula to the mother and increased length of separation of mother and baby appear to negatively influence decisions to initiate and adopt breastfeeding, whereas providing instruction on infant feeding appears to positively influence such decisions on breastfeeding, regardless of maternal infant feeding intention. These findings highlight the crucial role played by hospital policy and personnel in efforts to promote and sustain breastfeeding.

Almost 80 percent of the women who intended to breastfeed their infants at prenatal enrollment did so. Breastfeeding was initiated by 49 percent, 60 percent, and 55 percent of the women in the videotape, peer counseling, and combined intervention study clinics, respectively, compared with 27 percent of women in the control clinic. However, these crude differences were not significant when intention to breastfeed was entered into the analytical model.

The data indicate that the number of breastfeeding mothers dropped by almost one-half in each of the study and control clinics by 7-10 days postpartum. The mean duration of breastfeeding in weeks in the control, video, peer counseling, and combined clinic was 1.1 (+2.8), 4.2 (+6.4), 5.0 (+6.9), and 4.5 (+6.3), respectively. A significant effect on duration of breastfeeding \( (p < .001) \) was identified for each of the three intervention clinics.

Data indicated that women in this population experienced a number of impediments and problems as they attempted to establish breastfeeding, and often abandoned breastfeeding during the first week of an infant’s life, even when they reported an intention to breastfeed. When a number of factors in a multivariate model of women who ever initiated breastfeeding were controlled for, the factors that predicted breastfeeding at 1 week included (1) breastfeeding intention before 24 weeks’ gestation, (2) receipt of free infant formula in hospital, and (3) maternal leave policy. Qualitative data indicated that decisions about infant feeding in this study population were based on a complex array of perceived advantages and barriers. The barriers to breastfeeding in the population were most often cited as “time” (due to work/career or other demands on time), uneasiness with breastfeeding in public, lack of knowledge of alternatives to breastfeeding in public, and pain.

Clients cited the importance of significant support persons in influencing their infant feeding decision. The significant person was infrequently the partner, more often a female relative, female friend, or health provider. Given the short amount of time available to the WIC providers to counsel clients about infant feeding choices, the WIC provider could assist clients interested in breastfeeding in identifying a support person. Data indicated that the infant feeding decision could best be made by each woman through discussions with a person who has time, interest in the client, and knowledge about breastfeeding. WIC can promote breastfeeding among clients by raising the issue, giving clients an opportunity to openly consider their choice, and helping each client identify a resource person for the information and support she needs.

In this population, many more women intended to breastfeed, initiated breastfeeding, and in fact, adopted breastfeeding than expected based on statistics gathered by WIC, indicating that WIC-based statistics may underestimate breastfeeding practices. Overall WIC-based statistics do indicate an increase in breastfeeding among African-American women, suggesting that in addition to any program effect, a secular trend may be occurring as a result of factors within and outside of WIC that are influencing breastfeeding rates in this urban African-American community. The results suggest that public health
interventions should capitalize on the high level of interest in breastfeeding and the relatively high initiation rates by retargeting programs and policies to support women who indicate an intention to breastfeed.

Publications

Articles, Books, and Chapters


Abstracts


Presentations


Bronner Y. 1994. Breastfeeding peer counselors: Their role in breastfeeding promotion. Presented at the International Lactation Consultant Association meeting, Atlanta, GA.

Bronner Y. 1993. Breastfeeding promotion from the peer counselor’s and mother’s perspective. Presented at the Maryland Breastfeeding Promotion Project, Baltimore, MD.


initiation. Presented at the American Public Health Association Annual Meeting, Washington, DC.


Paige DM. 1994. Breastfeeding patterns and the determinants of initiation and duration of breastfeeding. Presented at Advances in Pediatric Nutrition, Division of Gastroenterology and Nutrition, Department of Pediatrics, The Johns Hopkins University School of Medicine, Baltimore, MD.


Russ J. 1993. Lessons learned from ethnography regarding desired qualities of a peer counselor: Use of this information in selection and training of peer counselors in the WIC breastfeeding promotion project. Presented at the Maryland Breastfeeding Promotion Project, Baltimore, MD.


Evaluation of the Guidelines for Maternal Transport

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Year 2 $229,654 $251,856
Year 3 $179,733 $178,644
Year 4 no cost extension
Year 5 no cost extension
Year 6

Year 2000 Objectives

Study Design
Quasi-experimental

Time Design
Longitudinal

Care Emphasis
Noninterventional

Population Focus
Pregnant women, Neonates, Infants

Racial/ Ethnic Focus
None

Summary

Statement of the Problem

As maternal transport has become widespread, the need to establish guidelines within specific areas, apart from the transport of the woman in premature labor, has become increasingly important. Yet little is known about the full impact that could be achieved through maternal transport, particularly with regard to the postpartum health status of mothers with complications or the health status of their newborns who were not transported to a facility with the necessary capabilities.

The importance of this research stems from its use in a sizable geographic area of a large population-based sample of all pregnant women who had complications that might lead to maternal transport. The importance of this research stems from the use of a large population-based sample of all pregnant women in a large geographic area who had complications that might lead to maternal transport. Previous population-based studies have been constrained by sample size and limited to transported mothers who delivered very-low-birthweight infants. The results of those studies are mixed, partly because of potential selection bias in the regions where the studies were conducted. The evaluation of the guidelines for maternal transport represents a significant contribution of this research.
**Research Questions or Hypotheses**

The purpose of this study was to evaluate the guidelines for the transfer of high-risk mothers from community hospitals to perinatal centers. The study used data from a sample of women admitted for labor and delivery in 1984 and 1985 in the 15 hospitals that were part of the Southern New Jersey Perinatal Cooperative (SNJPC).

Two major hypotheses were evaluated:
1. The transfer of pregnant women to a tertiary center conforms to the recommended guidelines for maternal transport; and
2. The transfer of pregnant women to a tertiary center is optimal when their newborns are expected to develop complications requiring intensive care, because the technology needed to manage high-risk infants is available immediately after birth.

**Study Design and Methods**

The project was designed as a nonconcurrent prospective epidemiologic study. Using medical records data, the study followed participating women from the prenatal period to delivery, and their newborns from birth to hospital discharge or death. By design, the study sample was restricted to women at greatest risk for needing transport. The sample included all women (1) who were admitted for labor and delivery at one of the 15 hospitals providing perinatal care in the 7 southernmost counties in New Jersey at the time of the study, and (2) who had complications of pregnancy that were likely to lead to transport. The sample included all women (1) who were admitted for labor and delivery at one of the 15 hospitals providing perinatal care in the 7 southernmost counties in New Jersey at the time of the study, and (2) who had complications of pregnancy that were likely to lead to transport. The study sample and/or population.

A total of 278 women were identified as being transported, based on the above hospital designations and time periods. Of these 278 women, 98 were transported from Level I hospitals, 145 from Level II hospitals, and 29 from Level IIA or Level III hospitals; for 6 of the women, no information was available on the referring hospital. Data on labor and delivery were available for a total of 239 women (86 percent of...
the eligible sample of known maternal transports. Of these, 82 of the women (84 percent) were transported from Level I hospitals, 130 women (90 percent) from Level II hospitals, and 27 women (93 percent) from Level III/IIA hospitals. A total of 1,554 nontransported women were identified as eligible for the study sample. Of these, 307 delivered at Level I hospitals, 658 at Level II hospitals, and 589 at Level III/IIA hospitals (413 at Level III and 176 at Level IIA). Data from medical records were available for 1,445 of these women (93 percent).

The sample for the analysis of the likelihood of maternal transport and for the evaluation of the effect of transport on postpartum morbidity in the mother was restricted to women who delivered a potentially viable fetus. Excluded from the sample analysis were women whose pregnancy resulted in stillbirth (N = 162), whose fetus was born before 20 weeks (N = 1), or whose infant weighed less than 500 grams at birth (N = 9). For women with multiple gestations, the research team selected at random one of the multiple births to yield only one record for the mother. The resulting sample for analysis included 1,512 women, of whom 228 (15.1 percent) were maternal transports. The analysis of the data on newborns included 1,422 mothers for whom newborn data were obtained (94 percent of the 1,512 mothers with maternal data).

The primary data source for the study consisted of the medical records from the 15 SNJPC hospitals to which the pregnant women were initially admitted and the Pennsylvania or Delaware hospitals to which they were transported. Data were abstracted from the records of mothers and their babies for all study hospitals to which they were admitted during the intrapartum, postpartum, and neonatal periods. The abstracted data included demographic information about the mother, diagnoses and signs and symptoms of the most commonly occurring complications in the mother and newborn, and major procedures or therapeutic treatment given to the mother or newborn.

The study focused on both the process and outcome of transport. The dependent variable included in the study of the process of transport was the likelihood of transport. The transport variable became an independent variable in the study of the appropriateness of transport. The dependent variables in the study of the appropriateness of maternal transport included both maternal and newborn outcomes. Maternal outcomes were the length of maternal postpartum hospital stay and the presence or absence of significant postpartum morbidity and postpartum infection. Newborn outcomes included 5-minute Apgar scores, resuscitation at birth, length of nursery stay, presence and severity of respiratory distress syndrome, confirmed neonatal sepsis, seizures, intraventricular hemorrhage, necrotizing enterocolitis, and early neonatal mortality.

Among the independent variables, maternal obstetric and medical complications included premature rupture of membranes, preterm labor, maternal hypertension, multiple gestation, third trimester bleeding, diabetes, heart disease, other chronic disease, isoimmunization, and maternal infection. The research team defined (when feasible) varying levels of severity of these complications. Other independent variables included in the analysis were cesarean delivery and demographic and prenatal care variables.

The first step in the analysis involved investigation of the variables associated with maternal transport. In this step, the sample for analysis included all maternal transports from Level I, Level II, and Level III/IIA hospitals and all nontransported women who delivered at these hospitals. The analysis was performed separately for each level of hospital. A bivariate association between the likelihood of transport and maternal obstetric complications, medical complications, maternal demographic variables, and the hospital and
prenatal care variables was performed first, followed by a multiple logistic regression. The variables defining maternal complications and their severity, gestational age, maternal demographic variables, and prenatal care use were included in the regression analysis. This analysis was performed separately for Level I and Level II hospitals, and the results of the regressions were compared to evaluate possible interactions of the effect of the variables on transport rates by level of hospital.

The first step in the analysis of the impact of transport was a bivariate analysis in which maternal and newborn outcomes were compared for transported and nontransported women, followed by a multivariate analysis. Logistic regression was used for the dichotomous dependent variables and multiple linear regression for the continuous dependent variables (the same approach as in the likelihood of transport). The regression coefficients were compared for the Level I and Level II hospitals, with primary focus on the coefficient for maternal transport.

The final step in the analysis was to evaluate each case, using a Maternal Transport Index (MTI). In this analysis, women were assigned a value of the MTI based on the complications they experienced, and the MTI was related to the odds of mortality in the newborn.

**Findings**

In general, the study findings support the hypotheses that the predictors of transport conform to the ACOG guidelines for transport and that differences in transport rates between Level I and Level II hospitals are greatest for women with severe complications. The findings also suggest that improvements in maternal outcomes may be gained with transport of mothers at risk for major complications. For the most part, however, any improvements in newborn outcomes occurred only with regard to 5-minute Apgar scores. Transport did not appear to increase the occurrence of problems in the newborn.

Women who presented at the hospital with early gestation, who had preeclampsia, acute bleeding, incompetent cervix (premature dilation of the cervix), chorioamnionitis, and multiple pregnancies were more likely to be transported from Level I or Level II hospitals than women without these complications. All of these conditions were included in the guidelines. On the other hand, intrauterine growth retardation, diabetes, and other chronic illnesses were not related to maternal transport. The most interesting findings with regard to the predictors of maternal transport involved the effects of the source of prenatal care. Women who received prenatal care from private doctors were less likely to be transported from Level I or Level II hospitals than women who had other sources of prenatal care, independent of their complications. This effect was stronger at Level I than at Level II hospitals.

None of the measures of maternal outcomes were related to transport status with the exception of the mother’s length of hospital stay in Level II hospitals. Here, the shorter stays of transported women remained significant even with adjustment for maternal complications, length of pregnancy, and cesarean delivery.

Maternal transport had a positive effect on 5-minute Apgar scores. Resuscitation scores were significantly higher among transported babies, independent of gestational age, suggesting that the technology needed for the newborns of high-risk mothers was made available to them following maternal transport. However, the positive effect of maternal transport did not extend past the time of birth, in that mortality and morbidity rates were no better for the infants of transported mothers and were worse only for infants with respiratory distress syndrome whose mothers had been transported from Level I hospitals.

The findings that may have the most important
policy implications address the selective retention of private patients at Level I and Level II hospitals. In order for a regionalized system of care to work effectively, there must be cooperation and communication among providers. It is surprising that in an area with a formal cooperative of hospitals working together for the health of the mother and the newborn, such selective behavior was noted.

A second implication of the findings involves the positive effect of transport on maternal length of hospital stay and 5-minute Apgar scores. These findings suggest that the availability of immediate intensive postpartum care can improve both the mother’s and the newborn’s outcomes. The fact that the higher-risk mothers were transported and that they had similar outcomes to nontransported mothers also supports the continued need to utilize the resources of tertiary centers in an area.

This population-based study needs to be repeated in a more contemporary population. The issues of managed care and selective retention of patients may be even more pressing today than in 1984 and 1985. It is difficult to tell from the results whether this retention may have a negative effect on the mother or newborn.

Publications

Articles, Books, and Chapters

Abstracts
None to date.

Presentations
None to date.
Young Adult Users of Services for Children with Special Health Care Needs: Service Utilization, Psychological Status, and Developmental Tasks

Summary

Statement of the Problem

Older adolescents and young adults with serious physical health conditions may encounter difficulties in making the transition from pediatric programs to adult services. Anecdotal reports have identified various problems, including decreased access to care, problems in finding appropriate services, and lack of assistance in coordinating care. However, few empirical studies have documented the nature and extent of these problems. Moreover, this group of youth may be at risk for poor mental health and developmental outcomes. Research on mental health status for this population has yielded contradictory findings because most studies use clinic-based samples, which tend to be small and seriously biased. Few studies analyze mental health and developmental data from community-based samples. In view of the paucity of previous empirical research, this study addressed issues related to (1) health services, (2) mental health status, and (3) developmental outcomes for the population of young adults with chronic illnesses and disabilities.

Research Questions or Hypotheses

This study addressed critical gaps in the literature by describing access to care and service use for a sample of young adults with chronic illnesses and disabilities and by identifying risk, protective, and mediating factors that influence mental health and developmental outcomes. Analyses tested the fol-
lowing hypotheses related to three primary domains of interest: Health services (hypotheses 1–3), mental health (hypotheses 4–5), and developmental outcomes (hypothesis 6).

Following are the study hypotheses:
1. Both age and impairments will affect use of both primary care and subspecialty care;
2. Age influences access to care after other key variables are taken into account, such as functional status, educational attainment, employment status, and family composition;
3. Greater access to condition-related or general health care services is associated with having help in service coordination;
4. Mental health status is worse in respondents with selected condition characteristics (e.g., those who have some or many functional limitations, compared with those who have no functional limitations);
5. Perceived impact of the condition mediates the influence of condition characteristics on mental health; and
6. Disabilities, age, and parental education have significant effects on rates of education, employment, and idleness.

Study Design and Methods

This study used a cross-sectional cohort survey design with 45-minute telephone interviews of youth who were randomly selected from lists of users of Children with Special Health Care Needs (CSHCN) programs in two States, Illinois and Ohio.

Study Sample and/or Population

In total, 424 youth ages 20–24 or their parents constituted the sample for this study. Of the 424 persons interviewed, 286 were young adults and 138 were parents. Parents responded when youth themselves were unable to communicate over the telephone as a result of their disabilities.

More than one diagnosis was reported by 38.2 percent of the sample and more than 70 distinct diagnoses were reported by respondents overall. As a whole, the sample was predominately white and all but 10 percent of the subjects had received a high school diploma or had pursued further education. Most respondents had never been married and were living with parents or relatives. Approximately half were not employed (either part-time or full-time). About 20 percent said they were receiving Supplemental Security Income (SSI) benefits and slightly more said they were receiving welfare assistance. Compared with many previous studies of youth with a chronic illness or disabling condition, this sample was a relatively advantaged group of young adults. However, compared with youth of similar ages without an ongoing physical health condition, they were more likely to be unemployed and unmarried.

Findings

Access to Health Services: Of the total sample, 13.8 percent said that they did not have a regular source of care for their condition, and 18.6 percent said they had no regular source of general health care. Less than 5 percent of the sample had neither source of care. Other key findings included the following:
1. Respondents ages 22–24 were more than twice as likely to lack a regular source of care than respondents ages 20–21.
2. SSI recipients were less likely to lack a regular source of care for both condition-related services and general health services, whereas respondents not receiving SSI were almost four times as likely to lack a regular source of care for their condition.
3. Youth who had functional impairments were less likely to lack a regular source of care for both chronic conditions and general health, compared with those who had no functional impairments.

4. Of the total sample, 75.8 percent said they had no one to help them with service coordination. Service coordination was available to 32.8 percent of those with SSI; in contrast, only 19.9 percent of those without SSI reported having someone to help them work with other agencies.

5. Having a regular source of care doubled the likelihood of having service coordination and informational support.

Mental Health Status: The mean Psychiatric Symptom Index (PSI) score for the total sample was quite high (21.25), compared with normative samples (10.5); 45 percent of the sample fell above the score of 20, the point indicating “high” symptoms. Other key findings included the following:

1. Respondents who had some or many functional limitations had more symptoms, compared with those who had no such limitations.

2. Respondents reporting a need to watch for sudden changes in their physical condition had more psychological symptoms in comparison with those who had no such need.

3. Respondents whose condition was likely to deteriorate reported more psychological symptoms, in comparison with those whose condition was likely to improve.

4. Respondents with more than one condition reported more psychological symptoms than those with only one condition, and respondents with hearing and speech problems reported more symptoms than those without such sensory impairments.

5. Respondents’ perceptions of the negative impact of their condition mediated the relationship between selected condition characteristics and psychological symptoms.

Developmental Tasks: Overall, 37 percent of the subjects were enrolled in some kind of educational program, and 48 percent were employed on either a part-time or full-time basis at the time of the survey. Considering these variables together, 17 percent were both in school and employed, 20 percent were in school and not employed, 30 percent were employed and not in school, 33 percent were neither in school nor employed, and 23 percent were “idle” according to our definition. Other key findings related to developmental tasks included the following:

1. Compared with a random sample of healthy youth in the same States, proportionately more youth in this study were in school, fewer were employed, and more were idle; differences were larger in the older age group.

2. Youth whose parents had more than a high school education were more than three times as likely to be in school, compared with youth whose parents had less than a high school education.

3. Parental education was associated with employment in a somewhat curvilinear fashion: Proportionately more youth with parents who had a high school education (56.2 percent) were employed, compared with the other two groups (38.8 percent and 41.3 percent); youth with parents who had a high school education were more than twice as likely to be employed, compared with youth whose parents had less than a high school education.

4. Youth who had a chronic condition in addition to mental retardation were more than twice as likely to be in school and significantly less likely to be employed, compared with youth who had a chronic condition and no additional disability.

5. Respondents who had a chronic condition and mental retardation were more than four times as likely to be idle as those who had a chronic condition alone; respondents who had a chronic con-
dition and a physical disability were more than three times as likely to be idle, compared with those who had a chronic condition alone.

6. Overall, when the effects of age, parental education, and disability status were considered simultaneously, rates of school enrollment were independently influenced by age, parental education, and disability status; rates of employment were independently influenced by parental education and disability status; and rates of idleness were independently influenced only by disability status.

The results of this study led to several recommendations for State CSHCN programs. First, the results suggest that State CSHCN programs will need to enhance access to someone who can help older adolescent participants with coordination of services and ensure that these youth receive both primary care and specialty services. Second, to help improve developmental outcomes for these youth, State programs will need to develop methods for identifying individuals with mental retardation and multiple disabilities; special efforts are needed to assure that these youth are given opportunities for employment as they move into adulthood. Finally, difficulties in recruiting a sample for this study underscore the lack of adequate tracking procedures in many State CSHCN programs. Better information systems are needed urgently. If such systems can be put in place, they may yield a data base that can be used for more comprehensive outcome studies.

The results also indicated that it may be possible to identify young adults at high risk for mental health problems, and support the importance of a careful exploration of the perceptions of limitations that youth believe have ensued from their disability. Such perceptions may result from “real” limitations (e.g., physical impediments or intransigent social attitudes) as well as from “imagined” limitations (such as the belief that a goal is not possible to obtain when it actually could be accomplished). Intervention with these young adults may require overlapping efforts to minimize real limitations in education, employment, and social opportunities as well as to change the meaning of the condition to the individual. Pediatricians, nurses, social workers, and psychologists working with adolescents who have chronic health conditions and disabilities can play key roles in ensuring that these obstacles do not prevent these youth from seizing educational and employment opportunities.

Publications

Articles, Books, and Chapters


Abstracts
None to date.

Presentations

Ireys H. 1993. Access to health services for graduates of State CSHCN programs. Presented at the Continuing Education Institute for Leadership in State CSHCN Programs, Columbus, OH.


Behavioral Intervention with IUGR Infants

Summary

Statement of the Problem

Intrauterine growth retardation (IUGR), or the failure to grow adequately in utero, affects the infant’s postnatal growth and development. Followup studies have shown physical growth (primarily height and weight) to be affected up to 15 years of age. Developmental problems include sensorimotor delays and language and cognitive deficits up to 13 years of age. However, a wide range of individual differences in both physical growth and development have been observed within this population. No mechanism has been postulated to explain these individual differences in developmental outcome among infants with IUGR.

The research team’s work and the work of others suggest that IUGR infants have behavioral characteristics that can affect their feeding capacities during the neonatal period. Some infants with IUGR are predominantly drowsy and lethargic and frequently display poor sucking, spitting up, choking, or gagging during feeding. These individual differences observed within the IUGR population might explain the slow postnatal growth displayed by some infants with IUGR.

Research Questions or Hypotheses

The present research was designed to study the impact and generalization of a parent/infant-based behavioral intervention during the neonatal period to prevent and/or ameliorate the negative conse-
quences of IUGR on the infant. The study was based on a theoretical model of development in which the impact of an early insult (IUGR) on the developing infant was partly a function of the characteristics of the caregiving environment (maternal behaviors). Moreover, interventions geared to the caregiving environment rather than to the infant alone are proven to have more long-lasting effects, especially if they are based on the individual behavioral characteristics of the infant. Therefore, the research team postulated that an intervention geared to the mother that was based on her infant’s behavior during feeding might alter her immediate responses to her infant’s behavior, increase her sensitivity and responsiveness to her infant, and ultimately enhance the infant’s developmental outcome.

The research team hypothesized that mothers and infants assigned to intervention would show more positive mother-infant interaction patterns than mothers of IUGR infants who received no intervention or mothers of infants without IUGR.

**Study Design and Methods**

The present study involved two sites (Providence, Rhode Island, and San Juan, Puerto Rico), with three groups at each site: (1) Infants with IUGR randomly assigned to an intervention group, (2) infants with IUGR randomly assigned to a control group, and (3) a comparison group of infants without IUGR. The intervention took place twice at birth (at the hospital prior to discharge) and at 2 and 4 weeks of age. The basis for the behavioral intervention with infants with IUGR was a body of research showing the effects of IUGR on neonatal behavior. In general, these characteristics can be summarized in the following dimensions: (1) State control and regulation, (2) motoric process, and (3) behaviors during feeding. The intervention consisted of two main components: (1) general information given to the mother about the importance of feeding and behavioral characteristics of neonates, especially related to newborns with IUGR, and (2) a review of videotape segments depicting both problems and positive aspects of the interaction.

The impact of the intervention was assessed longitudinally from birth to 18 months of age with repeated measures of physical growth at birth, at 4 weeks, and at 4, 8, 12, and 18 months; repeated measures of caloric intake and mother-infant interaction at birth, and at 2, 4, and 16 weeks; maternal sensitivity at 8 months; and developmental outcomes at 12 and 18 months.

**Study Sample and/or Population**

The population studied consisted of full-term infants (37–42 weeks’ gestation) recruited at each site (Women & Infants’ Hospital in Providence and Hospital Universitario in San Juan) and stratified according to two factors: IUGR and intervention. Infants with congenital syndromes or infections were excluded, as were those whose mothers had a documented history of substance abuse. Approximately half of the infants at each site had IUGR, and approximately half were randomly assigned to intervention.

**Findings**

At the Providence site, mothers of infants with IUGR who received the intervention tended to stimulate their infants more often at 2 weeks and to insert the bottle, wipe the infant, and check the bottle more often at 4 weeks. No effects of the intervention were observed on the infants’ behavior. At the San Juan site, positive effects of the intervention were observed at 2 and 4 weeks on maternal vocalizations and on total positive maternal behavior. No effects of the intervention were observed on the infants’ behavior.

In the Providence sample, positive effects of the
intervention were observed in proportional change between birth and 1 month for most parameters of growth. Specifically, infants with IUGR who received the intervention had a higher proportional change in weight, skinfold thickness, and length than infants with IUGR who did not receive the intervention or infants without IUGR. In the San Juan sample, infants who received the intervention had greater proportional change in length between birth and 4 weeks than the other two groups. No other intervention effects were observed until 18 months: Infants who had received the intervention showed greater proportional change in weight between 12 and 18 months than infants with IUGR who did not receive intervention. No intervention effects were observed in any of the dimensions of the Home Observation for Measurement of the Environment (HOME) assessment, inclusive of verbal and emotional sensitivity at either site.

The final sets of analyses evaluated the impact of the intervention on the infants’ developmental outcomes. No systematic effects of the intervention were observed at either site.

The study was designed to test the efficacy and generalizability of a perinatal behavioral intervention on the growth and developmental outcome of infants with IUGR. The impact of the intervention was significant, although limited to the areas of feeding interactions and physical growth. Specifically, the effects of the intervention were observed during feeding interactions on quantitative (but not qualitative) aspects of mother-infant interactions during feeding at both sites.

In terms of the effects of the intervention on subsequent physical growth, more general and consistent positive effects of the intervention were obtained (although short-lived) in Providence but not in San Juan. Thus, the findings obtained in the Providence site suggest that an individualized behavioral feeding intervention can accelerate early growth in full-term infants with IUGR.

However, several caveats need to be stated. First, this initial acceleration did not result in ultimate catchup growth over the 18-month duration of the study. One interpretation of these findings is that the intervention’s positive effects on growth are seen as long as the intervention was carried out (between birth and 1 month), but not after it was discontinued.

The second limitation of these findings is that the positive effects of the intervention were observed most consistently in one site but could not be replicated in the second. Differences in maternal characteristics might explain this differential because the mothers in Providence were older, more educated, and of higher socioeconomic backgrounds and might have incorporated the learning aspects of the intervention more readily. However, cultural differences might also play a role in the impact of the intervention. The malleability of developmental outcome (including growth) differs among different ethnic groups. Specifically, the issue of how much and through what mechanisms a caregiver can alter an infant’s behavior and, ultimately, the infant’s developmental outcome differs among cultures. Thus, the impact of any intervention has to consider the cultural constructions of development as a fundamental part of implementing any intervention that is geared to changing maternal behavior. The present study has only started to address these issues by trying to replicate the impact of an intervention across two cultural settings. But more in-depth assessments have to be conducted to fully comprehend the interactions between the implementation of an intervention and the day-to-day cultural context of mothers and their infants.

This study was proposed as a demonstration project of the utility of this kind of intervention with the IUGR population. If positive findings had been obtained, this study was expected to ultimately impact
anticipatory guidance and discharge planning for infants with IUGR, through which parents could be given guidelines on how to promote their infant’s feeding behaviors, postnatal catchup growth, and sensorimotor and language development. Although the present findings do not support the formulation of such guidelines, they suggest that the impact of a long-term preventive intervention is a very important area of investigation. It is recommended that future studies evaluate the impact of interventions that go beyond the neonatal period or perhaps are more comprehensive.

Publications

Articles, Books, and Chapters


Abstracts

None to date.

Presentations


Computerized Screening of Pregnant Women for Nutrition Risk

Summary

Statement of the Problem

Improved organization, delivery, and quality of prenatal nutrition services are needed within a framework of cost containment. Low-cost improvements in prenatal health services require a system in which professional and nonprofessional personnel can use a standardized procedure to classify pregnant women according to nutritional status and to refer those at nutritional risk for special nutritional services. Also required are efficient and effective mechanisms for providing essential nutrition services for pregnant women. Widespread use of an efficacious system has been impaired by the lack of a practical, tested method for classifying pregnant women according to nutrient intake. Scores from nutrition assessments can be combined with data from other indicators of nutritional risk to provide a sound basis for screening and referral.

While the long-range implementation of the Food Frequency Questionnaire (FFQ) in prenatal health services is to improve the scope and quality of nutrition services while containing costs, we anticipate that the FFQ will also be used to collect dietary data in wide-scale epidemiologic studies of associations between nutrition and outcomes of pregnancy.

Research Questions or Hypotheses

This research involved (1) developing and evaluating the FFQ for use in classifying low-income pregnant women according to nutritional risk; (2) test-
ing the practicality of administering the questionnaire by direct computer entry or by paper copy with computerized scoring; and (3) considering the methodological issues pertaining to the evaluation of the instrument.

In related studies, the research team evaluated the FFQ for stability and selected aspects of validity by determining how reproducibility and validity measures are associated with the method of administering the questionnaire and the characteristics of the women. In this report, the research team focused on comparing the paper copy and the computerized version of the FFQ.

**Study Design and Methods**

This project used a convenience sample in a non-experimental study design in three sites that provided prenatal care services to low-income women. The sites were selected by the relatively large numbers of pregnant women served and by ethnic diversity. Three sites participated in the study, two hospital-based prenatal clinics and one community health center. All three sites received Title V support for prenatal services. All pregnant women were eligible to participate unless they spoke neither English or Spanish.

The instruments used for the study were a semi-quantitative food frequency questionnaire designed specifically for use with low-income pregnant women. The validation study of the paper copy has been previously reported. The computerized version has the same food list in an easy-to-use format. Three keys (spacebar, enter, and backspace) allow the user to select responses, enter responses, and make corrections, respectively. In addition to using the spacebar to select the desired response, participants may use the up and down arrows. Color coding greatly facilitates the use of a standard keyboard. Participants contributed to the selection of the colors. The enter key was coded green, designating “go” or “OK,” the spacebar pink, and the backspace key yellow. An instructional sequence at the beginning of the program was designed to be understood by people with limited reading ability without supplementary oral instructions. The instructions focused on food intake, incorporated practice in the use of the three color-coded keys, and gave positive reinforcement by using the participant’s first name. Periodically, the user was given positive reinforcement with statements such as “You are doing well, Mary.” At the completion of the questionnaire, there was a message thanking the participant for using the program.

**Study Sample and/or Population**

The director of nutrition services at each site was the primary contact for the study. Each site volunteered to use the computerized version of the FFQ for as many subjects as they could recruit over a 3-month period. The computerized version (N = 306) was compared with the scores on the paper version (N = 265) collected on a similar sample in a prior study of tool validation.

In both samples, 60 percent of the women received medicaid assistance. Both samples were comparable in education and marital status. A higher proportion of the sample using the computerized version designated race as “other” because one site had a high proportion of Hispanic women. The two samples were comparable in the time during pregnancy at which they completed the FFQ.

**Findings**

Although the amount of time needed to complete the paper version was impossible to measure precisely in a clinic setting, it was estimated to be less than 16 minutes for most women. The time to com-
The computerized version was measured electronically; the median time was 13 minutes. For one site, the research team compared the amount of time needed to complete the English version (N = 83) and the Spanish version (N = 66) of the FFQ. The median time needed to complete the English version was 14 minutes, and the median time for the Spanish version was 17 minutes. The means were 14 ± 6 minutes and 18 ± 6 minutes, respectively, with a p value of 0.0001 based on Wilcoxon Rank Sums.

As reported in the validation study, a substantial percentage (18 percent) of the women completing the paper copy had estimated caloric intakes in excess of 4,500 Kcal per day. The research team found much less overestimation (less than 5 percent) when subjects used the computerized version. The overestimation was across many foods and therefore contributed to all of the nutrients. The women using the computerized version were less likely to select all the foods, suggesting that women may tend to respond to each food item separately when only that item is before them. Nineteen percent of the women using the computerized version responded that they had used alcohol in the last month, compared with 8 percent of women respondents who had used the paper version.

The estimated caloric intake mean for the total sample using the computerized version was 1,893 Kcal, compared to 2,386 Kcal for the total sample using the paper version (after removing the responses of those with a caloric intake >4500 Kcal). The paper copy showed higher estimates of calories compared with either diet recalls or the computerized version. The computerized version approximated the series of diet recalls in the validation study. Of particular note is the overestimation of vitamin A on both versions of the FFQ. However, the computerized version was again closer to the estimates by diet recalls.

Further investigation of the feasibility of using self-administered, computerized questionnaires as a dietary data collection method in health care settings should be considered. The principal advantages of such an approach would be (1) the ability to collect and analyze rather detailed information and produce useful reports in a manner requiring minimal time and effort by the health care provider, and (2) the simplification of the data collection process for the client. Without an inordinate amount of time, no manual method can produce information comparable to that prepared automatically by the computer. A computer program can tabulate and summarize data on both food and nutrient intake and can make comparisons with whatever standards are selected. Once the programming is completed and staff have received the minimal training required to run the program, the potential for an efficient operation is great.

If the software is designed to be easy to read and use, it appears that low-income women who have basic reading skills can respond to the FFQ quickly and easily. Those who do not have adequate reading skills can be identified through the brief self-training portion of the program. In contrast, people who cannot read can easily mask this problem when asked to complete most paper FFQs.

In summary, there are serious limitations regarding the extent to which the paper version of the FFQ can be simplified and still provide useful information. Computerized versions of the questionnaire can circumvent this problem.

**Publications**

**Articles, Books, and Chapters**


**Abstracts**
None to date.

**Presentations**
None to date.
Parent-Focused Intervention to Reduce Pain During Procedures

Summary

Statement of the Problem

Previously, the research team reported that the majority of parents prefer to be present when their children undergo common invasive medical procedures, such as venipuncture or intravenous cannulation. Of 250 parents who responded to a questionnaire about their preferences, 78 percent indicated that they would want to be present if their child needed to have “blood drawn or an IV started.” There has also been research that reported the preference of physicians with respect to parental presence, namely that for common procedures, the majority of physicians are comfortable with parents being present. However, as procedures become more invasive (e.g., arterial blood sampling or chest tube insertion), physicians prefer that parents not be present.

Despite these reports, what actually happens during encounters when children undergo procedures is unclear. In 1991, the research team reported the results of an observational study of 50 children undergoing venipuncture or intravenous cannulation in the pediatric emergency department (PED). Parents remained with their children during 62 percent of the procedures. Parents were more likely to stay if the child or a sibling had previously undergone a procedure. Only 43 percent of the parents who did stay were given that option by the physician, and of those who did not stay, 37 percent reported that the physician asked them to leave.

Physician ambivalence about parental presence results from a number of factors. First, some physi-
cians perceive themselves as less proficient at procedures if parents are present. Parents can make practitioners nervous. Second, parents are anxious when their children are ill and can be difficult when procedures are performed during prolonged emergency department evaluations. Third, having parents present can be time-consuming. Sometimes, it is just faster to “get the procedure done.” Last, and most important, some parents are uncertain how best to help their children during procedures. Although some instinctively soothe and calm their children, parental anxiety and fear may prevent them from offering optimal support for their children.

Research Questions or Hypotheses

The research objectives were to determine (1) the effect of a parent-focused intervention on the pain and performance of routine procedures, anxiety of the parents and physicians, and parental satisfaction with care; (2) whether parents and physicians perceive pain similarly; and (3) whether parents can be taught how to implement the intervention.

Study Design and Methods

Believing that parental presence during procedures is important and that parents should be instructed in how to help their children, the research team designed a study in which parents were taught how to help their children during common invasive medical procedures. The intervention was kept simple, so it could be used in other settings, and focused on younger children, since they are more amenable to an intervention than older children.

The study was a randomized controlled trial with three groups: Parent(s) present and given instructions on how to help their child (intervention); parent(s) present, but no instructions given (present); and parent(s) not present. Children younger than 3 years of age who were being seen in the PED and undergoing venipuncture, intravenous cannulation, or ureteral catheterization were eligible. Attending physicians, residents, and nurses performed the procedures.

Consent Procedure: Subjects were randomized with a technique developed by Zelen referred to as prerandomization. Traditionally, informed consent is obtained prior to randomization. With prerandomization, participants are randomized prior to obtaining informed consent. There were two benefits to using this technique: (1) Participants were less likely to withdraw since they were not specifically aware of the other groups; and (2) the measure of anxiety was less influenced by parents being assigned to a group they did not want (hence, the measure of anxiety more accurately reflected anxiety related to the procedure rather than group assignment). The study was approved by the Human Investigation Committee of the Boston City Hospital.

Parental Instructions: Parents were instructed in how to calm and relax their child. The intervention was brief and was based upon data suggesting that children are calmer and their vital signs return to normal more quickly when two sensory modalities (touch and sound) are engaged. The parents were asked to sit at the head of the bed and talk to, touch, and maintain eye contact with their children. They were told not to help restrain their children. The research assistant recorded whether the parents followed the instructions.

Pain Assessment: Pain was measured by using analysis of cry and an observational scale completed by the physician and parent. These two measures were chosen because they reflect physiologic and behavioral measurements and have been reported to change when infants and children undergo painful procedures. Over the last decade, computerized analysis of cry has been used in a number of investigations.
of infants and young children. In general, computer-
ized analysis of cry confirms the reports of parents
that the cry of children in pain is higher in pitch and
more turbulent. Each procedure served as a stimulus
for the cry. Each 30-second cry signal was filtered
above 10kHz and digitized at 20kHz by the computer.
For each cry utterance (defined as a cry sound last-
ing at least 0.5 seconds), Fournier transformation was
used to compute the log magnitude spectrum for each
25 millisecond block of the cry utterance. Variables
analyzed included level of energy; frequency vari-
ables (fundamental vocal fold vibration, first for-
mat–first resonance frequency resulting from the fil-
tering of the sound by the vocal tract); cry modes
(phonation-periodic signal with a fundamental fre-
quency no greater than 1000 Hz, hyperphonation-
aperiodic signal with a fundamental frequency exceed-
ing 1000 Hz, dysphonation-turbulent or aperiodic
sound); and the number of cry utterances. Frequency
variables were determined for each 250ms block in
the phonation mode. The cry mode was determined
for each 250ms block. The percentage of blocks in
each cry mode was determined for each cry utterance.
The analysis controlled for age, because cry technique
has generally been used only for children younger
than 6 months of age.

There are a number of scales available to measure
the pain of procedures, although none have been
widely used in infants. Because the study was con-
ducted in an urban PED, there were significant time
and space constraints; hence, the research team chose
to use a global measure of pain that could easily be
completed by the parents and clinicians. Each was
asked to rate the extent of pain of the procedure on
a three-point categorical scale, with 1 = severe/great,
2 = moderate, and 3 = some/little.

Performance of the Procedure: The performance
of the procedure was measured by assessing (1) the
number of needles/catheters used; (2) how often the
procedure was completed by the first physician or
nurse attempting it; and (3) the amount of time
from insertion of the needle to withdrawal of blood
(or insertion of the catheter to withdrawal of urine).

Anxiety of Parent and Physician: The anxiety of
the parents, physicians, and nurses was measured
with the State-Trait Anxiety Inventory (STAI). The STAI
is a 20-item forced-choice questionnaire that mea-
sures current anxiety. It has excellent reliability and
validity.

Satisfaction with Care: Parents were asked, “Overall,
how satisfied were you with the care your child
received?” There were five possible responses rang-
ing from extremely unsatisfied to extremely satisfied.
For the first 100 enrollees, satisfaction was assessed
48–72 hours after discharge from the PED. However,
because of difficulty contacting families, satisfaction
was assessed at the end of the visit for the remainder
of participants.

Study Sample and/or Population

Children younger than 3 years of age who were
seen in the PED and undergoing venipuncture, intrave-
 nous cannulation, or ureteral catheterization were
eligible to participate. Parents were excluded if chil-
dren needed emergent medical attention, had pre-
viously participated in the study, or had a history of
chronic disease (such as sickle cell anemia) that
frequently requires invasive procedures.

The sample was drawn from the PED at Boston
City Hospital (BCH). BCH serves a predominantly
inner-city minority population. The hospital is located
in a medically underserved community and patients
are seen regardless of their ability to pay. Care is free
for residents of the City of Boston without either pub-
lic or private health insurance.

In 1994 there were approximately 25,000 visits
to the PED. When this study was conducted, only chil-

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Children up to age 18 were seen in the PED. Approximately 20 percent of children seen in the PED are uninsured, 50 percent receive medicaid assistance, and the remainder have private insurance. The majority (> 75 percent) are nonwhite.

**Findings**

In total, 431 of 572 eligible parents (75 percent) consented and participated in the study: 153 in the intervention group, 147 in the present–not taught group, and 131 in the not-present group. The groups were equivalent with respect to parental and child sociodemographic variables, parental experience in the PED, procedure performed, and frequency of hospitalization. The accompanying parent was usually the mother (87 percent), most were between the ages of 20 and 24, described themselves as African American and single, and had completed high school.

The majority of children were male (57 percent) and younger than 1 year of age (53 percent; 33 percent were admitted to the hospital. The most common procedure performed was venipuncture (62 percent), followed by intravenous cannulation (28 percent) and ureteral catheterization (10 percent). The majority of procedures were done by residents.

Parents who did not consent to participate were similar to those who did consent with respect to relationship to child (86 percent were mothers), ethnicity (59 percent were African-American), and educational level (47 percent had completed high school). Nonparticipants (65 percent) were more likely than participants (30 percent) to be assigned to the not-present group \( (p < .001) \).

Pain Assessment: No differences between groups emerged with respect to the following cry variables: Mean level of energy, mean fundamental frequency, mean variability of the fundamental frequency, mean first-formant frequency, mean variability of the first-formant frequency, mean percent hyperphonation or dysphonation, and number of cry utterances. Age was found to affect the following cry variables: Mean level of energy, mean variability of the fundamental frequency, and first formant.

There were no differences between the groups in the global pain ratings of the parents, physicians, and nurses. In the intervention and the present groups, parents rated their childrens’ pain as extreme/great in 55 percent and 50 percent of the encounters, respectively.

Since the research team’s previous work and clinical experience suggest that some parents are better at following instructions, reanalysis of the physician/nurse ratings was done based upon the ability of parents to successfully implement the intervention. Physicians rated the pain of children whose parents successfully implemented all three aspects of the intervention (spoke to, touched, and maintained eye contact with their children, \( N = 106 \)) as significantly less (pain rated extreme/great in 10 percent of cases), in comparison with ratings of pain in children whose parents were not as successful in using the intervention combined with those in the present–not taught group (pain rated extreme/great in 19 percent of cases). Similar analysis of parent ratings approached statistical significance.

The comparison of physician and parent pain ratings showed poor agreement. Parents in the intervention and present groups rated their children’s pain as extreme/great for 52 percent of the procedures while physicians rated 15 percent of same procedures as extreme/great.

Anxiety of Parents and Physicians: Parents who were not present reported being more anxious than parents who were present \( (p = .025) \). There were no differences in anxiety scores among the three groups for the physicians and nurses \( (p = .430) \).

Performance of Procedure: There were no dif-
ferences between the three groups in the performance of the procedure. Only one needle was used for 78 percent of the procedures, and 90 percent of the procedures were completed by the first physician or nurse. The time needed to complete the procedure was similar for the three groups.

Satisfaction with Care: 71 percent of parents indicated that they were extremely satisfied with the care they received. There was no difference between the three groups, although there was a trend suggesting that parents in the intervention group were more likely to report being extremely satisfied (94 percent) than those in the present (86 percent) and not present groups (87 percent).

Overall, the intervention was not successful in reducing the pain of routine procedures. However, parental presence did not affect performance of the procedure or the anxiety of the physicians and nurses. Parents who were present reported less anxiety than those who were not present. In general satisfaction with care was high, with a trend suggesting that parents who were in the intervention group were more satisfied than parents in the other two groups.

The difference in pain ratings of parents and physicians is disturbing. Parents were more than three times as likely as physicians to report that the children were in severe/extreme pain. This has significant implications with respect to how practitioners alleviate the pain of procedures. If parents’ impression of children’s pain differs from that of practitioners, it may be difficult to convince parents that the pain of a procedure has been minimized. It may be necessary to use information from observational scales or physiologic measures to reassure parents.

Many physicians report that they are not as proficient at procedures when parents are present. The research team used three different measures of proficiency and could find no difference between the groups. It is possible that the residents, nurses, and attending physicians staffing the PED at BCH are comfortable with parental presence and hence it does not affect their performance. The similarity in anxiety rating scores of the physicians and nurses among the three groups support this position. If early in their training, residents expect parents to be present, it is likely that they become accustomed to it. With respect to the time of the procedure, although there was no statistical difference between groups, the procedure did take longer in the intervention group.

It is possible that if the intervention would have been more intensive, the research team would have found greater differences among the groups. However, the goal was to use an intervention that was simple, based on clinical experience and the research literature, and reproducible. Emergency rooms, inpatient units, and physician offices are busy places. Few providers have sufficient time to teach parents elaborate techniques to help their children. Asking parents to sit at the head of the bed and talk to, touch, and maintain eye contact with their children takes only a few minutes.

Although the intervention was not successful for all parents, many could follow the instructions, and for that group, parental perception of pain was significantly reduced. Practitioners should be more active with parents when their children undergo procedures. Some parents may instinctively know what to do to calm their children, but many others, anxious because of their child’s illness or the environment, do not. Practitioners should encourage parents to be present during procedures and need to educate them about how to help their children.

Publications

**Articles, Books, and Chapters**


Abstracts


Presentations


Preconceptional Vitamin Use and Neural Tube Defects

Summary

Statement of the Problem

Congenital disabilities resulting from abnormal development of the embryonic brain and spinal cord are among the most traumatic disabilities, both to families and to society. Collectively known as neural tube defects (NTDs), they include anencephaly (absent brain and skull) and spina bifida (various degrees of involvement of the spinal cord [myelomeningocele] and/or the surrounding tissues [meningocele]).

NTDs are relatively common disabilities, affecting approximately 1.5 per 1,000 births. Perhaps more important than the absolute numbers of affected infants are the effects on society in general and for the health care delivery system in particular. While NTDs include some disabilities of relatively minor consequence, and some that are incompatible with life, the majority present serious and persistent medical and functional disabilities.

The etiology for most NTDs is unknown, although they are widely believed to be of multifactorial origin. Based on experiments in animals and observations in women who previously had an NTD-affected pregnancy, it has been suggested that women who supplement their diets with multivitamins before conception can reduce by at least 50 percent their risk of having another NTD-affected pregnancy. In addition, although the evidence regarding preconceptional vitamin supplementation concerns only recurrent NTDs, it is generally assumed that first (occcurrent) NTDs might also be reduced by such supplementation. However, the potential risks of a massive precon-
ceptional vitamin supplementation effort among women of childbearing potential must be considered. Specifically, the risk of actually increasing congenital disabilities cannot be ruled out.

This situation requires resolution as rapidly as possible. The research team believed that the most rapid, efficient, and feasible approach was a case-control study specifically designed to examine the potential benefit of preconceptional vitamin supplementation with respect to NTDs, and, secondarily, to examine some of the potential hazards of excessive supplementation.

Research Questions or Hypotheses

A recent controlled trial has established that supplementation with .4 mg of folic acid before and during early pregnancy reduces the risk of recurrent neural tube defects by 72 percent. This study was designed to determine whether folic acid also reduces the risk of occurrent NTDs. A secondary hypothesis was to assess whether high-dose vitamin intake increases the risk of any particular major malformation or group of malformations.

Study Design and Methods

This study followed the case-control approach to testing the primary and secondary hypotheses. A common data set was used for both hypotheses.

Study subjects (cases and controls) were recruited through an active surveillance network of hospitals and clinics in the metropolitan areas of Boston, Philadelphia, and Toronto. Cases and controls consisted of infants and fetuses with malformations, and included infants under 6 months of age, stillbirths, and therapeutic abortions (TAb).

For the primary hypotheses, cases were subjects with NTDs, and controls were subjects with other malformations. The distribution of disabilities in the control series approximated that found in the general population. Since pregnancies complicated by fetal malformation may be terminated by therapeutic abortion, it was important that the case series include NTDs that were electively aborted (and, therefore, that the control series included other malformations from the same setting). Vitamin supplementation may be related to socioeconomic status and health behaviors, which can be associated with both the opportunity for prenatal diagnosis and the decision to undergo a TAb. For these reasons, NTDs that were electively aborted were included in the study sample, along with their respective controls.

For the secondary hypothesis, there were various case groups. To test the hypothesis that excess vitamin A intake was teratogenic, case series included subjects with specific craniofacial, heart, and brain impairments. To consider possible effects of excessive supplementation with other vitamins and minerals, additional case series included craniosynostosis and aortic stenosis. In these comparisons, controls consisted of malformed subjects (with appropriate exclusions) not included in the respective case series.

A malformed control series was used in an effort to reduce the likelihood of recall bias, assuming that the accuracy of exposure reporting by mothers of malformed infants differed from that by mothers of normal infants.

Because it was important that bias not be introduced in the selection of cases and controls, the research team identified and enrolled all study subjects in an identical fashion. In addition, controls were selected from the same institutions as cases.

Information on exposure to vitamins and minerals was obtained by interviewing the mother. The nurse-interviewer in each study center sent an introductory letter to mothers of designated subjects, followed by a telephone call. Informed consent was
obtained prior to the interview, which was conducted in the mother’s home at a time convenient for her. Interviews were conducted at home because the research team felt this setting was more relaxed and less threatening; it also afforded the nurse the opportunity to examine available medication bottles. Interviews were conducted 3–6 months after delivery. The questionnaire, which took approximately 45 minutes to administer, included data on vitamin and mineral supplementation as well as other factors that may be related to supplementation or to the risk of NTDs or other congenital disabilities.

**Study Sample and/or Population**

All mothers of infants (or fetuses) with major congenital disabilities identified within 6 months of age and residing in the catchment area were eligible for inclusion in the study, with the following exceptions: Women who did not speak English and did not have a translator were excluded because the interviewers were English-speaking only; women who had given up the study child for adoption were excluded for social reasons; and women who had previously been interviewed for the Birth Defects Study were excluded to reduce the potential for information bias.

Study subjects included the mothers of 436 occurrence cases with neural tube defects and 2,615 controls with other major malformations. Demographic characteristics of the sample were as follows: 90 percent white, 5 percent black, and 5 percent other races. Ten percent of the mothers were 20 years of age or younger and 10 percent were over 35 years of age. Fifteen percent of the mothers had less than a high school education and 30 percent had a college degree.

**Findings**

In comparing the case and control groups, the research team found that mothers in the case group were younger, less educated, and had lower family income levels. Maternal race, religion, and geographic area of residence were similarly distributed among cases and controls. Mothers in the control group were slightly more likely than mothers in the case group to have planned their pregnancies, consulted a health care provider in pregnancy planning, had routine gynecological checkups, exercised routinely prior to pregnancy, and used seatbelts. Prepregnancy alcohol consumption was only 1.5 times more common among control group mothers than case mothers; the distributions of preconceptional supplementation and recreational drug use were generally the same for both groups. In summary, only maternal age, maternal education, and family income were associated with both periconceptional supplementation and case/control status and were therefore considered as potential confounders.

During the end of the data collection phase, the results of previous research were published, suggesting a 70-percent reduction in recurrent NTD risk for .4 mg of folic acid taken before conception. These findings are considered the most definitive in terms of the folic acid and recurrent NTD relationship, because any potential confounding effects were removed through the randomization process. These findings influenced the research team’s analysis because several questions about the folic acid/NTD relationship remained: Does folic acid supplementation reduce the risk of occurrence NTDs, particularly in more recent years when the background prevalence of NTDs has been declining? Does the timing or frequency of folic acid intake affect the risk? Does a dose lower than
.4 mg reduce NTD risk? And does the risk vary according to the type of NTD?

Daily use of folic acid supplements in the periconceptional period was reported by mothers in 8 percent of the case group and in 13 percent of the control group; the crude and multivariate relative risk estimates were .5 and .6, respectively. For less than daily use in the periconceptional period, the crude and multivariate estimates were both .9. Less than 2 percent of cases and controls used multivitamin supplements with an unknown folic acid content or without folic acid, and relative risks were not estimated. For first use of folic acid supplements in the second lunar month, crude and multivariate estimates were .7 and .8, respectively.

Not enough of the subjects participating in this study had been exposed to excessive amounts of vitamin A intake to allow for an evaluation of the second hypothesis.

In summary, the research team found an approximate 40-percent reduction in occurrent NTD risk for periconceptional folic acid supplementation when that supplementation was taken daily throughout the 28 days before and the 28 days after the last menstrual period. Less frequent supplementation or first use during the second lunar month (29 through 56 days after the last menstrual period) did not significantly reduce NTD risk. The latter findings are particularly important because the second lunar month is when pregnancy becomes clinically recognizable and when many women begin taking prenatal vitamins. These data suggest that supplementation must begin before the first missed menstrual period to reduce NTD risk.

Publications

Articles, Books, and Chapters


Abstracts

None to date.

Presentations


Mitchell AA. 1993. Epidemiological evidence for the association between folate deficiency and NTDs (case-control studies). Presented at the Consensus Meeting on Periconceptional Use of Folate, Hospital for Sick Children, Toronto, Canada.


Study of Psychosocial Factors in Maternal Phenylketonuria

Summary

Statement of the Problem

Women with phenylketonuria (PKU) are at risk for bearing children with mental retardation, microcephaly, congenital heart disease, and low birthweight. Dietary treatment during pregnancy, if initiated prior to conception, offers at least partial and perhaps complete protection to the fetus. However, women with PKU usually seek medical advice after they become pregnant. If treatment to prevent congenital disabilities is not initiated during pregnancy, the incidence of mental retardation from maternal PKU could approach the level that existed before the advances in newborn screening.

Research Questions and Hypotheses

The research team hypothesized that psychosocial factors determine whether a young woman with PKU is likely to plan her pregnancy and comply with medical recommendations for treatment. The research team designed a prospective longitudinal study to identify which factors predicted adherence to medical recommendations at each stage of treatment. The objectives of the study were to determine (1) the psychosocial factors related to successful outcome in maternal PKU pregnancies, (2) the differences between phenylketonuric women and women in two matched comparison groups (diabetic and healthy acquaintances) in their psychosocial adjustment and behavior, and (3) the applicability of
a stage model predicting unplanned pregnancies and noncompliance with medical recommendations. The model that was devised includes four stages of the maternal PKU life cycle, with each stage representing a goal for young women with PKU.

**Study Design and Methods**

Subjects from three study groups participated in one of four standardized protocols according to their current stage in the life cycle model. The protocols included interviews and questionnaires designed to obtain information about five categories of variables: (1) The outcome specific to each stage; (2) background characteristics, including IQ; (3) social support; (4) beliefs and attitudes; (5) personality; (6) knowledge of the disorder and treatment; and (7) quality of life. If a woman indicated that she was pregnant or planning a pregnancy, additional interviews were arranged. Except for quality-of-life measures and stage 1 (in which data were analyzed separately for each year), data from all years were combined for analyses of each stage.

In addition, the research team conducted a cross-cultural research study through the auspices of a United States–Israel Binational Science Foundation Grant to the Sheba Medical Center–Tel Aviv University in Israel. This study, although smaller in scale with a project period of 3 years, used identical instruments (translated into Hebrew) and similar methods. The principal investigators in Israel were Dr. Shoshanna Shiloh and the late Professor Bernard Cohen, from the Sheba Medical Center, Tel Hashomer Hospital, and Tel Aviv University.

**Study Sample and/or Population**

All young women ages 16–35 in New England who were known to have hyperphenylalaninemia without severe mental retardation were invited to participate. Two age-matched comparison groups were recruited: (1) Acquaintances of the women with PKU, and (2) a matched group of women with diabetes mellitus whose childbearing risks and need for metabolic control prior to pregnancy were similar. Acquaintances were recruited from a list of names obtained from each subject with PKU. In total, 208 women participated in the study: 70 women with PKU, 69 women with diabetes mellitus, and 69 acquaintances. The participation rate was greater than 90 percent for the women with PKU; the dropout rate was less than 8 percent.

**Findings**

Women with PKU appeared to be less socially advanced than women in the comparison groups in every category, except that of experiencing pregnancy. They also had a lower IQ, lower socioeconomic status, and fewer years of education.

Over the 5 years of the study, 63 women experienced a total of 96 pregnancies. More than 77 percent of the women with PKU and 75 percent of the women with diabetes had not planned to become pregnant; 48 percent of the women in the acquaintance group reported that their pregnancies were unplanned. Of the 96 pregnancies, 65 resulted in live births. Fifteen percent of the pregnant women in both the PKU and acquaintance groups and 13 percent of the women in the diabetes group elected to terminate their pregnancies. None of the planned pregnancies was terminated.

Among maternal PKU offspring, 18 percent had cardiac anomalies, 36 percent had other congenital anomalies, and 36 percent had microcephaly. Nineteen percent of the offspring performed in the borderline or mental retardation range with a developmental quotient of less than 85 on the Bayley Mental Scale.
Only one child born to a mother with diabetes mellitus and one child born to a mother in the acquaintance group were known to have a congenital disability.

Stage 1: Prevention of unplanned pregnancies

By the end of the study, 60 percent of the women with PKU were sexually active; 65 percent of this group reported always using contraceptives; 29 percent indicated they used no contraceptives. In comparison to the other study groups, women with PKU were less likely to be sexually active but more likely to avoid contraception when they were sexually active. Attitudes and social support related to contraception consistently correlated with reported frequency of contraceptive use among women with PKU. Scores on the social support scales indicated that the more peer-oriented the woman and the more supportive her peer relationships, the greater her frequency of contraceptive use. This was especially true for the women under age 20.

Stage 2: Reproductive decision making

Women with PKU were less likely to make a decision to have a child and were more likely to delay the decision than were their acquaintances or women with diabetes mellitus. The diet and metabolic monitoring were not mentioned as reasons for delaying the decision. No specific independent variables were associated with whether the women who had PKU made a conscious reproductive decision. Knowledge of the risks involved in maternal PKU were somewhat related, but not to a significant degree.

Stage 3: Initiation of treatment

Among the 34 women who initiated treatment, 60 percent of the women with PKU and 79 percent of the women with diabetes mellitus began treatment prior to conception. Cooperation with self-monitoring requests and consistency in attending clinic averaged about 60 percent in both the PKU and diabetes mellitus groups. However, these behaviors did not translate into good metabolic control. Despite the relatively large numbers of women who planned their pregnancies and initiated treatment prior to conception, the median percentage of phenylalanine levels within the 2 to 6 mg/dl range was less than 7 percent. Among women with diabetes mellitus, the median percentage of hemoglobin A1c levels less than 9 percent was 0, since only 4 of the 14 women were able to achieve any levels within this range.

Women with PKU who entered this stage before pregnancy felt greater comfort with the medical staff and had better relationships with their partners and their in-laws than did those who began treatment after conception. In addition, the women who initiated treatment earlier were more likely to acknowledge that they needed help from their friends and to feel that they received adequate support from their husbands or partners. Similarly, women with PKU who expressed a need for support (both practical and emotional) from their medical team were more likely to achieve metabolic control within the recommended treatment range.

Stage 4: Continuation of treatment throughout pregnancy

Fifty-eight pregnancies in 47 women were studied when the woman were in the seventh month of pregnancy. For women with PKU, the median percentage for blood phenylalanine levels within the recommended range was 41 percent. For diabetic women,
the median percentage for blood glucose levels within the recommended range was 30 percent, and for A1c levels, 71 percent. Attendance at clinic appointments was greater than 85 percent. The majority of the women with PKU sent in dietary records two-thirds of the time, and more than half of the women for whom the special formula was prescribed were rated as consistently taking the recommended amount.

Regression analyses indicate that for phenylketonuric women, maternal IQ, attitudes toward having a child with special health needs, and the degree to which activities were curbed during pregnancy accounted for 78 percent of the variance in the percentage of blood phenylalanine levels within the recommended range. Phenylketonuric women with higher IQ who were not overwhelmed about the prospect of having a child with special health needs and who did not perceive themselves as curbing their activities during pregnancy were more likely to achieve better metabolic control. Marital status ranked fairly low in the regression hierarchy, but was closely related to the percentage of blood phenylalanine levels within the recommended range, with married women achieving better metabolic control. Those with higher IQ were also more likely to be married.

Women who expressed negative feelings about the diet maintained their blood phenylalanine levels in the recommended range only 26 percent of the time. Women who reported positive feelings about the diet (such as experiencing more energy and clearer thinking) maintained their blood levels between 2 and 6 mg/dl 53 percent of the time. Interrelationships between outcome variables across stages

Approximately 40 percent of the women with PKU who were rated as “successful” in stage 1 (indicating that they always used contraceptives when sexually active) were also successful at stage 2 (having made a reproductive decision) and at stage 3 (initiating diet prior to pregnancy). Forty-seven percent of those successful at stage 2 were also successful at stage 3. The percentages are similar to those of the comparison groups. However, for women with PKU, success at stages 1, 2, and 3 was associated with success at stage 4 (maintaining metabolic control during pregnancy) no more than 25 percent of the time; however, for acquaintances and women with diabetes, success at any one stage predicted success at stage 4 between 40 and 60 percent of the time.

Quality of life

Analyses were performed to determine whether adherence to medical recommendations was associated with lower health perceptions or decreased social activities. The women with diabetes consistently scored lower on quality of life measures than the women with PKU and their acquaintances. However, at no stage and in no group did quality of life diminish as adherence increased.

Findings from the cross-cultural study

No significant differences were found between the Israeli and American groups in the percentage of sexually active subjects. However, of those who were sexually active, significantly more Israelis were married, had been pregnant, and had children. Significant differences were found in the type of contraception used, with more Israeli women using oral contraceptives, although frequency of contraceptive use did not differ.

The groups did not differ by age, socioeconomic status, level of education, IQ, general health status, or personality measures. American subjects demonstrated more knowledge both of family planning and maternal PKU. The Israeli women perceived the quality of their overall health as poorer, and more reported feeling that PKU had a negative impact on their lives.
This may have influenced the health and reproductive behaviors of the Israeli women in ways that differed from those of the Americans, who perceived themselves as more “normal” yet had more unplanned pregnancies.

Since no medical, socioeconomic, educational, IQ, personality, or social support differences were found between the two national groups, differences in contraceptive use and rates of planned pregnancies were attributed to culturally imbedded factors among the Israeli women, such as more conservative attitudes toward premarital sex, higher rates of marriage, and higher values placed on having biological children (versus adoption or sterilization). The cultural context of these women’s relationships seems to have contributed to greater use of more highly effective contraceptive methods.

The results of the longitudinal study of the maternal PKU life cycle clearly indicate that specific psychosocial factors predict adherence to medical recommendations in maternal PKU. The two most important factors were social support and positive attitudes toward treatment. However, social support correlated significantly with health-related behaviors only when it was defined as the degree to which a desired behavior is believed to be sanctioned by a social support network or the degree to which others offer encouragement and practical help. Parents, extended family, peers, and health care providers all play an important role, but due to practical considerations and perhaps developmental issues, those offering support may need to adjust their involvement depending on the individual woman’s stage in the maternal PKU life cycle. The study demonstrates that maternal PKU presents a life cycle experience that is unique. Women with PKU differed from their acquaintances and women with diabetes in nearly every dimension.

This study was designed for practical reasons, namely, to solve the critical health problem of PKU pregnancies that are unplanned or those in which treatment is poor or delayed. The main implication of this study is that no single support or intervention alone will solve the problems associated with maternal PKU. In the early stages, programs are needed to provide social support for addressing issues of sexuality and contraception. Compared with other women, women with PKU appear to be dependent upon explicit positive reinforcement to use contraception in order to reliably prevent unplanned pregnancy. Younger women need this support from peers while older women relied more on their mothers. As young women mature, they need to face decisions about childbearing. This study suggests that many women who are not sexually active or who delay making decisions about childbearing deny the possibility of pregnancy. Health professionals need to be more explicit about the importance of conscious, well-articulated decision making. It may be helpful not only to emphasize decision making, but also to link decisions with their logical behavioral consequences in terms of treatment or prevention. A delay in making the decision cannot be translated into inaction.

The time during which women initiate treatment for maternal PKU is the time when they need the most intensive advice from knowledgeable health professionals with whom they have supportive, trusting relationships. At this stage, support from mothers of young children with PKU who are familiar with the treatment may be able to supplement the support available from PKU programs. A Resource Mothers Program has been established in New England and preliminary reports suggest that these resource mothers, trained to work in the homes of young women with PKU who requested treatment, provided needed information, encouragement, and practical assistance.

After the woman’s pregnancy is well established, support from relatives becomes critical. However, it seems that attitudes and personality guide behavior
more than support, particularly with locus of control. Work has been done to instill a more internal locus of control in adolescents. Similar programs may be of long-term benefit. As a direct outgrowth of this study, a maternal PKU camp has been established and operated successfully for 3 years. The camp focuses on building social support for adherence to medical recommendations and instilling positive attitudes about treatment.

The results of this study suggest that individuals with a metabolic disease such as PKU require and benefit from programs especially designed for them. The programs need to be “transmedical,” helping those with PKU to gain access to medical services, adhere to medical recommendations, and use other available services. The research team cannot underestimate the need for a broad social support network. This can be accomplished by increasing the level of knowledge about PKU, both among professionals and in the general population. A first step would be to inform MCH directors and MCH programs about metabolic disorders and provide training for staff.

Services for individuals with PKU need to be paid for through grant programs or incorporated into existing programs. For example, the Resource Mothers could be included in outreach projects that work to prevent prenatal damage in high-risk populations.

Future research might focus on the next generation of young women with PKU who have maintained the diet throughout their lives. Although the research team believes that social support and positive attitudes will continue to be the best predictors of adherence to medical recommendations in maternal PKU, the team would like this hypothesis to be tested. Other research efforts should focus on evaluating programs designed to instill positive attitudes and increase social support. Finally, more cross-cultural studies are needed to determine what happens in the maternal PKU life cycle in other contexts. It may be that religious values and attitudes toward illness play a larger role than is currently known.

Publications

**Articles, Books, and Chapters**


Abstracts
None to date.

Presentations
None to date.
Predicting Teenage Pregnancy

Summary

Statement of the Problem

Based on a review of the literature as well as theoretical considerations, this project takes the position that a number of different causative complexes probably account for adolescent pregnancy. Rather than seeking a homogeneous profile of the adolescent who is at high risk for pregnancy, the researchers used profile analyses to identify various pregnancy risk profiles. The set of characteristics determining each profile should be useful in indicating potential interventions that are most likely to be effective in reducing risk in the adolescents exhibiting that profile.

Research Questions or Hypotheses

This longitudinal project was designed to identify risk profiles for ninth-grade females and for ninth-grade males, based on variables that previous studies have found to be related to teen pregnancy. The teens were assessed 2 years later, in 11th grade, in order to determine the females who had become pregnant and the males who had impregnated a female during the 2-year interim. The ninth-grade profiles were then related to the pregnancy outcomes to determine whether teens with certain profile characteristics were more likely to have been involved in a pregnancy than teens with other profile characteristics. The predictive power of the profile structure was compared with a linear multivariate procedure, the logistic regression analysis, with both analyses based on
the same set of ninth-grade predictor variables.

**Study Design and Methods**

This study employed a longitudinal prospective design. Social, psychological, and background factors were measured with self-report questionnaires, teacher ratings, and school records. The respondents were again interviewed in their schools at completion of 11th grade.

At retest, questions about pregnancy experiences were embedded in a short self-report measure of life events. Females were asked whether they had become pregnant; males were asked whether they had caused someone to become pregnant. Profile analyses and logistic regression analyses were performed on half the sample (Sample A) and the results tested for stability in the cross-validation (Sample B).

**Study Sample and/or Population**

Approximately 3,886 male and female adolescents from 7 school districts located in 3 counties in the Detroit metropolitan area constituted the original sample for this study. Two years later, 3,326 students from the original sample were located and retested, for a retention rate of 85.9 percent. Of this number, 1,749 were females (820 African-American and 929 white) and 1,577 were males (701 African-American and 876 white).

**Findings**

The cluster analysis was extremely successful in identifying females in ninth grade who were at risk for later teen pregnancy, and exceeded the logistic regression analysis both in predictive power in the original sample and in accuracy of prediction in the cross-validation sample.

Three complexes of variables stood out as indicators that the females in a cluster were at significant risk for teen pregnancy, particularly as these complexes of variables interacted with whether the females attended schools with high mean achievement test scores versus schools with low scores. The three complexes of variables were (1) dating (age at which female started dating and frequency of dating in ninth grade); (2) problem behaviors such as crashing a car, flunking a grade, etc., and school discipline referrals; and (3) school performance and goals (with grades being the most predictive variable in this complex, but college-bound expectations also relating well).

For clusters in which the z scores for all three complexes were in the moderate to strong range, females in both the high-achievement and low-achievement subclusters were at significant risk for teen pregnancy. If one or two of these three complexes of variables was in the high-risk direction on a cluster, the pregnancy rate for that cluster was above average for females in schools with low achievement scores, but not for females in schools with high achievement scores.

The correlations of the pregnancy rates for clusters of the two samples yielded \( r = .72, p < .001 \). In other words, if Sample A females in a particular cluster had a high teen pregnancy rate, it was very likely that females from that cluster in Sample B would also have a high teen pregnancy rate. In Sample A, the high pregnancy subclusters accounted for 65 percent of the pregnant teens, with only 26 percent false positives. In cross-validation to Sample B, if high pregnancy subclusters were defined as those that were high on Sample A, the research team correctly identified 59 percent of the teens who became pregnant by 11th grade, with 33 percent false positives. After the 19 clusters for Sample A were dummy coded, the multiple regression between the clusters and pregnancy yielded \( r = .38 \). The corresponding multiple
correlation for the cross-validation Sample B was $r = .29$. Thus, only a moderate amount of shrinkage occurred in accuracy of prediction from Sample A to Sample B. The predictive power of the profile analysis exceeded that of the logistic regression. For the logistic regression, the log linear $r$ for females for Sample A was .30 but decreased to .20 in cross-validation.

The superior predictive power of the profile analysis over the logistic regression appears to reside in the ease with which the profile analysis can accommodate interactions between and among variables. Each cluster is a complex statement of an interaction. One very important advantage of profile analysis in the present study is that no single complex was found consistently in all of the at-risk clusters. Although in theory logistic regression could also accommodate interactions, in practice this becomes very cumbersome. To illustrate the problems encountered in using logistic regression with the interactions, the research team examined the variables that were significant in the logistic regression analysis. Consistent with logistic regression, more of the low-achievement than high-achievement subclusters were associated with above-average pregnancy rates. However, four of the low achievement subclusters were not associated with above-average pregnancy rates, and two of the high-achievement subclusters were associated with above-average pregnancy rates.

Low socioeconomic status (SES), another significant variable in the logistic regression, was a factor in only two of the eight above-average pregnancy subclusters and was present in one of the below-average pregnancy clusters for females in both high-achievement and low-achievement schools. Dating at an early age occurred in only six of the eight subclusters; troubled behaviors occurred in six of the eight. Thus, in the cluster analysis, predictions of significant risk for teen pregnancy appear to be based on patterns of relationships among variables, rather than the linear combination of scores on some specific set of variables.

Consistent with other studies, male teens were involved in fewer pregnancy situations than female teens. (For the most part, female teens were impregnated by older men.) With respect to teen pregnancy, the ninth-grade profile structure for the males was very different from that for the females. However, the males’ profile structure proved very predictive of pregnancy involvement and more predictive than the logistic regression.

Publications

Articles, Books, and Chapters
None to date.

Abstracts
None to date.

Presentations


Summary

Statement of the Problem

In 1970, the U.S. Surgeon General issued a statement shifting the focus on childhood lead poisoning from case findings to prevention. The Surgeon General advocated mass screening and early identification of children with undue lead absorption (defined at that time as a blood lead level of 40 µg/dL or more). However, recent studies have provided evidence that mild to moderate elevation of blood and tooth lead levels in children is predictive of significant developmental delays in subsequent years.

As a result of these findings, the Centers for Disease Control and Prevention further lowered the lead action level in 1991 from 25µg/dL to 10µg/dL. According to this new action level, 1.7 million children in this country are considered at risk for lead toxicity. Currently, the public health approach to childhood lead poisoning is based on case findings and environmental investigation. Once a child with lead poisoning is identified, the source of lead is found and eliminated to prevent further ingestion. For children with lead levels between 10 and 20µg/dL, it may not be possible to identify a single environmental source responsible for the exposure.

In addition, lead is ubiquitous in the environment and its removal will take decades; consequently, children will continue to be exposed to environmental lead. A strategy that prevents the absorption of environmental lead could protect children from the toxic effects of lead while cleanup efforts continue. This study represents the first step in exploring
such a strategy. The study examined the effectiveness of adding the nutritional supplement calcium glycerophosphate to infant formula to reduce lead absorption from the gastrointestinal tract. This is the first longitudinal epidemiological study that attempts to demonstrate the effect of a nutritional supplement in preventing lead poisoning in children.

Calcium is the most thoroughly studied nutritional factor in lead metabolism. There is good evidence that dietary calcium competitively inhibits lead absorption by binding to and displacing lead from a common mucosal carrier on the intestinal tract. Dietary phosphorus also appears to inhibit lead absorption, presumably by binding with lead in the small intestine to form an insoluble complex. Moreover, calcium and phosphorus, when given together, show additive effects on lead absorption. However, the effect of these dietary factors is likely to be short-lived. Evidence indicates that in order to prevent lead absorption, the ions must be present with the lead as it passes through the absorptive areas of the intestinal tract. For this reason, infant formula is an excellent medium to provide the calcium glycerophosphate supplement. Because children drink formula frequently during the day, the effect of the supplement should be greater than if given in single or twice-daily dosing schedules.

Research Questions or Hypotheses

This study was designed to test the hypothesis that calcium glycerophosphate supplementation of infant formula will decrease the absorption of lead in infants and that decreased absorption of lead will be reflected by lower blood lead concentrations (lead retention) in children taking the formula supplemented with calcium glycerophosphate. The primary objectives of this study were to (1) determine the safety of calcium glycerophosphate–supplemented formula in children and the acceptability of this approach to parents, and (2) estimate the degree of reduction in lead retention in a cohort of children using calcium glycerophosphate–supplemented formula, in order to plan for the larger studies that would be required to show the efficacy of this approach in preventing childhood lead poisoning.

Study Design and Methods

This was a double-blinded, randomized clinical trial. After a 1-month run-in period during which infant eligibility was determined, 103 infants were randomized to either a control group or a treatment group. The control group received standard iron-fortified formula (Enfamil with iron) containing 465 mg Ca/L and 317 mg P/L. Infants in the treatment group received Enfamil with iron that was supplemented with calcium glycerophosphate to a concentration of 1.8 g Ca/L and 1.39 g P/L. Both groups received the assigned formula for a period of 9 months. Only infants who were drinking at least 20 ounces of formula per day prior to randomization were allowed to participate.

Parents returned with their infants monthly to monitor the infants’ formula tolerance and intake, growth, and excretion of urine calcium and creatinine. Blood lead concentration was measured for all infants at baseline, at 4 months after randomization (month 5), and at completion of the study (month 10). Venous blood specimens were obtained for blood lead, which was analyzed with anodic stripping voltammetry. The research team also monitored iron status (serum ferritin, total iron-binding capacity [TIBC], erythrocyte protoporphyrin [EP], hematocrit), serum calcium, and serum phosphorus. Environmental exposure to lead was measured by obtaining dust and water samples from the infants’ homes. These samples were collected approximately 30 days following randomization. Additional samples were collected if an infant changed residence during the course of the study.
Study Sample and/or Population

This study was conducted in Lawrence, Massachusetts. Historically, Lawrence has one of the highest rates of lead poisoning in the State; in 1982, 4.5 percent of the children screened had Class II lead concentrations (at that time blood lead $\geq 30$ µg/dL) or above. In 1988, door-to-door screening revealed that 2.7 percent of the children under 6 years of age had Class II (blood lead $\geq 25$ µg/dL) lead concentrations. In order to maximize the chances of enrolling children who were at risk for elevated blood lead, only infants living in a specific geographic area identified as a high-risk area for lead poisoning were eligible to participate in the study. All infants began the study between 3 and 7 months of age.

Findings

Of the 516 infants who were screened, 314 were enrolled in a 1-month run-in period to evaluate their eligibility; 103 of these infants were eventually randomized to participate in the trial and 81 (79 percent) completed the trial. Final blood samples were obtained from 10 of the 22 children who dropped out of the study. Infants in the treatment and control groups were similar at baseline with respect to demographic characteristics, lead content in dust and water from their homes, mean formula intake, height and weight, median blood lead concentration, serum calcium, serum phosphorus, TIBC, and urine calcium/creatinine excretion. The treatment group had a significantly lower median serum ferritin (45.1 ng/dL) at baseline than did the control group (69.9 ng/dL).

Median blood lead concentration for the two groups was not significantly different at month 5 or month 10, but mean change in blood lead concentration between baseline and month 5 was significantly lower for the infants who received calcium glycerophosphate-supplemented formula than for the control group. During the first half of the study, the median blood lead concentration increased by 80 percent (from 2.5 to 4.5 µg/dL) for the control group, compared to a 57-percent increase (from 2.6 to 3.5 µg/dL) for the treatment group. However, this effect did not persist during the latter half of the study. By month 10, both groups had similar median blood lead concentrations and the change in blood lead between baseline and month 10 was not significantly different for the two groups.

In the treatment group, the mean calcium intake of slightly more than 1,700 mg/day for the first 5 months and slightly more than 1,500 mg/day during the latter half of the study was not associated with any adverse effects. Median urine calcium/creatinine excretion was similar for both groups throughout the study. Ten children who were evenly distributed between the treatment and control groups had at least one urine sample with a Ca/Cr ratio above the age-related norm. None of these high ratios was associated with hematuria, and 90 percent of these infants had ratios in the normal range when a repeat urine sample was obtained.

Children in the treatment and control groups had similar mean serum calcium concentrations throughout the study. Mean serum phosphorus was significantly higher for the treatment group than for the control group at month 5, but no abnormally high phosphorus levels were present in either group. Twenty-two infants had serum phosphorus levels that were lower than the age-related norms. These children were equally distributed between the treatment and control groups. In only one case was the phosphorus level below 4 mg/dL. When a serum ferritin level of $<12$ ng/dL was used to define iron deficiency, a higher proportion of children in the treatment group were iron deficient at month 5 and month 10, compared with those in the control group. At month 5, 32
percent of those in the treatment group were iron deficient, compared with 10 percent in the control group; at month 10, 37 percent in the treatment group were iron deficient, compared with 18 percent in the control group. However, it is likely that the higher prevalence of iron deficiency (by this definition) in the children receiving the calcium glycerophosphate–supplemented formula is due to the lower serum ferritin concentrations in the treatment group at baseline.

Mean TIBC was similar for the two groups at baseline and at month 5 and month 10. Moreover, there was no significant difference between the two groups in the mean change of TIBC or serum ferritin from baseline to month 5 or month 10.

The majority of the children in this study exhibited a very small and clinically insignificant rise in blood lead over the study period. Because of low exposure to environmental lead, this trial does not adequately evaluate the effect that calcium glycerophosphate supplementation has on blood lead in infants between 3 and 17 months of age. Although the effect of the calcium on blood lead during the first half of the study tends toward the direction and magnitude expected, it is not clear why this effect disappears by month 10. Changes in blood lead in children who sustain low environmental exposure may be due to factors that would not be affected by dietary calcium intake, such as the inhalation of dust lead and/or the reabsorption of bone lead. These factors may be playing a larger role in determining blood lead concentration than they would in children with a higher exposure to environmental lead.

The low lead concentrations of the children in the study may reflect a nationwide trend toward lower blood lead concentrations of the entire U.S. population. This trend is attributed primarily to the deleading of gasoline. Selection bias also may have contributed to the low level of exposure among the children in the study. By selecting mothers who were most likely to comply with the study protocol and least likely to drop out after randomization, the research team also increased the chances of selecting infants who were at lower risk for lead poisoning. The data from a concurrent study examining blood lead levels in Lawrence, Massachusetts, revealed that the mean blood lead level in children ages 1–2 years was 8.1 µg/dL. This is significantly higher than the mean blood lead level of the children in the study (p = 0.001). Other prospective studies of at-risk populations of children must consider the tradeoff between enrolling high-risk children and the potential loss to followup. Although this trial did not adequately assess the impact of the calcium glycerophosphate–supplemented formula on blood lead, it did establish the safety and acceptability of the formula for children ages 3–17 months. Data from this study will simplify the implementation of future trials to examine the effect of calcium supplementation in a more highly exposed population.

Publications

Articles, Books, and Chapters


Abstracts


Presentations

None to date.
Predicting Preschool Function from Contingency Intervention

Summary

Statement of the Problem

Most early intervention programs for infants with disabilities are concerned with the acquisition of developmental milestones. This study evaluated the long-term impact of an intervention designed to motivate infants with developmental disabilities to explore their environment. This approach is of particular importance in improving the functional status of young children with disabilities because it teaches infants how to actively and productively engage their physical environment. Providing systematic contingency experiences early in development promotes the generalization of learning and problem-solving strategies in lieu of teaching a series of specific skills. When added to traditional intervention regimens (particularly in the areas of cognition, motivation, and adaptive skills), this type of intervention may improve long-term outcomes in children with disabilities.

Research Questions or Hypotheses

The contingency intervention was designed to help infants become more active in approaching and controlling the physical environment. The program provided immediate, concrete, enjoyable incentives for simple limb movements, allowing children to experience direct control of environmental stimulation. Preliminary findings indicated that the immediate goals of the intervention program were met. There was evidence that infants with developmental disabilities learned to control toys contingent on their...
activity. In addition, short-term changes in developmental status, means-ends behavior, and attention were observed as a function of time spent in intervention and percentage of time spent actively attending contingency information. Therefore, the goal of this study was to determine whether early contingency intervention was related to preschool status.

**Study Design and Methods**

Several outcome domains were assessed, including measures of cognition, motivation, and adaptive life skills. It was expected that the amount of time in the intervention and the amount of time attending contingent information would contribute to better functioning in the preschool period in one or more outcome areas over and above the effects of pretest status and background variables.

Data on pretest and posttest status of infants as well as intervention variables were extant. All participants had been assessed initially 2-3 weeks before beginning the contingency intervention. Likewise, all had received 3 months of home-based, individually tailored contingency intervention sessions administered either by mothers and/or by the project staff member who visited weekly. Time spent in contingency intervention sessions was recorded online via a computer that recorded minute-by-minute data on the child’s learning and other observations such as the child’s attention to the contingency; the data were input by staff during the weekly visits. Finally, all children were retested at the end of this period.

For this preschool followup, the research team collected new information on the children’s status and updated the database on a number of background variables such as child health. The measures examined in relation to outcome included background variables, pretest status, and intervention measures. The outcomes examined were the child’s cognitive status, several domains of adaptive living skills, and motivation as assessed by examiner ratings of attention and motivation during assessment.

Preintervention and postintervention measures of child status included scores on the Bayley Scales of Infant Development. Intervention measures included the number of minutes the child spent in contingency intervention as logged on the intervention computer, as well as an observer’s online record of the time the child spent actively attending during the intervention sessions. The battery of preschool outcome measures collected were cognitive status as assessed by either the Bayley Scales of Infant Development or the Stanford-Binet Intelligence Scale as appropriate, the Vineland Adaptive Behavior Scales, and examiner ratings of children’s motivation and other relevant behaviors during testing. The background variables expected to influence outcomes included family socioeconomic status, disability type, parental stress, and child health information.

**Study Sample and/or Population**

The participants in the study were 51 children with Down syndrome, 24 children with cerebral palsy, and 17 children with other developmental disabilities who had participated in the contingency intervention program as infants. All were showing at least a 25-percent lag in mental development at the time of initial enrollment. They had originally been recruited for the study when they were 3–15 months of age and had been seen most recently 1 year after the contingency intervention. The sample of 92 children represents 89 percent of those who initially received the contingency intervention. Of those not seen, 8 percent had either died or were unavailable due to long-term hospitalization; the remainder could not be located or were unable to participate. The mean age of the children was 4.5 years. All had experienced approximately
2–3 years of preschool for children with disabilities in the State but had not yet entered kindergarten.

**Findings**

The research team found that a few of the preschool outcomes were related to contingency intervention. By far the strongest predictor of all preschool outcomes was pretest status. However, the amount of contingency intervention time contributed significantly to the variance for several specific outcomes. The two measures of intervention examined also showed differential effects on outcome. Total time spent in contingency intervention predicted a more favorable motivational profile in preschoolers with developmental disability. Children who had greater contingency intervention time expressed more positive emotion and were less likely to engage the examiner socially than children who had less intervention time. (Fewer social bids to the examiner was related to greater focus on the tasks and materials during assessment.) The percentage of time attending contingent consequences predicted the preschooler’s mental age. Mean differences favored subjects who attended more during the intervention and confirmed the regression results. The more the intervention was attended, the greater the child’s mental age at time of followup. Children who spent more time attending contingencies also had better communication scores on the Vineland than did those who spent less time attending contingency.

Contingency intervention, when combined with more traditional stimulation and therapy regimens, appears to be an intervention technique that can contribute to improved functional outcome in children with developmental disabilities. Immediate effects on motivation, attention, and cognitive status were observed when infants received a short-term but consistent program of learning to control environmental outcomes. There was also evidence that more contingency intervention and more active involvement in learning contingencies as measured by attention contributed to better outcome at ages 4–5.

It is important to provide systematic contingency experiences in infancy when expectations about control and means-ends behavior are normally established. Due to physical and cognitive delays, children with developmental disabilities may require added contingency experience to propel greater motivational and cognitive development. Remarkably, participation in the intervention still had measurable effects on specific outcomes in the preschool period. This finding is striking when one considers the program’s short-term nature and the lack of further systematic interventions specific to contingency learning. The findings suggested that infants readily generalized their contingency learning experiences to new settings at the time of the initial intervention. Because contingency experiences may generalize readily to new contexts and serve as the basis of new learning experiences, the finding of long-term effects is plausible.

The contingency intervention was designed to augment nonsocial contingencies early in the disabled child’s life. Such contingency learning occurs and is consolidated during infancy. Contingency experience early in life is thought to affect the child’s developing awareness of self-efficacy and competence. Contingency intervention enhanced disabled children’s development through the systematic provision of simple but varied learning experiences. Relatively inexpensive, low-end technology is readily available to provide contingency experiences in early intervention settings on a broad scale. Switches, adapted toys, or any type of toy that requires independent activation, control, or manipulation by the child are cost-effective practical tools that can promote motivation and cognitive functioning in the young disabled child.
There is no reason that such technology cannot be used on a regular basis in conjunction with occupational and physical therapies in intervention settings and in the home.

To make this a reality, funding should be developed to provide basic contingency and technology resource services at intervention centers. Staff would thus have at hand a variety of toys and devices with which to design appropriate contingency opportunities for children with a wide variety of sensory and motor difficulties. These could then be available for home use. In early intervention settings, not enough attention is currently placed on quickly providing adaptive aids to young children to allow them normal levels of self-initiated contingency play; yet research in general and the results of this study show that this type of stimulation may be the most important.

The involvement of parents in providing contingency experiences was key to the success of the project. Parental involvement not only made possible the systematic provision of contingency intervention, but also provided parents with concrete evidence of their child’s ability to learn, given appropriate support. It is clear from the study that contingency devices and toys need to go home, but they also need to be varied systematically to promote learning. At each center, programs should be developed by which parents might readily purchase and recycle or loan and return contingency toys and adaptive devices as their child outgrows them or needs change.

Increased availability of technology is not sufficient, however. Appropriate training is needed for intervention personnel, especially occupational, physical, and speech therapists, in addition to special educators. Given the multiple sensory and motor deficits of many children, a team approach is important in identifying the positions and movements with which children can most comfortably and readily experience contingencies and learn. All team members need to be familiar with the possible technology options as well as the cognitive, behavioral, and physical limitations of their clients. Both inservice and preprofessional training should be held to provide professionals with information on adaptive equipment and resources. Training should also focus on the nature of early learning and motivational development, behavioral assessment techniques, and their application to intervention with adaptive technology.

Besides the incorporation of contingency activities into early intervention in the short-term, consideration should be given to long-term goals of designing and evaluating developmentally appropriate interventions that increase opportunities for contingency and environmental control in the daily lives of children with disabilities. The general principles of contingency intervention can be used to develop new applications in the areas of mobility and language development. Research on the impact of contingency intervention on development of mobility and language could lead to new strategies for improving functional outcomes for children with developmental disabilities.

Publications

Articles, Books, and Chapters


Lewis M, Sullivan MW. 1996. The role of situation and child status on emotional interactions. In M Lewis, MW


Abstracts


Presentations


A Telephone Educational Intervention for Rural Children with Asthma

Summary

Statement of the Problem

Children with moderately severe to severe asthma represent a significant population with special health needs. Recent advances in self-care education programs coupled with state-of-the-art medical care have had an impact on morbidity, health care utilization, health economics, knowledge about asthma, and self-efficacy for children with asthma and their families. Implementation of these programs has not been attempted in rural minority populations.

The Children’s Medical Services of New Mexico and the University of New Mexico Pediatric Pulmonary Division determined that a major problem for children with asthma and their families in New Mexico involves identification and referral to appropriate services, medical and educational intervention, and followup in the communities. Because of the largely rural nature of New Mexico and the large population distribution of Hispanics within the State, a collaborative program was initiated to determine effective methods for rural case management, to establish an educational program with telephone followup adapted to family needs, and to encourage collaboration for effective delivery of tertiary and primary care.

Research Questions or Hypotheses

The purpose of this investigation was to determine whether a comprehensive medical and educational self-management program for children with asthma who live in rural communities had an impact on asthma...
morbidity as well as on cost of medical care and family stress. To address this question, two groups of children were studied. One group received comprehensive medical care (CMC); the other received comprehensive medical care plus a structured self-management education program and periodic telephone followup by a nurse educator (CMC-Plus).

The study tested the following hypotheses: Provision of CMC-Plus (compared with CMC alone) would
1. Reduce asthma morbidity and health care utilization as indicated by decreased emergency room visits, hospitalizations, and daily symptoms; fewer school days and parent workdays missed, and improved pulmonary function parameters.
2. Reduce family stress, as measured by the Parenting Stress Index.
3. Enhance self-management and self-efficacy as measured by self-report on structured interview.
4. Enhance self-reported satisfaction with delivery of asthma-related health care services, both at the tertiary and primary care levels.
5. Reduce hospitalization and emergency room costs, but not decrease the overall costs of providing asthma services.

Study Design and Methods

The population was divided into the CMC or CMC-Plus group. Subjects were followed for 2 years and data were collected every 6 months. The following instruments were used to collect data relevant to the hypotheses: The Basic Asthma Questionnaire and the Satisfaction with Care Questionnaire (both developed for the project), the Pulmonary Function Test, and the Parenting Stress Index.

Study Sample and/or Population

The study sample comprised 302 subjects, randomized by county of residence. The mean age for the combined sample was 8.5 years; 36 percent of the subjects were female and 64 percent were male. The ethnicity of the sample population was as follows: 61 percent Hispanic, 28 percent non-Hispanic white, 8 percent Native American, and 4 percent other. The average family size was 4.7 members. Forty-three percent of the mothers were high school graduates and 37 percent had attended trade school, junior college, or college; 48 percent were homemakers or unemployed. Thirty-five percent of the fathers were high school graduates, and 35 percent had attended trade school, junior college, or college. Forty percent of the families reported earning less than $10,000 per year, and an additional 39 percent reported earning between $10,000 and $20,000 per year. Forty-seven percent of the families had a current smoker in the home.

Although 73 percent of the families reported living within city or town limits, a number of families had to travel some distance to receive their medical care. Most families (66 percent) reported that they received regular asthma care fairly close to home (i.e., within 10 miles or less), but 14 percent reported having to travel 30 miles or more for regular care, and 10 families traveled 75 miles or more. Sixty-three percent of all families had a hospital within 10 miles of home, but 11 percent had to travel 30 miles or more to reach a hospital, and 4 families had to travel more than 75 miles. CMC-Plus families reported being farther away from a hospital, 18.2 (± 25.4) miles compared to CMC families, 10.9 (± 11.7) miles (p = .0019).

The CMC and CMC-Plus groups were comparable on all baseline demographic data except for age and father’s education. CMC patients were significantly older than CMC-Plus patients: The mean age for CMC patients was 9.4 years, compared with 7.2 years for CMC-Plus patients (p = .0001). The fathers of CMC
patients had significantly less education: 37 percent of CMC fathers had not completed high school, compared with only 19 percent of CMC-Plus fathers (p = .01).

Findings

Asthma morbidity and health care utilization decreased significantly in both groups, as measured by reported hospitalizations, emergency room visits, symptoms, school days missed, and parent workdays missed. This decrease was observed at 6 months, with very little additional decrease later in the project period. This effect was sustained for 2 years. There were no significant differences between the two groups. Therefore, structured self-management education and phone followup by nurse educators did not have a measurable impact over individual education alone with respect to morbidity and health care utilization. No differences by ethnicity, income, or any other demographic variables were observed, with the exception of age: Children 4 years and younger were hospitalized more frequently, and parents reported more symptoms for children 5 years and older.

Pulmonary function was measured by percent predicted for FVC, FEV1, and FEF 25–75 percent. None of the lung function measurements significantly improved over time with the exception of FVC, but the small increase observed in the FVC was not clinically significant. There was no significant difference between the two groups for any measures with the exception of the FEF 25–75 percent, which was higher at most time points for the CMC group. Methacholine challenge parameters did not change over the project period, nor were there any differences between groups.

Family stress, as measured by the Parenting Stress Index, did show an overall reduction in the total stress score in the CMC group. This reduction may have occurred because of the high baseline score in this group. The mean score for the CMC-Plus group did not change over time.

Self-management skills significantly increased over time (p < .0001). The CMC-Plus group scored marginally higher (p = .0556) than the CMC group at all time points until the 2-year visit. In both groups, the largest increase in self-management skills occurred in the first 6 months. Parental self-efficacy increased significantly over time in both groups (p < .0001), and it appears that there was a trend (although not statistically significant) for the CMC-Plus group to score higher than the CMC group. Parents felt more confident in treating an asthma episode than in preventing an episode.

The CMC-Plus group expressed more overall satisfaction with the program, but the only individual satisfaction-related variable that differed between the groups was the perception of their local physicians’ knowledge about asthma. The CMC group perceived that their physicians’ knowledge about asthma increased more than did the CMC-Plus group.

Publications

Articles, Books, and Chapters

None to date.

Abstracts


**Presentations**


Hanson JE. 1995. Acquisition of asthma self-management skills in parents. Poster presentation at the American Thoracic Society Meeting, Seattle, WA.


Hanson JE. 1995. Home remedies for asthma in New Mexico. Poster presentation at the First Asthma Management Conference, Washington, DC.

Hanson JE, Murphy S. 1994. Acquisition of asthma self-management skills in parents. Poster presentation at the American Thoracic Society Meeting, Boston, MA.

Lapidus J. 1995. A nursing phone follow-up intervention in pediatric asthma. Poster presentation at the American Thoracic Society Meeting, Seattle, WA.


Murphy S. 1995. Impact of a statewide asthma program on rural asthma morbidity. Slide presentation at "Asthma: Theory to Treatment," a conference sponsored by the American Academy of Allergy, Asthma and Immunology and the American Thoracic Society, Chicago, IL.

Murphy S. 1994. Impact of a statewide asthma program on rural asthma morbidity. Poster presentation at the American Thoracic Society Meeting, Boston, MA.


Summary

Statement of the Problem

Weight gain during pregnancy has been shown repeatedly to be associated with infant birthweight. Birthweight in turn is highly associated with perinatal mortality, even in infants delivered at term. Precisely why birthweight and maternal weight gain are associated is not known. Despite the lack of a detailed mechanism demonstrating a causal relationship, it is common practice to encourage maternal weight gain, with the expectation that appropriate weight gain will optimize fetal development.

In 1990, the Institute of Medicine (IOM) issued new weight gain guidelines for pregnancy. The recommendations were determined after a review of the literature that related weight gain to pregnancy outcomes of mothers and birth outcomes of infants. The literature on pregnancy weight gain was silent on the issue of how maternal weight gain and body composition changes, particularly fat gain, were related. In addition, little information was available relating maternal fat or other body component changes to birthweight. The information that had been reported was generally based on simple and imprecise estimates of body composition. Yet there is wide interest in fat gain during pregnancy, since the conventional wisdom has been that pregnancy weight and fat gain contribute to obesity in U.S. women.

To understand the relationship of maternal weight gain to fat gain, it was necessary to study weight gain and body composition changes in a sufficiently large group of American women so that different body mass...
index (BMI) subgroups could be examined separately. Because concerns persist about differential birth outcomes in black, white, and Hispanic women, the study included women from these groups.

**Research Questions or Hypotheses**

The main purpose of this research was to test the following hypotheses:

1. There is a positive correlation between gestational weight gain and body fat gain (i.e., higher weight gain is associated with higher fat gain) in adult pregnant black women and adult pregnant white women.

2. White women store more fat than black women during pregnancy, after adjustment for gestation duration (after 37 weeks), initial body fat, height, parity, and age.

3. Fetal growth (birthweight, length, and head circumference) is greater in white women than in black women after adjustment for initial body fat, height, parity, age, gestation duration (after 37 weeks), and infant’s sex. The research team postulated a positive correlation between fetal growth and gestational fat mass increase in both ethnic groups. Therefore, fat mass increase will be a significant covariant (predictor) of fetal growth.

**Study Design and Methods**

Body composition was measured twice during pregnancy, at 14 and 37 weeks on average. Many different body composition measures were used, so that in addition to the determination of body fat based on the most advanced body composition models, a variety of approaches to body composition assessment could be evaluated. Selected measurements obtained were combined with bone mineral mass measurements determined at 3 weeks postpartum, and used in a multicompartiment model to estimate changes in fat and lean tissue during the measurement period. The fat estimate obtained in this way for each woman was used to evaluate historical approaches to body composition assessment, including estimates based on anthropometry, total body water, body density, and total body potassium.

**Study Sample and/or Population**

Two hundred nonsmoking, healthy black, white, and Hispanic women ages 18–35 were recruited from prenatal care clinics located at Harlem Hospital Center, Presbyterian Hospital in the City of New York, St. Luke’s Roosevelt Hospital, and the Maternity Center, all in the borough of Manhattan, New York City.

**Findings**

The study showed that as weight gain increased during pregnancy, fat gain also increased in all BMI categories. Underweight women, the group for whom the highest weight gain was recommended, gained the most fat between weeks 14 and 37, when they were gaining as recommended (for the whole of pregnancy). Obese women gaining as recommended did not gain body fat during the measurement period.

An array of biological and demographic variables was examined for a relationship to birthweight, with backward elimination regression analyses. The key findings of these analyses were as follows: First, higher weight gain was associated with increased birthweight, but higher fat gain was associated with lower birthweight; second, when total body water was studied in place of fat gain, higher body water was associated with increased birthweight and weight gain was no longer an independent predictor of birthweight.

Study of prior anthropometric equations for the prediction of body fat demonstrated that these equa-
tions, which were developed based on nonpregnant women, significantly misestimated body fat, particularly at the second measurement (at or after week 37 of gestation). New equations were developed with a random half of the study population. In an internal validation study, these equations predicted fat at weeks 14 and 37 and fat change from week 14 to 37 in the remaining sample of the study women.

Weight gain, fat gain, and birthweight did not differ among the black and white women studied. The methodologic studies of the standard methods used traditionally to estimate body composition (underwater weighing, total body water, total body potassium) indicate that they can give significantly different estimates of body fat when each measure is used separately. The research team has reported preliminary data comparing these methods and allowing fuller interpretation of differences in fat changes reported in studies using the different methods.

The anthropometric equations developed in this study should be tested for use in the clinical setting so that those women whose fat gain near term has been high can be identified and counseled before delivery about weight control measures that might be advisable postpartum. Further study is also needed concerning the factors that interfere with loss of gestational fat gain.

Studies should be directed at determining whether specific dietary patterns can influence the partitioning of nutrients between the mother and the infant, so that birthweight can be optimized while maternal fat gains are limited.

Finally, efforts are needed to assist breastfeeding women during the early weeks of lactation, especially in light of the recent reductions in length of postpartum hospital stays.

Publications

Articles, Books, and Chapters


Abstracts


**Presentations**


Lederman SA. 1994. Pelvic and total body bone density at three weeks postpartum and at 6 months and one year postpartum. Presented at the Annual Meeting of Experimental Biology, Anaheim, CA.

Lederman SA. 1993. Weight gain and fat gain in pregnant women of different BMI. Presented at the Annual Meeting of Experimental Biology, New Orleans, LA.


tions for estimating body fat in pregnant women using anthropometry. Paper presented at the American College of Nutrition Annual Meeting, Chicago, IL.


Summary

Statement of the Problem

In developing countries, breastfeeding is associated with lower infectious morbidity. In the United States and other developed countries, the association between breastfeeding and infectious morbidity is still unclear. Clarifying this relationship has become a major public health issue in view of recent campaigns to increase the percentage of breastfed infants. Research supporting the claim that breastfeeding is protective is contradictory and has numerous research flaws.

Research Questions or Hypotheses

The principle aim of this study was to determine the relationship between infant feeding and infectious illnesses during the first year of life.

Study Design and Methods

The design of this study attempted to correct previous methodological flaws in studies examining the relationship between infant feeding and infectious illnesses. Prior studies investigating the relationship between infant feeding and infectious illnesses in developed countries have provided conflicting data about whether breastfeeding protects against common infectious illnesses early in life. These conflicts may be due in part to the failure to consider the following methodologic issues: (1) Collecting data prospectively at frequent intervals for detection of infections and of feeding practices; (2) specifying what is...
meant by infectious illnesses and breastfeeding; (3) controlling for confounding variables such as social class or the presence of siblings in the household; and (4) applying appropriate analytical strategies to a population in which both feeding and exposure to illness change over time.

The research team obtained information from mothers during a postpartum interview and mailed questionnaires monthly during the first year of the child’s life. Study participants were living in Copenhagen, Denmark. Rates of illness were compared in breastfed and formula-fed infants with incidence density ratios (IDR), controlled for major covariants.

Enrollment and postpartum interview

Study participants were informed that the research team was examining infant feeding and illness during the first year of life, but were told neither the specific illnesses nor the preconceived hypotheses regarding the relationship between infant feeding and illness.

Interviews were conducted by the principal investigator or by one of three research assistants trained to use a structured precoded Danish interview. The questionnaire was piloted to ensure that the information was obtained and recorded in a reliable manner by all four interviewers.

The purpose of the postpartum interview was to collect demographic information as well as information on the mother’s plans for infant feeding and child care. Socioeconomic status was assessed with the Hollingshead Scale of Social Class and a standardized Danish classification of social class based on the mother’s job and education. Both classifications use a scale from 1 (highest social class) to 5 (lowest social class). The research team found no important or statistically significant differences between the results of the Hollingshead and Danish classifications.

Monthly questionnaire

The purpose of the questionnaires was to gather information about feeding, infectious illnesses, and covariants that might be related to the risk of infection. A questionnaire was mailed to each participant every month during her child’s first year of life. To ensure that it would be completed correctly, the questionnaire was reviewed for clarity and understanding with the mother after the postpartum interview. To elicit information about illnesses, the mother was asked whether the child had been sick, the type and duration of symptoms, and how the mother responded to the symptoms (e.g., called a friend or physician, went to a physician, etc.). To elicit data about symptoms in a systematic manner, the mother was asked about a list of 17 specific symptoms (e.g., “Did the child have a temperature >38.5°C?”). Feeding histories and changes in feeding method also were obtained; the research team asked specific questions about the frequency (time and number) of feedings with breastmilk and formula, the brand of formula, and whether solid foods were given. Finally, information was obtained on illnesses in the household and on child care arrangements.

Classification of feeding method

Each infant’s feeding method for the month was categorized in one of five feeding groups, by using the amounts of breastfeeding and formula feeding reported in the monthly questionnaire. This categorization was based on a modified version of the World Health Organization’s classification of infant feeding. The categories were (1) 100 percent breastfeeding; (2) breastfeeding > formula feeding; (3) breastfeeding = formula feeding; (4) breastfeeding < formula feeding; and (5) 100 percent formula feeding. For the basic analyses, the research team defined the “breastfeeding group” as categories 1 and 2 and the “formula feeding group” as categories 3, 4, and 5. This classification of feeding was independent of the feeding of solids.
Classification of infectious illnesses

Diagnoses of infectious illnesses were based on the mothers’ monthly reports of specific symptoms of illnesses and on information learned about their child’s health through doctor visits. In this study, the research team focused on four types of illnesses: (1) Gastroenteritis (GE), (2) upper respiratory illnesses (URI), (3) otitis media, and (4) lower respiratory illnesses. The diagnoses of gastroenteritis and upper respiratory infections were made by a computer algorithm, based on the presence of several symptoms and the timing of these symptoms as reported by the mother.

A diagnosis of GE required one of the following mutually exclusive categories: (1) The presence of at least two of the following symptoms for a duration of 2–20 days: temperature > 38.5°C, increased frequency of stools, loose stools, or vomiting; (2) at least three of these symptoms if the duration of symptoms was not reported; or (3) a physician diagnosis of gastroenteritis as reported by the mother after consulting with the physician in person or by telephone.

A diagnosis of URI required one of the following mutually exclusive categories (after excluding patients who received a physician’s diagnosis of otitis media or lower respiratory infection such as bronchiolitis, croup, pneumonia, and asthma): (1) The presence of at least two of the following symptoms for 2–20 days: temperature > 38.5°C, rhinorrhea, cough, or fast breathing; (2) at least three of the above symptoms noted if the duration of the symptoms were not reported; or (3) a physician diagnosis of upper respiratory illness as reported by the mother after consulting with the physician in person or by telephone.

The diagnoses of otitis media and lower respiratory infectious illnesses (pneumonia, bronchiolitis, and croup) were made based on the mother’s report of that diagnosis by a physician.

Classification of covariants related to risk of infection

Five susceptibility factors were considered: (1) Factors obtained while the mother and child were still in the hospital, namely, birthweight, social class, and the number of other children in the family; and (2) factors obtained from the monthly questionnaires, namely, child care and other illnesses in the family.

Social class was classified in two categories, upper (groups 1, 2, and 3) and lower (groups 4 and 5). Child care was classified in three categories, no child care, small-group child care (1–4 children), and large-group day care (5–20 children). “Other children in family” was classified in two categories, none and at least one. “Other infectious illnesses in family members” were classified in two categories, none and at least one other family member having an infectious illness.

Study Sample and/or Population

After obtaining informed consent, mothers were enrolled consecutively on the third or fourth postpartum day if their babies met the following criteria: (1) birthweight > 2000 grams, (2) gestational age > 36 weeks, and (3) no evidence of serious congenital disabilities or underlying illness. This population was chosen to exclude infants who might be preferentially fed in a specific manner and/or those at increased risk for infections due to an underlying condition.

This study was a prospective evaluation (over the first 12 months of life) of 500 infants born consecutively at the Gentofte University Hospital, a university-affiliated community hospital serving the Northeast region of greater Copenhagen. Between February 1 and June 30, 1985, women whose children were eligible were invited to participate in the study until a cohort of 500 was reached. To enroll this number, 548 women were contacted, and 48 refused. Potential sub-
jects were infants delivered consecutively (except for weekends).

The return rate of monthly questionnaires was 92 percent at 1 month, 75 percent at 6 months, and 44 percent at 12 months. Of a possible 6,000 infant months (500 subjects X 12 months), the research team obtained data for 4,364 infant months (73 percent).

Findings

All or mostly breastfeeding decreased from 88 percent at 1 month to 20 percent at 12 months of life. After adjusting for major covariants, the research team found no statistically significant relationship between the type of infant feeding and the incidence of four categories of infectious illnesses: Gastroenteritis, upper respiratory illness, otitis media, and lower respiratory illness. The adjusted incidence density ratio was 1.067 for gastroenteritis and .984 for upper respiratory illnesses. These data suggest that breastfeeding conveys no substantial protective effect against the occurrence of infectious illnesses early in life in a largely middle-class urban population in a developed country.

As expected, during the first 6 months of life, there was a predominance of breastfeeding, while during the second 6 months, formula became the predominant method of feeding.

The monthly incidence densities of illness in each feeding group were similar, suggesting no substantial effect of infant feeding. The results were similar when the research team examined the relationship between infant feeding and infection using two different categorizations of feeding: (1) no breastfeeding versus at least some breastfeeding (which included categories 1, 2, 3, and 4); and (2) each of the original feeding categories compared simultaneously. To examine whether there was a delay in the biological effect of breastfeeding, the research team also examined the method of feeding at each month and the occurrence of infections in the following month. Again, no significant protective effects of breastfeeding on the incidence of illnesses were found by using this method.

Breastfeeding had a statistically significant protective effect for otitis media even after adjustment for birthweight, social class, number of children in the family, child care, and other illness in the family. However, when the research team added the age variable, this effect was no longer statistically significant, although there was still a trend favoring breastfeeding. The change from statistically significant to nonsignificant reflects the age-dependent nature of otitis media. Finally, breastfeeding had no protective effect on lower respiratory illnesses.

To examine whether children who dropped out of the study affected the results, the research team compared subjects who continued in the study and those who dropped out. At each 3-month interval, subjects who returned the questionnaire at the end of the interval were considered as continuing in the study. Subjects who missed the last month of the interval, but had returned the questionnaire of the previous month were considered as having dropped out. Of the 32 comparisons (8 comparisons for each 3-month time period), there were statistically significant differences between the two groups at 3 and 6 months only in terms of (1) more representation of the upper social classes in those who continued in the study at 3 and 6 months, and (2) more representation of older mothers who continued in the study at 6 months. There were no statistically significant differences at 9 and 12 months.

The research team also found no substantial difference in feeding patterns between those who “stayed in” versus those who “dropped out” within the upper respiratory and gastroenteritis illness categories. The results of this prospective evaluation suggest that breastfeeding does not provide substantial protection
against common infectious illnesses during the first year of life in a largely middle-class urban population in a developed country. The lack of a protective effect of breastfeeding against infectious illnesses has been noted in other studies in developed countries. Few studies, however, have attempted to address the specific methodologic problems noted in recent critiques of this field of research.

A potential bias might have occurred in this study. It is well known that breastfed infants have more frequent and softer stools than formula-fed infants during the first few months of life. Could this have produced a detection bias due to overreporting of illness of apparent diarrhea among mothers who breastfed their infants, and therefore obscured a true protective effect of breastfeeding? The research team believed that this was unlikely to have happened, because the instrument asked whether the child had been sick and then inquired separately about changes in 17 specific symptoms. In addition, the algorithm specified that the symptoms had to be of short duration.

There are a number of limitations of this study. First, although the research team ascertained subjects’ illnesses and feeding histories each month (a relatively short time interval), a shorter period of recall by parents may have provided more accurate information. Second, the research team did not supplement parental reports of illness by reviewing physicians’ records or by directly examining the children. Such procedures would have been extremely costly. Third, the research team was not able to study severity of illness to determine whether breastfeeding protected infants from severe versus nonsevere illnesses. Fourth, the research team did not have complete information on every subject for all 12 months of the study. Although there were a few demographic differences between the two groups, such differences may have occurred by chance. In contrast, there were no differences in the incidence of illnesses and feeding behaviors in these comparisons. Fifth, all of the subjects were enrolled during a short time period (February–June, 1985). Since there was only a 5-month difference between the youngest and oldest child, all of the infants were subjected to the winter viruses at a narrow range of ages. The research team could not examine the possibility of a protective effect of breastfeeding on infants who were born later in the year and were exposed to these viruses at a younger age.

By paying careful attention to the various methodologic issues, the research team found no protective effect of breastfeeding against common infectious illnesses early in life in this population. It is likely that the information derived from this study in Denmark may be extrapolated to middle-class populations in the United States. The frequency of illnesses in the cohort was roughly similar to those of other studies in this country, and a recent study showed that the percentage of women breastfeeding in the United States was similar to that found in this study.

Most importantly, the conclusions cannot be extrapolated to developing nations, where the evidence for the value of breastfeeding in reducing infections is strong, nor can the conclusions be extrapolated to rural or low-income urban populations in developed nations. Further efforts should be directed toward examining whether breastfeeding may be protective in these latter groups, which often have high rates of infectious morbidity.

Publications

Articles, Books, and Chapters


Abstracts


Presentations


Rubin DH. 1988, October. The relationship between infant feeding and infection. Invited guest speaker at Pediatric Grand Rounds, University of California, San Francisco General Hospital, San Francisco, CA.


After the common cold, otitis media or middle ear disease is the most prevalent illness of early childhood and the most common diagnosis made by physicians in children under age 15. When there is fluid in the middle ear, the condition is called otitis media with effusion (OME). Fluid in the middle ear may persist for several weeks or even months after the onset of an episode of otitis media. Children with OME generally have some hearing loss that continues as long as the fluid is present. The loss is usually mild to moderate in degree, averaging about 25 dB HL, although the loss can range from none to as much as 50 dB HL. It has been hypothesized that children who experience hearing loss due to repeated bouts of otitis media during the early formative years of language learning will experience later speech and language disorders, learning disabilities, and academic problems. Many studies have found that children who experienced repeated or persistent bouts of otitis media have poorer scores on measures of speech, language, and academic performance during their preschool and school-age years. Although a growing number of studies have shown a significant relationship between OME and later measures of speech, language, and learning, many studies have not supported this association. Further, others have criticized the validity of previous OME language learning studies and claim that no reliable relationship has been identified.
Research Questions or Hypotheses

This study examined how otitis media with effusion (OME) and its associated hearing loss during early childhood relate to the development of language and learning during the preschool years. The specific aims were to examine (1) the relationship between the amount of OME with accompanying hearing loss during infancy and the preschool period and the patterns of speech, language, and neuropsychological development during the preschool period, and (2) other factors, such as stimulation within the home environment or quality of the child care environment, which might interact with OME to predict later development of language and learning skills.

Study Design and Methods

Ear status was assessed with pneumatic otoscopy and immittance measures every other week. Hearing sensitivity was measured with age-appropriate pure tone measures every 3 months as well as during episodes of OME. Beginning when the child reached 12 months of age, speech and language and other developmental measures were administered annually.

On average, children’s ears were examined with otoscopy and tympanometry 71.9 times (SD = 18.6) between study entry and 4 years of age. Children’s hearing was tested, on average, 20.6 times (SD = 4.1) during this period. The number of completed developmental assessments and the age of administration are as follows: 95 children assessed at 12 months, 87 at 18 months, 88 at 24 months, 88 at 30 months, 88 at 36 months, 87 at 42 months, and 87 at 48 months.

Patterns of development over time for the outcome measures were studied in relation to hearing loss and OME. Structural equation analyses and regression analyses were used to examine how OME, OME-associated hearing loss, and mediating factors (child’s home and child care environments) affected the development of children’s language and cognitive skills. Based on study findings, guidelines were developed for intervention with children with persistent OME.

Study Sample and/or Population

In total, 87 African-American children attending center-based child care participated in the study through 4 years of age. Two-thirds of these families had low income levels. All parents of African-American infants enrolled in nine community-based child care centers in two small southern cities were invited to join the research project. At entry into the study, the mean level of maternal education was 12.5 years; 27 percent of the mothers had not graduated from high school, 31 percent had completed high school only, and 42 percent had pursued education beyond high school.

Findings

The results showed a higher incidence of OME than reported in previous studies among young children. From 6 to 12 months of life, children experienced bilateral or unilateral OME 89 percent of the time; 80 percent of the OME was bilateral. From 12 to 24 months, children experienced OME 55 percent of the time. The incidence of OME decreased to 21 percent of the observations between 2 and 3 years and to 15 percent between 3 and 4 years. Sixty-five percent of the children had at least 4 months of continuous bilateral OME between the ages of 6 months and 2 years; in 76 percent of children, this had resolved by age 2. Hearing loss (defined as 25 dB HL or greater for more than half of the frequencies tested) was present 57 percent of the time in children from age 6 months to 1 year, 40 percent from 1 to 2 years, 18 percent from 2 to 3 years, and 9 percent from 3 to 4 years.
There was a direct association between OME and associated hearing loss and measures of children’s language and cognition at 1 and 2 years of age. However, these relationships were no longer significant when the quality of home and child care environments were taken into account. In other words, there were indirect associations between OME and associated hearing loss and language and cognitive skills at 1 and 2 years of age as mediated by the quality of the home and child care environments: Children with more frequent OME and associated hearing loss tended to have less responsive home and child care environments, and this association was linked to poorer performance in language and cognitive development at 1 and 2 years of age.

Subsequently, longitudinal analyses examining OME, hearing loss, and communication and cognitive measures were conducted at 1, 2, and 3 years of age and controlled for child, family, and child care characteristics. These results showed that OME and associated hearing loss during the preschool years appeared to be related to a developmental pattern of a slightly slower acquisition of receptive and expressive language skills over time. By age 3, the children with the most (versus least) amount of OME differed by as much as 3 months in expressive language and 2 months in receptive language. Thus, during the preschool years we are finding a very weak but direct association between OME and associated hearing loss and language skills. Measures of the home and child care environments, however, did explain more of the variance in the cognitive and language skills than did OME and associated hearing loss.

Further analyses examined how other factors, including the quality of the child care environment and stimulation within the home environment, influence children’s cognitive and language development during early childhood. Children attending high-quality child care settings with smaller teacher/child ratios in infancy and the preschool years tended to have higher scores on standardized assessments of cognitive and language skills during the first 3 years of life. For example, on average, a difference of one point on the Infant Toddler Environment Rating Scale (a 7-point rating scale of child care quality, with 1 = inadequate, 3 = minimal, 5 = good, and 7 = excellent) was related to differences of about 6 points in cognitive development and 3 points in language development. Further, mothers who elaborated more on their children’s verbalizations had children who scored higher in language skills. In addition, the number of social and family risk factors (e.g., living in poverty, stressful life events) also predicted developmental outcomes in infancy: The greater the number of risk factors, the lower the children’s scores on the developmental outcomes.

The results of these studies have several implications for health care delivery. First, given that OME is highly prevalent in early childhood, particularly among children in child care settings, it is important to monitor children’s middle ear status and provide routine hearing screenings for children at risk for OME or for those who have experienced repeated or prolonged bouts of OME. Second, given the finding of a weak association between OME and language outcomes, the language of children with recurrent or persistent OME should be screened. Third, given the importance of the caregiving environment in the context of a relationship between OME and later development, families, child care providers, and other health care providers should receive information about the signs and symptoms of OME, hearing loss, and language delay. Further, they should be encouraged to use strategies that promote health, language, listening, and learning among children who experience chronic OME. Examples of these promotion strategies include frequent handwashing (health promotion), responding positively to children’s communication attempts...
(language promotion), decreasing background noise in noisy environments (listening), and reading often to children, checking to see whether they understand what is being read (learning).

Finally, it is not possible to recommend more aggressive surgical management of children with frequent and/or persistent OME until research studies have examined the long-term effects of a history of OME into the school-age years. The research team is currently following the study children until second grade. The finding that quality of child care in community-based child care programs is related to cognitive and language development during the early preschool years has important implications. Community-based child care programs, especially for families living in poverty, should ensure that children receive high-quality child care beginning in infancy.

Publications

Articles, Books, and Chapters


Roberts JE, Medley L, Mundy M, Roush J, Zeisel S, Neebe E, Burchinal M. 1996. Otitis media, hearing sensitivity, and language development of two year olds. In DJ Lim, CD Bluestone, M Casselbrant, JO Klein, PL Orgra, eds., Recent Advances in Otitis Media (pp. 325-328.)

Roberts JE, Medley LP, Swartzfager JL, Neebe EC. 1997. Assessing the communication of African American one-
Abstracts


Presentations

Burchinal MR, Roberts JE. 1996. Quality of infant center care. Poster presentation at the Society for Infancy Studies, Providence, RI.


Medley LP, Roberts JE, Zeisel S. 1993. Resources on ear infections, communication, and hearing. Presented at the Zero to Three/National Center for Clinical Infant Programs, Eighth Biennial National Training Institute.


Roberts JE. 1996. Otitis media and speech-language sequelae in young children. Oral presentation at the University of Minnesota Otitis Media Research Center, Minneapolis, MN.


Roberts JE. 1993. Otitis media (ear infections) and child development: Research and implications for training and policy. Presented at the Frank Porter Graham Child Development Center 25th Anniversary Celebration, Chapel Hill, NC.

Roberts JE. 1990. Otitis media and its relationship to speech, language and academic achievements. Presented at the Manhattan Eye, Ear and Throat Hospital, New York, NY.


Zeisel SA. 1993. Incidence of otitis media with effusion in infants and young children. Poster presented at the 18th National Primary Care Nurse Practitioner Symposium, Keystone, CO.


Infant Mortality and Socioeconomic Status

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Costs

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Year 2000 Objectives
14.1, 22.4

Study Design
Observational

Time Design
Longitudinal

Care Emphasis
Noninterventional

Population Focus
Infants

Racial/ Ethnic Focus
African Americans

Summary

Statement of the Problem

Previous research based on data from metropolitan Ohio in 1960, 1970, and 1980 clearly revealed the existence of a pronounced inverse relationship between infant mortality and socioeconomic status. The nature and magnitude of the relationship has varied over time and often varies among particular subgroups in the population. Given the continued (albeit slower) declines in infant mortality during the 1980s, and especially the more rapid reduction in neonatal mortality, additional research is needed to determine whether these declines are characteristic of all socioeconomic segments of the study population and whether they have had any impact on the nature of the long-standing inverse relationship between infant mortality and socioeconomic status.

Research Questions or Hypotheses

The overall objective of this study was to follow up and expand the previous research on trends in the relationship between socioeconomic status and infant mortality in metropolitan Ohio. The general aims were to (1) measure and describe the nature and magnitude of the relationship between infant mortality (total, neonatal, and postneonatal) and the aggregate family income status of urban residential areas, for both whites and nonwhites, by sex; and (2) assess the role of particular causes of death in contributing to any observed economic differentials.

The specific aims were to (1) update to 1990 the
longitudinal analysis of the relationship between socioeconomic status and infant mortality in the three-city aggregate (Columbus, Dayton, Toledo) on which the previous research was based; and (2) take advantage of a larger data base involving several additional cities to undertake a more detailed analysis of the relationship for the 1990 period.

Study Design and Methods

The relationship between infant mortality and socioeconomic status was examined within an ecological framework in which the basic unit of analysis was the census tract of the mother’s usual residence. Although some multivariate analyses were carried out, the major approach involved a social area analysis wherein the census tracts of the Ohio metropolitan centers were aggregated into broad economic areas, which were then ranked and compared in terms of infant mortality levels. These comparisons were carried out separately for whites and nonwhites, by sex, and for broad cause-of-death categories. In line with the specific aims of the research, two sets of comparisons were made: One based on a three-city aggregate comparable to the 1959–61, 1969–71, and 1979–81 aggregates that formed the basis of previous research; the other, based on a seven-city aggregate that provided an expanded data base for a more detailed cause-specific analysis for the 1989–91 period.

Study Sample and/or Population

The study population comprised the universe of infants less than 1 year of age in the major cities of Ohio between January 1, 1989, and December 31, 1991. The primary independent variable was defined as the percentage of low-income families in each census tract at the time of the 1990 census. As in previous research, the low-income cutoff point ($15,000 in 1990) was set at roughly half the median family income for metropolitan Ohio. The dependent variable data consisted of counts of the number of live births in each census tract during 1990, and counts of the number of infant deaths occurring during the 3 years centering on the census data, thus providing the data needed to calculate conventional 3-year average infant mortality rates.

Findings

The findings revealed a very strong and persistent inverse relationship between infant mortality and family economic status in metropolitan Ohio. There appeared to be a blurring and general weakening of this relationship in 1970, but by 1980 and again in 1990, there was a pronounced and consistent inverse association between these two variables.

The general trend characterized by a weakening of the inverse differential in 1970 and its clear reemergence in 1980 was observed for both males and females, with the differential consistently more pronounced for males. It was generally characteristic of both whites and nonwhites, although nonwhite infant mortality rates were notably less sensitive to differences in economic status than those of the white population. Further, the overall trends and patterns were found to characterize both exogenous and endogenous cause-of-death categories. Although there were more deviations from the general pattern when more specific subgroups were considered, the existence of a general inverse association between infant mortality and income status was apparent in 1990. In fact, the magnitude of the inverse socioeconomic infant mortality differential was somewhat stronger in 1990 than it had been 30 years earlier. Based on these data, the research team concluded that despite the substantial declines in the overall infant mortality rate since 1960, there has been no progress in closing the
gap that separates the more affluent from the poorest members of society.

Analysis of the expanded 1990 data base confirmed the preceding conclusion. Not only was the overall infant mortality rate higher in the seven-city aggregate than in the three-city aggregate, but many of the deviations noted earlier were eliminated. The inverse association was somewhat stronger in the seven-city aggregate, notably for postneonatal mortality. One exception concerned the nonwhite population. Although a modest inverse association was apparent for the three-city data base, it was considerably weakened in the expanded sample.

A more detailed cause-specific analysis revealed that both exogenous and endogenous death rates were inversely related to economic status, with the differential being widest for the exogenous causes but most consistent for the more prevalent endogenous causes. There were variations for some specific causes, and among specific sex-race groups, but not enough to detract from the overall major finding of the study. There continues to be a pervasive and pronounced inverse association between infant mortality and the aggregate family income status of residential neighborhoods in metropolitan Ohio.

These findings have identified three basic policy needs. First, there is a clear need to provide better and more accessible maternal and child health care for the economically disadvantaged groups in society. Second, there is a need to expand educational efforts aimed at reducing the incidence of unhealthy behaviors such as poor eating habits and/or smoking or other drug use during pregnancy. Finally, society needs to make a stronger commitment to reducing many of the existing economic inequalities that are the major determinants of many of the current infant mortality differentials.

The findings of this research also point out three areas with an especially important need for additional research. First, there is a need for a large-scale national study of the relationship between socioeconomic status and infant mortality with a sufficiently large sample so that it is possible to control for such important variables as ethnic status, urban/rural residence, city size, and geographic region. Second, there is a serious need for continued research to clarify the etiologic mechanisms of sudden infant death syndrome (SIDS). A better understanding and control of this single cause would have a substantial impact on reducing the overall level of infant mortality in general and narrowing the gap between the higher and lower income groups in particular. Third, there is a continuing need for research on the development of more effective health intervention strategies so that economic status is not the basic criterion determining both the amount and quality of maternal and child health care received and the risk of infant death.

Publications

Articles, Books, and Chapters


Abstracts

None to date.

Presentations

Stockwell EG, Goza FW. 1994, October. Sudden infant death syndrome and the relationship between period and cause-specific death rates in infancy. Presented at the annual meeting of the Southern Demographic Association, Atlanta, GA.


Early Cortisol Deficiency and Bronchopulmonary Dysplasia

Summary

Statement of the Problem

Bronchopulmonary dysplasia (BPD), chronic lung disease following neonatal lung injury, is a leading cause of morbidity and mortality in very low birthweight (VLBW) babies. BPD occurs in about 30 percent of all babies weighing less than 1,500 grams, thereby affecting approximately 15,000 babies each year. BPD also has a well-recognized inverse relationship with birthweight, occurring in up to 70–90 percent of surviving babies weighing less than 750 grams. The introduction of exogenous surfactant therapy for respiratory distress syndrome has significantly decreased mortality rates in VLBW babies. Unfortunately, this therapy has had either modest or no success in decreasing the percentage of these babies who develop BPD. The introduction of a therapy that significantly reduces the incidence of BPD would be expected to substantially improve neonatal care and outcome for these small premature infants and decrease the cost of that care.

BPD may develop in response to oxygen toxicity and barotrauma; however, increasing evidence indicates that inflammation plays a key role in its pathogenesis. The research team and others had found elevated markers of inflammatory activity in intubated neonates who develop BPD. Additionally, the research team found a group of babies in whom basal cortisol values during the first week of life appeared to be disproportionately low for the severity of clinical illness. The research team postulated that these babies have a period of dampened responsiveness of their adrenal
axis, which allows the inflammatory process to be amplified and which may lead to the development of chronic lung disease.

Research Questions or Hypotheses

This study was designed to test the three hypotheses:
1. At the end of the first postnatal week, all VLBW infants develop a nadir in cortisol concentration, independent of sex and gestational age and unresponsive to continued significant clinical acuity;
2. A transient cortisol deficiency develops in a subset of VLBW infants, resulting in an uncontrolled inflammatory response; and
3. Abnormally low cortisol concentrations in the first week of postnatal life result in BPD.

Study Design and Methods

This research was designed as an observational study, conducted at two centers. The eligible population included appropriate-for-gestational-age newborn infants weighing less than 1,501 grams at birth. The research team measured basal serum cortisol values on days 2, 4, and 6 of postnatal life. On one of those days, the research team administered cosyntropin (ACTH analog) and measured the stimulated cortisol concentration 30 minutes later. The research team collected tracheal lavage fluids from these babies on day of life 0, 2, and 6 if they were intubated, for measurement of markers of inflammatory activity. The research team also collected urine samples during the first 2 weeks of life for measurement of epidermal growth factor concentrations.

Basal cortisol concentrations and the response to ACTH stimulation were correlated with gestational and postnatal age, clinical measures of respiratory illness, markers of inflammation in tracheal aspirates, and urinary epidermal growth factor concentrations.

The research team evaluated the role of cortisol deficiency in the development of chronic lung disease by correlating cortisol concentrations and response to cosyntropin with the outcome variables for bronchopulmonary dysplasia (need for supplemental oxygen at 28 days of life) and chronic lung disease (need for supplemental oxygen at 36 weeks’ postconception).

Study Population

The research team enrolled 161 patients from 2 centers: The Milton S. Hershey Medical Center (HMC) and the University of New Mexico (UNM). Selected demographic and clinical data for the two sites are listed below.

| Characteristics of Newborn Infants Weighing Less than 1501 g at Two Medical Centers |
|---------------------------------|----------------|----------------|
|                                 | HM C (n=87)   | UNM (n=74)    | TOTAL (n=161) |
| Birthweight, g                  | 1,005 ± 269   | 1,051 ± 224   | 1,026 ± 249    |
|                                 | (523–1,484)   | (570–1,500)   | (523–1,500)    |
| Gestational Age, weeks          | 27.5 ± 2.3    | 28.5 ± 2.0    | 28.0 ± 2.0     |
|                                 | (23–33)       | (24–32)       | (23–33)        |
| Surfactant Given                | 63 (72%)      | 45 (62%)      | 108            |
| Males/Females                   | 56/31         | 36/38         | 92/69          |
| Prenatal Steroids               | 16            | 17            | 33             |
| Died Before Discharge           | 5             | 7             | 12             |
| Withdrawn                       | 3             | 1             | 4              |
| BPD                             | 44/79         | 39/66         | 83/145         |
Abstract

The research team found that during the first week of life, babies who subsequently developed BPD had lower serum cortisol concentrations compared with babies who resolved their respiratory disease. This was true despite the additional finding that basal cortisol values were inversely correlated to gestation (i.e., less mature babies had higher basal cortisol concentrations).

The research team found that within this population of premature infants, the less mature newborns had lower responses to ACTH than did the more mature infants. At any gestational age, however, a decreased response to ACTH at the end of the first week of life correlated with an increased probability of developing BPD. Additionally, the population of babies who subsequently developed BPD showed a pattern through the first week of life of decreasing response to ACTH stimulation, whereas babies who recovered without BPD showed an increasing response to stimulation during this time period.

These findings are consistent with the hypothesis that babies who develop BPD exhaust their adrenal reserve during the first days of postnatal life, rendering them more susceptible to continuing lung injury. Less mature babies may have less adrenal reserve or may have less sensitivity to feedback mechanisms, predisposing them to develop BPD.

Other evidence of cortisol effect during the first postnatal week included the following findings: (1) As cortisol concentrations increased, urinary epidermal growth factor (EGF) concentrations also increased; (2) babies with higher cortisol values were more likely to be on oral nutrition by the end of the first week of life, independent of gestational age; and (3) cortisol concentrations correlated directly with weight loss during the first week, suggesting that cortisol is important for the diuresis of the newborn infant.

The research team found a significant inverse relationship between basal cortisol concentration and tracheal fluid proteins and between cortisol and tracheal fluid interleukin 6. For interleukin 1 and 8, the slope of the regression was negative, but the correlation was not significant.

This correlation provides evidence of a potential mechanism for a relationship between early cortisol concentration and respiratory outcome, namely, that cortisol insufficiency may potentiate increased inflammation and protein leak in the lung, resulting in chronic lung disease.

The data from this study strongly support, but do not prove, the hypothesis that decreased cortisol effect during the first week of life is causally linked with adverse respiratory outcome.

The findings also do not address whether supplementation with exogenous hydrocortisone would ameliorate this adverse outcome. These findings, in concert with the meta-analysis of previously conducted trials of early high-dose steroid therapy, clearly provide a theoretical basis to support the development of a randomized trial of early hydrocortisone replacement therapy to decrease the incidence of chronic lung disease in this population. This trial would evaluate the effectiveness of low-dose replacement therapy, thus decreasing exposure to high concentrations of exogenous steroids.

Publications

Articles, Books, and Chapters


Abstracts


Watterberg KL, Scott SM. 1995. Babies who develop bronchopulmonary dysplasia (BPD) and chronic lung disease (CLD) have decreased serum cortisol [C] concentrations in the first week of life. Pediatric Research 37:356A.

Watterberg KL, Scott SM. 1995. The effect of chorioamnionitis on serum cortisol concentrations [C], tracheal interleukin 1B, and respiratory distress syndrome (RDS) in very low birth weight (VLBW) infants. Pediatric Research 37:244A.


Presentations


Watterberg KL. 1995. Babies who develop bronchopulmonary dysplasia (BPD) and chronic lung disease (CLD) have decreased serum cortisol [C] concentrations in the first week of life. Presented to the Society for Pediatric Research.

Watterberg KL. 1995. The effect of chorioamnionitis on serum cortisol concentrations [C], tracheal interleukin 1B, and respiratory distress syndrome (RDS) in very low birth weight (VLBW) infants. Presented to the Society for Pediatric Research.


Summary

Statement of the Problem

Hypertension is a major health problem. Epidemiologic studies have demonstrated racial and geographic differences in incidence rates for essential hypertension (EH). In the United States, blacks have a greater prevalence of EH. This difference is further accentuated by vital statistics data on mortality. Blacks have a threefold greater mortality from hypertensive disease than whites. This disproportionate mortality rises to more than six times greater among blacks ages 35–54. Thus, the consequences of morbidity associated with hypertensive diseases are several times greater in blacks, particularly in young to middle adulthood. Risk factors for future cardiovascular disease, including EH, can be identified in the young.

Emerging evidence indicating the presence of significant risk of cardiovascular disease in the adolescent population demonstrates a need for comprehensive and effective intervention programs. Surveys that focus on the health behaviors of adolescents indicate that nutrient intake does not meet recommended guidelines, fitness levels are compromised, and substance abuse is not unusual. The risk of EH in low-income urban adolescents is increased by environmental stress, fragmented use of available health care, and lack of a network for reinforcing positive health behaviors. In adults and younger populations, behavioral interventions designed to modify cardiovascular risk factors have been applied with some success.
Research Questions or Hypotheses

The goal of this project was to modify health-related behaviors that contribute to cardiovascular disease, specifically the cardiovascular disease of essential hypertension. The overall goal was to deliver a comprehensive and effective risk-factor intervention program to a young urban population at high risk for essential hypertension. The project was designed to test the following hypothesis: Behaviors that contribute to the development of essential hypertension can be modified in a high-risk urban adolescent population.

Study Design and Methods

This project focused on modification of risk factors for essential hypertension. The study design included randomization of high-risk high school students to intervention and nonintervention (control) groups. Behavioral objectives for the intervention group were to (1) attend intervention classes, (2) participate in a fitness program, (3) modify diet, (4) reduce stress, and (5) achieve normal weight. Dependent variables used to assess changes in risk-related behaviors included measures of anthropometrics, blood pressure, dietary content, and physical fitness. Repeat assessments of these variables in control and intervention groups before and after intervention permitted an evaluation of the intervention to achieve a reduction of risk factors and alter health-related behaviors.

The intervention program consisted of health education and behavior modification methodologies provided during two classes held weekly at each of six high schools. Health educators sensitive to the needs of the study population taught the intervention classes. A curriculum was designed by the project staff to meet the needs of the target schools and the project goals. The 10-week intervention class replaced the students’ standard health class.

Instruments used to test the effectiveness of the program were (1) measurement of blood pressure, (2) the Canadian fitness test (step-test), (3) standard 24-hour food intake with computer analysis, (4) the American Heart Association cardiovascular knowledge quiz, and (5) measures of height, weight, fat-folds, and circumference. Intervention students completed a program evaluation.

Basic and descriptive statistics and correlations have been computed for each subject on all variables. Data have been obtained for both intervention and control subjects at baseline and postintervention. A repeated measures three-way (treatment versus control, obese versus thin, schools) analysis of covariance (ANCOVA) was used to test for statistically significant differences between intervention and control groups. The significant changes that occurred in each of the parameters for the intervention group alone were also examined. Using a repeated measures analysis of variance (preintervention versus postintervention, and obese versus thin), the researchers tested for significant changes between time points.

Study Sample and/or Population

The target population consisted primarily of African-American urban adolescents, the population that carries the greatest risk for developing EH and attendant morbid sequelae. The population for the study was identified through blood pressure screenings performed at six urban public high schools. All 9th and 10th grade students present in the school on the days of the screenings were evaluated for blood pressure, weight/height, and family cardiovascular risk factors. The project’s health educators coordinated the screenings with each school through the physical education departments. Medical and nursing students, volunteers certified in blood pressure measurement tech-
nique, and school nurses assisted the project staff during the screenings. Students found to be at risk during the screening were recalled 1 week after screening to have their blood pressure rechecked. The rechecks were performed by the project’s health educators. Students who were at risk following four blood pressure measurements on two separate occasions were invited to join the project.

Findings

Staff from the target high schools and school district administration were engaged in regular meetings to review project activities and discuss school-specific needs such as space, student schedules, and grading systems. The meetings facilitated open communication between the project staff and the schools, thereby enhancing project activities.

There was a significant increase in the knowledge score for both the thin and obese students who attended the intervention group. Similar improvement was not seen in the control group. There was a small but not statistically significant decrease in body mass index (BMI) for both the intervention and control groups. Although there was no change in the activity score for the control group or the thin intervention group, as measured by the usual activity scale, the obese intervention group did show a significant increase in reported usual exercise. The increase in reported exercise in combination with no change in BMI for the obese intervention group may indicate some change in exercise behavior and the intent to modify usual exercise behavior, but not to a level that would reduce weight. Measures of systolic blood pressure in the intervention and control groups showed no significant change. The diastolic pressure showed a significant reduction in the thin and obese intervention groups.

All subjects provided dietary information by means of the 24-hour food intake. In general, the students rarely consumed vegetables or fruit; they replaced fruit juice with fruit punch and frequently obtained meals from street vendors, neighborhood stores, or fast food restaurants. Analysis of dietary intake revealed little modification in the diet of the thin intervention group. There appears to be a small but not statistically significant decrease in this group’s calorie, sodium, cholesterol, and fat intake. Postintervention analysis of the obese intervention group clearly indicates a modification of food intake. There was a statistically significant reduction in total sodium and cholesterol intake. This group reduced the percentage of calories derived from fat. The increase in calories from carbohydrates, with a corresponding decrease in calories derived from sucrose, indicates that fat calories were replaced by complex carbohydrates.

This project also provided an opportunity for project staff to become closely involved with health-related activities within each school. Project staff members participated in school-based health fairs, taught topic-specific classes for 11th and 12th grade health classes, assisted in student health promotion video production, provided continuing education for school nurses, and were available as resource personnel for school staff. One staff member wrote and performed health raps. The raps proved to be a very effective means of communicating health information to the students. The health educators became closely involved in the management of several students identified through screenings as being in immediate health danger from high blood pressure; the health educators made home visits to assist families in obtaining appropriate care for their children. In order for students to receive a grade, they had to attend the intervention class and complete a cardiovascular risk reduction project. In an evaluation of the intervention pro-
gram, the students enthusiastically supported its concept and content.

This project has demonstrated that (1) public high schools will allow cardiovascular risk reduction programs to be provided to their students; (2) students will participate in screening and intervention programs; (3) students at risk for cardiovascular disease can be identified; (4) increase in cardiovascular knowledge can be achieved; (5) some modification in specific health-related behaviors can be accomplished; and (6) use of nontraditional teaching methods such as raps are effective. In general, adolescents do not worry about the impact of current behavior on future health status. Knowledge obtained by students through participation in this project may be utilized as the students become older and more concerned about health-related behaviors.

The health behaviors of high-risk adolescents identified through this project are similar to the behaviors of all students in the target high schools. All students would benefit from participation in this curriculum, which encourages them to evaluate and modify health-related behaviors for themselves and their families. Through exercises in self-efficacy and increased knowledge, students gain the information necessary to make appropriate health-related decisions and take appropriate action.

Publications

Articles, Books, and Chapters


Abstracts


Presentations


Barr S. 1993. Hypertension, nutrition, and drinking and driving. Public service announcements (rap format), Channel 35.


Barr S. 1992. Use rap to address, it gets the facts across the best. Minority health issues for an emerging majority. Presented at a conference of the National Heart, Lung, and Blood Institute, National Institutes of Health.


Summary

Statement of the Problem

With this country’s expanding number of low-income, single-parent families with young children, empirically based descriptions of the unique needs, resources, characteristics, and functioning of this population become increasingly critical for early childhood service providers. Early intervention programs (EIPs), along with Head Start and other community-based early childhood centers located within major urban settings, serve a disproportionate number of children from low-income, single-parent families, a population with a substantial incidence of high-risk factors. In order to reduce risk and improve general developmental outcomes, many of these publicly funded “interventive” early childhood programs have begun to offer a variety of family support services in addition to traditional child-focused educational services, an idea embraced in P.L. 99–457.

The success of EIPs and other related early childhood programs in reducing risk and improving developmental outcomes for low-income, single-parent families depends on each program’s ability to involve or engage parents in available support services. Parent utilization of family support services depends in turn on the program’s ability to match services with the unique characteristics, needs, functioning, and resources of low-income, single-parent families. Currently, there are major gaps in available empirical data for programs to use in creating an optimal “goodness of fit” model for low-income, single-parent families. When studies focus on single-parent families, they...
tend to be treated as a one-dimensional family form without regard to the many different possible household and caregiving configurations that exist in low-income communities. It is not known which variations in this population are important to consider when developing policies and programs; inattention to this contextual variable could lead to policies and programs that do not sufficiently reflect the differing needs within this population.

Although no reported studies to date address actual service utilization rates with a specific focus on low-income, single-parent families, several reports suggest that these families are less likely to become involved in parent-related services than two-parent, middle-income families. A related problem is the absence of empirical data to identify those factors that influence the use of family support services by this population. This information is needed in order to address the equally important question of the types or patterns of service utilization that may be related to specific parent or family outcomes. Such knowledge could promote more meaningful parent participation in early childhood programs and prevent the development of chronic patterns of disengagement between families and educators.

Research Questions or Hypotheses

The overarching purpose of this study was to provide data that will enhance the delivery of family support services for urban low-income, single-parent families with young children. Four major research questions were addressed:

1. What is the structure and functioning of low-income, single-parent families who have children attending an early childhood program that offers family support services?
2. What types of services and relationships do low-income, single parents want from early childhood programs?
3. For low-income single parents with children in early childhood programs, what is the nature of the parent-professional relationships and the services received?
4. How do parent/family and program characteristics influence the services received by this population?

Study Design and Methods

This nonexperimental, naturalistic study involved four data collection phases. Within the first 6 months of the child’s enrollment in an early childhood program, a structured interview was administered to the primary caregiver, consisting primarily of standardized questionnaires. Information was obtained on child and family demographics, parental expectations of programs, parent support network, sources of stress, individual child and parent functioning, parent-child interaction, family functioning, and parenting knowledge. A 20-minute free play observation of the caregiver and child was also recorded.

The second data collection phase was ongoing, occurring during the period between the first and second interviews with the primary caregiver (between 8 and 12 months). During this phase, a standardized developmental assessment was administered to the child. The study also regularly sampled the nature and scope of parent participation in or use of services. Every 6 to 8 weeks, a one-page questionnaire was completed by as many as four early childhood program staff members who regularly interacted with specific parents. In addition, a 5-minute questionnaire was periodically administered to parents by telephone, to ascertain parent participation in program activities and parent interaction with pro-
gram staff members.

The third data collection phase included a second structured interview with the primary caregivers. In total, 92 percent of the sample completed this second interview. Child and family demographics were updated and information was again obtained on parent support networks, sources of stress, parent and family functioning, parent-child interaction, and parenting knowledge. The 20-minute free-play observation of the caregiver and focus child was again recorded.

The fourth and final data collection phase consisted in administering two instruments to the program staff and administrators. One instrument, developed by the authors, involved a program environment questionnaire administered at staff meetings; the other involved a semistructured interview with the program directors about their programs.

Study Sample and/or Population

A sample of 218 low-income single parents was recruited from 21 different early childhood programs; the study sample was primarily African American (87.6 percent). The sample comprised EIP families (67 percent), Head Start families (15 percent), and at-risk program families (18 percent). The primary caregivers ranged in age from 15 to 63, with a median age of 27.5 years. The children ranged in age from 1 to 5, with a median age of 2.4 years.

Findings

Question 1: Four major findings were related to the first research question. First, the low-income, single-parent families served by the three most common types of publicly funded interventive early childhood programs were found to be more alike than different in family needs, family structures, and family functioning. The top three family needs reported by parents in all of the programs were finances, personal discretionary needs, and employment.

Second, low-income, single-parent families across all types of programs and differing family structures were found to be a highly stressed population. A total of 68 percent of parents scored above the 75th percentile for parenting-related stress and 39 percent reported psychological symptoms of distress at sufficient levels to warrant a referral for treatment.

A third finding was the presence of significant diversity in family structure or household composition among low-income, single-parent families. Only 35.8 percent of single-parent households in our sample contained a solo caregiver. Other common family structures included the three-generational household, the couple-headed household, and the kinship household. Fourth, the family structure of low-income, single-parent families was found to be more descriptive of single-parent resources and sources of stress than the one-dimensional term “single-parent” conveyed.

Question 2: Findings related to the second research question suggested that, although low-income, single parents prefer child-focused services, they also have a strong desire for parenting-related services such as support groups, parent training groups, and family counseling. Parents were also open to mental health-oriented support services. Parents across all three types of programs were virtually unanimous in their expectation that programs should welcome input and involve parents in all decisions about their children’s education or treatment.

Question 3: With respect to the third research question, the findings supported the idea that parent involvement is a multidimensional construct. Two important contextual dimensions providing insight into the nature of parent involvement were (1) the mechanisms by
which parent-professional contact occurred (such as phone, informal conversation, planned meetings) and (2) the type or focus of the services utilized (i.e., basic or enhanced activities). Although most single parents in this study showed some level of involvement with their children’s early childhood programs, service utilization was directly related to the emphasis that programs placed on parent-related services. Parents involved in at-risk programs utilized a significantly higher number of total services and a greater diversity of services than parents in either EIPs or Head Start programs. There was a general decrease in parent-related service utilization over the first year of a child’s enrollment. This decrease was most dramatic for parents in at-risk programs and was due primarily to decreased utilization of enhanced or discretionary services.

Question 4: Findings related to the fourth research question strongly suggested that parent involvement was dependent on the needs, stresses, and support systems of the caregivers. The single parents who used parent/family-related services most frequently had numerous family needs and high stress levels but were not involved with a romantic partner and/or were in conflict with their mothers. The only child variable related to service utilization was age. The most critical program variable related to service utilization was the quality of the caregiver’s relationship with the child’s teacher.

This study has identified significant diversity among low-income, single-parent families and has demonstrated the importance of considering family diversity when designing meaningful services that focus on caregivers and their families. Participation rates are linked to family diversity. In order to ensure accurate identification of the primary caregiver(s), providers of early childhood services will need to review assessment and enrollment procedures. Programs need to guard against assuming that the single parent is parenting alone or in a social vacuum or that family structures are permanent. Changes in caregiving arrangements and program participation status are relatively common in this population of families and must be incorporated into program planning.

For all publicly funded interventive early childhood programs serving this population of families, the child’s diagnosis or developmental status may be the least relevant factor when designing services for the parents. While the majority of low-income, single parents are functioning well, as a group they are highly stressed, with a sizable subgroup experiencing significant psychological symptoms of distress. A greater focus on the emotional health of children and families in these programs is strongly recommended. The findings suggest that this population of parents would be open to using mental health-oriented services associated with the early childhood programs, particularly if the orientation is one of “promoting” coping and problem-solving strategies, as opposed to more traditional pathological approaches. The parents strongly indicated a desire to be collaborators with service plans that are developed for themselves or their children.

Dialogue and debate are needed among policymakers, service providers, and parents regarding the future role of early childhood programs in fostering family development. Programs participating in this study were clearly ambivalent about their mission as related to goals for family-focused change, and this was reflected in tremendous variability in the ways parent/family-related services were implemented. Further research is recommended to determine the extent to which more effective matching of parent/family-related early childhood services in low-income, single-parent family populations would influence parenting and family outcomes.
Publications

Articles, Books, and Chapters


Abstracts

None to date.

Presentations


Summary

Statement of the Problem

The impact of mental retardation within a family has effects that are both reciprocal and circular. Family members are affected by the presence of retardation in a child and the child is affected by the family’s response. The interactional and transactional nature of this process is likely to be influenced primarily by the family’s adaptation.

Although the importance of familial adaptation has long been a focus of clinical concern, little empirical research has addressed this issue. In general, pathological outcomes have been expected in families of children with retardation because of the stresses associated with the presence of retardation in a child, with such outcomes subsequently related to less adaptive outcomes for the retarded child. However, not all families seem to demonstrate poor adaptation, suggesting the existence of some combination of factors that mediate familial response.

This study proposes a model in which familial adaptation to a child with retardation is a function of the degree of perceived stress related to the presence of retardation in the child, moderated by the availability and use of varying coping resources. The coping resources in turn are mediated by the various ecological contexts in which the family operates. Further, it is proposed that the adaptive skill of children with retardation is likely to vary as a function of familial adaptational response. As yet, little data are available to test this model, and the current project was
specifically directed toward explicating aspects of these processes.

Previous research on various attributes of families with retarded children suggests the potential utility of the model, although little is generally known about these families. Perhaps the greatest reason for this lack of knowledge is that the methodological approaches involved in the previous research have been narrow in focus. Research in this area has been unidimensional (focusing on a specific family member or one specific variable) and unimodal (using only interviews, questionnaires, ratings, or, rarely, behavioral observations). Additionally, no prospective longitudinal studies have been reported that assess family functioning and its consistency over time. The descriptive information on families of children with mental retardation is similarly inadequate. Many descriptive studies have involved clinical case reports or group data without controls. This project was designed to consider the informational needs in this area and to overcome the methodological inadequacies of previous work.

The stresses associated with the presence of a developmental delay or disability in a child are likely to have a significant impact on both the physical and psychological well-being of all family members. The ways in which the family members cope with such stress are likely to dictate adaptational response and subsequently each member’s general well-being, as well as the integrity of the family as a whole. In this sense, the study of stress and familial adaptation to a child with a developmental delay or disability has specific implications for health care delivery to these families. Identification of the specific stressors as well as the most effective coping strategies may suggest specific interventions with families to promote more positive adaptations.

Research Questions or Hypotheses

This investigation was directed toward examining differences both within and between two groups of families, those having a young child with nonspecific developmental delay (DD), and those having a young child without DD. Coping with the stress of a child with developmental delay is the primary variable of interest, particularly in determining its impact on familial functioning and adaptation. Further, this study examined the effects of a number of variables that may be used by the family and its members in the coping process. Since coping is not a static process, the longitudinal nature of this study was central to the ability to explicate not only the process of coping with this crisis over time, but also the pattern of parental use of coping resources.

Within the group of families with a developmentally delayed child, the research team examined the relationship of stress to (1) the child’s developmental status, and (2) parent-child interactions. Additionally, the research team attempted to find those variables predictive of differential family adaptation from the initial diagnosis through the preschool years. The project intended to fill both the descriptive and methodological gaps apparent in previous research on families of children with mental retardation through a prospective longitudinal design that used a multimodal approach (interview, questionnaire ratings, and observation).

Study Design and Methods

The quasi-experimental design matched families of preschoolers with developmental delay (DD group) and families of preschoolers without DD (comparison group) on the child’s age, sex, race (Caucasian versus non-Caucasian), public assistance (presence versus absence), mother’s marital status, and mother’s
education. Groups were also balanced for child’s birth order.

Both groups were seen two times in a 12-month period. For the DD group, the visits included a clinic visit at the initial formal diagnosis and a second clinic visit 12 months after diagnosis. In the interim, a phone interview was conducted 6 months after diagnosis to maintain subject contact and collect additional data. For the comparison group, visits took place at chronological ages matched to those of the developmentally delayed group. Both of the visits to the laboratory involved direct behavioral observations of mother-child interaction, developmental assessment of the child, a family interview that included background information, and assessment of maternal attitudes. Measures of stress, social support, marital functioning, maternal and paternal coping style, and family functioning were obtained.

Study Sample and/or Population

The research team longitudinally followed 40 families of developmentally delayed preschoolers and 66 families of preschoolers without DD for 12 months from the time the children with DD were diagnosed. (More children without DD were needed in order to provide two comparison groups: One matched to the DD sample on mental age, the other on chronological age.)

The specific criteria for selection of subjects in the DD group included the following: (1) Diagnosis of mild or moderate developmental delay based on one or more psychometric tests (e.g., Bayley Scales of Infant Development, Stanford-Binet Intelligence Scale); (2) child’s age between 1 and 5 years; (3) no moderate or severe sensory handicaps (vision or hearing), motor syndromes, or bodily disfigurements; (4) no known biological/genetic syndrome that would be related to potential mental delay; (5) child’s residence with biological mother; and (6) residence within 2 hours’ driving distance of the University of Washington.

Findings

At time of diagnosis, families of children with developmental delay did not appear to differ significantly from families of comparison children in important functional attributes, when matched carefully for socioeconomic status and other confounding factors unrelated to child status. In fact, the two groups of families were remarkably similar despite the fact that many families of children with DD suspected the developmental problems before they were diagnosed. The two groups of children varied greatly in terms of developmental skills. Chronological age matching allowed for more direct comparisons between the families of children with DD and those of children without DD.

Of most interest were the group comparisons at followup. This represents a time period during which the families of children with DD had 1 year to respond to their children’s diagnosis. Pathological models of family functioning would suggest that the families of the children with DD should be less functional across a variety of domains. However, this was not the case. In fact, the families of children with DD and the families of children in the comparison group remained similar at followup (as at the time of diagnosis). Although families were carefully matched along many dimensions to ensure demographic equivalence, the finding of similar functioning across the two groups gives credence to recent suggestions that pathological family reactions to children with DD are not ubiquitous.

The amount of stress experienced by families of children with DD did not differ from that experienced by families of children without DD, either at time of diagnosis or at followup, with the exception that fathers
of children with DD perceived more daily parenting hassles. Nonetheless, it was apparent that families experiencing more stress were less functional across domains than were families reporting less stress. This was the case for single-parent families especially. In general, this was true for both groups, although the effects were more dramatic for the DD group: Single-parent families of children with DD reported the highest mean levels of stress.

Previous research studies have established that families of developmentally delayed children are more stressed, but those studies have addressed the stress specific to the condition of DD. This project addressed stress from a more generic perspective, which probably accounts for the finding that families of children with DD did not necessarily report greater stress consistently. Nevertheless, this research broadens the literature on stress, with the findings that families with developmentally delayed children may not experience more generalized stress, but the stress experienced appears to have more pervasive effects across multiple levels of family functioning and mother-child interactions.

As the findings indicate, there is great heterogeneity in the family life, stress levels, and coping ability of families with young children with nonspecific developmental delays. Aside from the issue of understanding and appreciating individual differences, the findings point toward a “de-pathologizing” of such families. However, having a child with DD is likely to place a family at greater risk under conditions that may already be challenging. Thus, single parents of children with DD appeared to have the greatest challenge and difficulties in this current sample of largely middle-class families.

Since it is unlikely that fully funded support programs will be available to all families of children with mild to moderate early delays, it is important to begin to identify what risk factors are the best indicators of need for additional emotional, financial, and/or technical support services. To do so requires that broader, larger studies be conducted in which samples of families with DD are representative of the ecologies of different segments of American life.

Publications

Articles, Books, and Chapters

None to date.

Abstracts

None to date.

Presentations


Prevention of Drowning of Young Children

Summary

Statement of the Problem

Each year, 700 children under the age of 5 die from drowning in the United States, making it the third leading cause of death in this age range. In this age group, children between 2 and 3 years of age are at greatest risk. Drowning carries a high risk of serious neurological sequelae in survivors (“near-drowning” victims), with poor outcomes from CPR and medical treatment. Thus, primary prevention remains the most effective way to significantly reduce the risk of mortality and serious morbidity from drowning.

To address this problem, passive approaches such as four-sided fencing around pools and pool alarms and covers have received attention. Despite their effectiveness when applied, these have not been widely adopted in the United States. Another prevention strategy involves teaching swimming and water safety skills to young children. This has been vigorously promoted by the Red Cross, the YMCA, and other organizations and institutions, and widely publicized by the mass media. Nevertheless, its effectiveness in reducing mortality and morbidity has not been adequately evaluated empirically. Some experts have even raised concerns that swimming lessons may increase the risk of drowning by lessening toddlers’ fear of the water and creating a false sense of security in parents.

Research Questions or Hypotheses

The purpose of this study was to initiate an investigation of the possibility of reducing the risk of drown-
ing among preschool children by providing training in swimming skills and water safety. It was not feasible to conduct a prospective trial with decreased drowning episodes as an outcome. The annual rate of drowning in this age group is approximately 6 deaths per 100,000; thus, over 1,000,000 children would have to be entered to observe confidently a 50 percent risk reduction. Increase in water safety skills and recovery from a simulated episode of falling into a pool were used as a proxy for decreased drowning risk.

The study was based upon five hypotheses. First, swimming ability would be positively related to the degree of participation in the water safety training program. Second, children with water safety training would exhibit safer behavior at poolside than children with less training. Third, children with training would act more competently in simulated high-risk situations than children with less training. Fourth, children’s swimming ability would be positively related to their water safety behavior. Fifth, children’s developmental and behavioral characteristics would have independent effects on water safety behavior prior to training and on changes due to instruction.

Study Design and Methods

The research study used a randomized control design with repeated measures at four times. Children were randomly assigned to either 12 weeks or 8 weeks of twice-weekly swimming and water safety instruction. To be included in the analysis at the conclusion of the study, children in the 12-week group had to have missed no more than 5 of the 24 lessons given, and children in the 8-week group had to have missed no more than 3 of their 16 lessons.

All children participated in twice-weekly water safety and swimming lessons. The curriculum was designed for preschool-age children, based on the American Red Cross program. It emphasized three sets of skills: Out-of-water safety behavior (deck behavior), swimming ability, and in-water safety skills. Instruction was provided in groups of approximately six children, accompanied in the pool by their parents.

Children’s water safety skills were measured by direct observation in three ways. The first measure, “deck behavior” (the risk of falling into the pool from the side, playing too close to the edge, and going near the water without parental permission), was assessed while the children were clothed and in their swimsuits. Deck behavior was scored during the few minutes before the actual swimming lessons began, with higher scores indicating riskier behavior. The second measure, “water recovery” (the ability to recover and stand up when dropped from 2 feet above the water) was assessed by the instructor releasing the child (or, if the child resisted, with the parent releasing the child). If the child resisted release from 2 feet above the water, the adult would attempt release from the water’s surface. The third measure, “jump-and-swim” (the ability to jump from the edge of pool into the pool and swim back to the side) was initially assessed by the instructor (or the parent, if the child resisted). If the child resisted jumping from the side, she/he was released by the adult in the pool to swim to the side. Water recovery and jump-and-swim were ordinarily rated from increasingly difficult series of challenges given to the children, with higher scores indicating greater skill. All were assessed four times (T1, T2, T3, and T4).

Using a structured grading scheme developed by Erbaugh, instructors rated children’s swimming ability. In this system, in which higher scores indicated greater ability, children were tested at T1, T2, and T3 for the 12-week group, and at T2 and T3 for the 8-week group. Examples of the skills on which the children were rated included holding their face in water for 3 seconds, recovering from prone position, rolling from back to front, propulsive kicking,
doing a beginner stroke for 5 feet, independently entering and exiting the pool, and jumping into the pool independently.

Water safety skills were initially measured in both groups at T1. The swimming ability of the 12-week group was measured at this time. Training in the 8-week group was delayed by 8 weeks (from the initial observation time) to allow assessment of the reactivity of the study instruments. After 8 weeks of training for the 12-week group, and 8 weeks of no training for the 8-week group, water safety skills were again measured (at T2); the swimming ability of both groups was measured at this time. After 4 more weeks of training for the 12-week group and 8 weeks for the 8-week group, water safety skills and swimming ability were measured in both groups (at T3). A final measurement of water safety skills was conducted 12 weeks following the end of the training in both groups (at T4). No attempt was made to control the amount of time spent in the water other than during the intervention.

A number of variables were assessed in the participating children and families. At the beginning of the study, parents were asked to provide information on their own and their spouse/partner’s education and occupation. They completed the General Development Scale of the Minnesota Child Development Inventory (MCDI) to estimate their children’s developmental levels, and the Achenbach Child Behavior Checklist (CBCL) for children ages 2–3 to measure behavioral concerns.

**Study Sample and/or Population**

At the beginning of the study (T1), 162 children were enrolled; 91 were randomly assigned to the 12-week group and 71 to the 8-week group. The entire sample’s average age at T1 was 34.1 months (SD ± 5.6 months), with boys constituting 53 percent of the sample. The two groups did not differ significantly on these characteristics. About 67 percent of the sample fell in the two highest socioeconomic status (SES) categories. While fewer families in the 12-week group were in the highest SES category than in the lower categories in comparison with the 8-week group, the variation was not significant.

By the end of the study, 109 children had met all of the criteria for inclusion in the analyses (61 had missed no more than 5 lessons for the 12-week group, and 48 had missed no more than 3 lessons for the 8-week group). Their average age was 34.2 months (SD ± 5.5 months), with boys constituting 54 percent of the sample. As at T1, the two groups did not differ significantly on these characteristics. Once again, 67 percent of the sample fell in the two highest SES categories. Despite apparent underrepresentation of families in the highest SES category in the 12-week group compared with those in the 8-week group, the variation did not reach significance.

Children and families were recruited in the Seattle area from middle-income area child care centers near public pools used in the study. Children were accepted only if they had no prior swimming training and no chronic medical or developmental disability, based on parents’ completion of the Revised Denver Prescreening Developmental Questionnaire (R-PDQ).

**Findings**

Swimming ability: Both groups showed highly significant improvements in ability during the 8 weeks following the beginning of training (T1 to T2 for the 12-week group, and T2 to T3 for the 8-week group) (p < .0001). This improvement continued significantly for the 12-week group to week 12 (p < .0001). The 8-week group was significantly superior to the 12-week group at the first lesson (T1 for the 12-week group,
and T2 for the 8-week group) and at 8 weeks (T2 for the 12-week group and T3 for the 8-week group), but not when compared with the 12-week group’s final ability. However, the improvement in the two groups over time did not differ significantly between groups.

Deck behavior: This varied significantly from T1 to T4, only because of a significant improvement at T4 (p < .03). There were no significant differences between the 12-week and 8-week groups.

Water recovery: With training, water recovery scores improved steadily and significantly in both groups (p < .001 for change over time). The 12-week group improved immediately and continued to do so through T4. The 8-week group made significant improvement between T2 and T3 (their training period). At the end of the training, there was no significant difference between the two groups.

Jump-and-swim: Similar to the water recovery scores, the jump-and-swim scores improved over time (p < .005), with the 12-week group’s improvement slightly but not significantly greater than the 8-week group’s improvement. Swimming ability was not significantly correlated with deck behavior, water recovery, and jump-and-swim scores for either the 12-week or the 8-week group at the beginning of training. Likewise, swimming ability was not significantly correlated with deck behavior at the last lesson for either group (end of week 12 or end of week 8, respectively), but was strongly correlated at the last lesson with water recovery scores (r = .54, p < .0001 for the 12-week group; r=.51, p < .0003 for the 8-week group) and the 12-week group’s jump-and-swim scores (r = 0.72, p < .0001), and moderately correlated with the 8-week group’s jump-and-swim scores (r = 0.28, p < .06).

Modest correlations (in the 0.2–0.3 range) were found between the developmental characteristics of chronological age, MCDI developmental age, and MCDI developmental quotient, and the swimming and water safety outcomes of swimming ability, deck behavior, water recovery, and jump-and-swim. In general, older children (chronologically and developmentally) had better water recovery and jump-and-swim scores at T2 and T3. However, none of the correlations between the developmental variables and the outcome variables at T4 were significant. Gender and the CBCL score were not significantly related to any of the outcome variables.

In this study of 109 young preschool-age children, instruction in swimming and water safety significantly improved their swimming ability as well as two measures of in-water safety skills that attempted to simulate drowning risk; out-of-water safety skills showed minimal improvement. The greatest changes took place during the first 8 weeks of instruction, although some improvements continued for children receiving 4 additional weeks of training. Improvement was stronger and appeared earlier for water recovery skills than for jump-and-swim skills. Water safety behavior was strongly related to swimming ability after 8 weeks’ training. This improvement in water safety skills was not only statistically significant but also reflected real changes in their abilities. The swimming skills acquired and the increased ability to recover from a fall into a pool represent potentially lifesaving skills.

While this study provided one of the few direct tests of the benefits of water safety instruction for young preschool-age children, it had several limitations. First, it used simulated risk as a proxy for drowning and near-drowning. The reasons behind this included poor feasibility of a cohort study or experiment with submersion incidents as the outcome, human subjects limitations on placing children at any greater risk, and the belief that the proxy used was a reasonable simulation of a young child falling into a pool. Second, the comparison group (8-week) received training as well as the full treatment group (12-week), diminishing the possible contrasts between
the two treatments. This control group allowed the research team to test the short-term changes in swimming skills without an intervention, as well as the possible effect of the testing procedures themselves on skills. In addition, it would have been difficult to recruit subjects without offering any training. Third, the study sample was self-selected (i.e., parents volunteered their children), and thus more likely to have some interest in water safety; the effect of this on the children’s outcome variables is unknown. Fourth, the artificiality of the study setting (i.e., participating in a research and training study, receiving payment) may have affected the behavior of the children and their parents, although the children’s age would lessen this effect. Fifth, the relatively short duration of the children’s involvement in the study limited the research team’s ability to assess how long the effect persists, especially if it is not reinforced.

Despite the above limitations, the results of this study offer several implications for parents and others interested in the safety of young children around water. First, water safety is not a simple entity. Different aspects are affected by training in different ways (e.g., deck behavior did not improve significantly, despite the improvement of in-water safety skills). Although water safety training for young preschool-age children may reduce their risk of drowning, it does not have a similar effect on their poolside behavior and the risk of falling in. Finally, while there was no support for the concern that water safety instruction increases young children’s risk of drowning, their improved skills do not reduce the need for adult monitoring, supervision, and safety awareness. The potential impact of such a program on decreasing parental vigilance must be further assessed. Vigilance must remain a crucial element of any drowning prevention program.

These results show that there are potential benefits for young preschool-age children in learning swimming and water safety skills. This study should be repeated by others; if the results are replicated, swimming and water safety training should be promoted as part of an overall drowning prevention program for this age range. A comprehensive approach would incorporate passive protection such as water barriers and personal flotation devices and active measures such as water safety and swimming instruction, and parental awareness and supervision. All such elements should be advocated strongly in order to optimize water safety and enjoyment for young children.

Publications

Articles, Books, and Chapters

Abstracts
None to date.

Presentations
Infant Temperament: Stability and Change in Rural Appalachia

Summary

Statement of the Problem

Infant temperament is recognized as an important influence on early parent-child interaction, with difficult temperament associated with subsequent behavior problems in the family and school. Despite the links between early temperament and socioemotional development, relatively few studies have examined infant and caregiving environment factors associated with stability and change in temperament. The low to moderate levels of stability typically reported for early temperament indicate significant instability or change. Learning more about factors associated with stability and change in infant temperament will increase understanding of paths of early socioemotional development, particularly with regard to risk and protective factors for behavior problems and early school adjustment. Such information will be especially useful for early intervention programs in high-risk populations.

Research Questions or Hypotheses

The aim of this investigation was to identify infant and family characteristics and interactional processes associated with stability and change in temperament in a group of economically disadvantaged infants in rural Appalachia. Infant temperament and individual differences in the caregiving environment were then related to infant attachment security and verbal communications skills early in the second year. The focus of the study involved the two broad dimensions of...
temperament believed to be most salient for caregivers, peers, and teachers: Negative emotionality/difficulty, and positive emotionality/social responsiveness. In addition, in this largely unstudied population of low-income rural Appalachian families, specific risk and protective factors were explored.

It was hypothesized that positive maternal and infant antecedent characteristics would distinguish infants whose negative emotionality/difficulty decreased or remained low and whose social responsiveness/positive emotionality increased or remained high, whereas less positive antecedents would distinguish infants whose negative emotionality increased and whose social responsiveness declined. In addition, it was expected that change in temperament would both foster and be influenced by particular patterns of mother-infant interaction and would lead to differences in attachment relationships and early communication skills. Specifically, it was expected that infants whose social responsiveness increased and/or negative emotionality declined would have mothers rated as more sensitive and less intrusive in their interactions and would be more likely to be securely attached and have above-average communication skills than infants whose social responsiveness decreased and/or negative emotionality/difficulty increased.

**Study Design and Methods**

This was a longitudinal multimethod investigation, beginning with prenatal assessments of mothers and neonatal assessments of infants. Assessments included interviews, questionnaires, and a variety of videotaped behavioral observations.

Initial assessments of the caregiving environment were obtained prenatally (mother personality and social support measures and family demographics) and initial assessments of the infant were obtained neonatally (alertness/orientation and negative reactivity), in order to have independent measures of mother and baby before any substantial interaction. At 4 and 9 months, the mother and infant were seen together in a variety of structured laboratory observations designed to elicit individual differences in infant temperament and mother interactional style. In addition to temperament ratings from these behavioral observations, mother-reported temperament measures were also obtained at these ages. At 15 months, two standardized outcome measures were administered, the Strange Situation and the MacArthur Communicative Development Inventory.

**Study Sample and/or Population**

Subjects were recruited from women receiving prenatal care at the Lincoln Primary Care Center (LPCC) in Hamlin, West Virginia, from May, 1992, to December, 1993; the acceptance rate was 69 percent. The cooperation of the LPCC Board of Directors and staff was crucial in gaining acceptance in the community, recruiting subjects, and carrying out the research.

Of 116 women enrolled who gave birth to normal term neonates, 17 either moved or declined to participate over the course of the study, and data on 5 other infant-mother pairs were excluded due to infant characteristics that might affect early development; this resulted in a sample of 94 at 15 months.

**Findings**

The study was successful in identifying infant, mother, and caregiving environment factors that significantly distinguished infants of stable temperament from those of changing temperament, infants with secure attachment from those with insecure attachment relationships, and infants with high verbal skills from those with low verbal communication skills. Overall, the results identify potential protective
and risk factors in a low socioeconomic status (SES) population and suggest that some degree of prediction of temperamental trajectories is possible.

Looking at groups of infants identified as high or low on a temperamental dimension indicated that both mother and infant characteristics contributed to predicting future temperament. Some general findings follow: (1) Maternal social support is associated with decreasing infant negative emotionality and stable high positive and social behavior in this population; (2) increased infant negative emotionality and stable high negative emotionality were more likely in families receiving public assistance; (3) maternal experience, as indexed by parity, was a predictor only for infants who were more negative early in life; and (4) perinatal risk was consistently higher in infants who subsequently changed in temperament.

Additional regression analyses also revealed that predictors differed depending on whether infants increased or decreased in negative emotionality and positive/social behavior over time. From the neonatal period to 4 months, infants who became more negative tended to be male, whereas becoming less negative was best predicted by neonatal alertness and orienting to stimuli. From 4 to 9 months of age, infants of primiparous mothers were likely to exhibit both more negative emotionality and more positive and social behavior. Infants with perinatal risk and those in families receiving public assistance were more likely to be more negative at 4 months but not at 9 months. Thus, a “risk” may affect temperament differentially by dimension or at an early age but not later. Higher focused attention in infants and more social support for mothers predicted positive changes in temperament.

Factors that distinguished infants with secure attachment relationships from those with insecure attachment relationships supported the hypothesis that more positive infant and caregiver characteristics would be associated with attachment security. Mothers of secure infants were less likely to be receiving public assistance, had more support from friends, had a more responsive attitude toward their infant, and were more facilitative when interacting with their infant. Mothers of insecure/avoidant infants were more likely to be receiving public assistance and tended to report lower support from friends; their infants had high toy focus (rather than orientation to persons) at 9 months. Mothers of insecure/disorganized infants had lower maternal responsive attitude scores and their infants had lower positive affect, were less likely to use mother as a secure base, and were more likely to be male.

Similarly, generally positive characteristics of infants, mothers, and families distinguished infants with higher productive vocabularies and use of communicative gestures at 15 months. Infants high in productive vocabulary more often were firstborn and had mothers with higher occupational status and social support. Even though these infants were more likely to have had minor perinatal risk and to have been less positive/social at 4 months, their positive/social behavior increased by 9 months and their mothers provided more contingent feedback at 9 months. Infants high in using communicative gestures had mothers with higher occupational status, more positive personalities, more positive feelings about their partner relationship, and more likelihood of being employed at 15 months. Their fathers also had more education.

For the entire sample of rural Appalachian infants, 15-month outcomes presented a mixed picture of infant development in a low SES group. Verbal communication skills at 15 months were very similar to those of normative samples, while rates of insecure attachment relationships (49.5 percent) were somewhat higher than typically found in low-risk, middle-class samples.

Prior information about infants and their caregiving environment has utility for predicting stability
and change in temperament and early socioemotional development. It is particularly important to consider the interaction of infant temperament and characteristics of the caregiving environment. In all cases, several indicators are more useful than single measures. Such findings lend themselves to the identification of sets of risk and protective factors for children’s development. It is the overall or cumulative pattern of indicators that is most useful in distinguishing between infants who will develop a more difficult or less difficult temperament, a secure or insecure attachment, high or low communication skills. It is recommended that health care providers and others working with low-income families who have infants attend to information beyond the family’s physical health, especially the overall pattern of family functioning. Early intervention with families who are experiencing an accumulation of stressors or risk factors may be helpful. In particular, infants who are notably low in positive affect and social responsiveness and who do not appear to use mother as a source of comfort/security may indicate infant-caregiver relationships that are not optimal.

Publications

Articles, Books, and Chapters


Abstracts

None to date.

Presentations


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Russ J. 1993. Lessons learned from ethnography regarding desired qualities of a peer counselor. Use of this information in selection and training of peer counselors in the WIC breastfeeding promotion project. Presented at the Maryland Breastfeeding Promotion Project, Baltimore, MD.


Silver RC, Wortman CB. Myths of coping with loss. Presented at the meeting of the Midwestern Psychological Association, Chicago, IL, April 1988.


Silver RC. Coping with SIDS loss. Invited participant at Canadian SIDS Foundation sponsored Public Awareness Night, University of Waterloo, Waterloo, ON, March 1982.


Silver RC. Coping with SIDS loss. Presented at the Canadian SIDS Foundation sponsored Public Awareness Night, University of Waterloo, Waterloo, ON, March 1982.


Silver RC. The presence and nature of ruminations following stressful life events. Presented at the International Conference on Ruminations, Self-Referent Cognitions, and Stress, Memphis State University, Memphis, TN, March 1987.


Silver RC. The role of positive emotion in coping with stressful life events. Invited address at the Midwestern Psychological Association Meeting, Chicago, IL, May 1989.


Silver RC. The role of positive emotions in the coping process. Presented at the meeting of the American Psychological Association, Washington, DC, August 1986.
Silver RL. Exploring the myths of coping. Keynote address at the Third International Conference on Stress and Adjustment in Time of War and Peace, Tel Aviv, Israel, January 1983.

Silver RL. Learned resourcefulness and coping among parents whose babies died suddenly. Presented at the International Symposium on Learned Resourcefulness, AABT/World Congress on Behavior Therapy, Washington, DC, December 1983.


Smilkstein G. 1994. Violence: What we can do as health care providers. FAP 195 Course: Health Care to the Medically Underserved, School of Medicine, University of California, Davis, CA.


Smilkstein G. 1995. Family violence. Abstracts of presentations given at the 14th World Congress of National Colleges and Academies of Family Medicine, Hong Kong.


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Spencer PE. 1988, July. Using parent-infant interaction situations to assess communicative functioning of deaf infants. Presented at the Summer Institute, Family Focused Early Intervention for Hearing-Impaired Infants, Gallaudet University, Washington, DC.

Spencer PE. 1988, October. Mothers as language teachers: Effective strategies with deaf infants. Presented at the Eastern Regional Conference for Teachers of the Hearing Impaired, Frederick, MD.


Spencer PS. 1988, April. Mother-infant interaction research: Applications for parent-infant programs. Presented at the Parent Education Workshop, Maryland School for the Deaf, Frederick, MD, and the Department of Deaf Education, Western Maryland College, Westminster, MD.


Stockwell EG, Goza FW. 1994. October. Sudden infant death syndrome and the relationship between period and cause-specific death rates in infancy. Presented at the annual meeting of the Southern Demographic Association, Atlanta, GA.


Sudela K. 1990, October. A pilot study: “high tech” home care for children with chronic health conditions. Paper presented at Ambulatory Care Pediatrics held at Baylor College of Medicine and Texas Children’s Hospital, Houston, TX.


Teaching Film of the Yale Observation Scales. 1984. Produced by Irving and Alberta Jacobi. New Haven, CT.


The abstracts listed above were presented at the Annual Meeting of the Ambulatory Pediatric Association in Washington, DC, in the years in which the abstracts appeared in American Journal of Diseases of Children.

The health and nutritional status of Mexican-American children. 1988, March. Testimony to the House Select Committee on Hunger, Washington, DC.


Turner-Henson A, Holaday B. 1989, April. Sampling rare populations. Presented at the Alabama State Nurses’ Association Nursing Research Conference, Birmingham, AL.


Turner-Henson A. 1989, April. Sampling rare populations. Presented at the Alabama State Nurses’ Association Nursing Research Conference, Birmingham, AL.


Watterberg KL, Scott SM. 1995. Babies who develop bronchopulmonary dysplasia (BPD) and chronic lung disease (CLD) have decreased serum cortisol [C] concentrations in the first week of life. Pediatric Research 37:356A.


Watterberg KL, Scott SM. 1995. The effect of chorioamnionitis on serum cortisol concentrations [C], tracheal interleukin 1B, and respiratory distress syndrome (RDS) in very low birth weight (VLBW) infants. Pediatric Research 37:244A.


Watterberg KL. 1994. Relationship of chorioamnionitis to respiratory distress syndrome and BPD in VLBW newborns, and to their serum cortisol concentrations. Presented at the Mid-Atlantic Regional Neonatal Research Conference.

Watterberg KL. 1995. Babies who develop bronchopulmonary dysplasia (BPD) and chronic lung disease (CLD) have decreased serum cortisol [C] concentrations in the first week of life. Presented to the Society for Pediatric Research.

Watterberg KL. 1995. The effect of chorioamnionitis on serum cortisol concentrations [C], tracheal interleukin 1B, and respiratory distress syndrome (RDS) in very low birth weight (VLBW) infants. Presented to the Society for Pediatric Research.


Wortman CB, Silver RC. In press. The myths of coping with loss. Journal of Consulting and Clinical Psychology.


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Wortman CB. Coping with irrevocable loss: Toward a theory of transformation. Invited address, Division 8, presented at the annual meeting of the American Psychological Association, Los Angeles, CA, August 1985.

Wortman CB. Coping with life traumas: Current research themes. Symposium conducted at the annual meeting of the American Psychological Association, Washington, DC, August 1986.


Wortman CB. The role of positive emotion in coping with critical life events. Invited participant in First International Conference on Crises and Loss Experience in the Adult Years, University of Trier, West Germany, July 1989.

Wynia BM. In press. My baby just died . . .: Don’t tell me God’s doing me a favor. Redbook.


Zeisel SA. 1993. Incidence of otitis media with effusion in infants and young children. Poster presented at the 18th National Primary Care Nurse Practitioner Symposium, Keystone, CO.
The submission of a comprehensive final report within 90 days after completion of the project is a requirement for all research grants awarded by the Maternal and Child Health Bureau. A file of such reports has been maintained since the inception of the MCHB Research Program and is currently housed at the National Center for Education in Maternal and Child Health (NCEMCH). Reports produced before 1980 are available only at NCEMCH, where they can be used as a reference resource. A list of these reports is available upon request from NCEMCH, 2000 15th Street, North, Suite 701, Arlington, VA 22201, phone (703) 524-7802, fax (703) 524-9335.

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| **Project Title** | Transactions of Pregnant Adolescents in Prenatal Care |
| **Investigator**  | Iris F. Litt, M.D.  
| | Fernando Mendoza, M.D.  
| | Stanford University  
| | Stanford, CA |
| MCJ060515      | PB92-135540       | A04        |
| **Project Title** | The Infant Health and Development Program |
| **Investigator**  | Ruth T. Gross, M.D.  
| | Stanford University  
| | Stanford, CA |
| MCJ060518a     | PB89-230759       | A05        |
| **Project Title** | Health and Nutritional Status of Mexican-American Children |
| **Investigator**  | Reynaldo Martorell, Ph.D.  
| | Emory University School of Public Health  
| | Atlanta, GA |
| MCJ060526      | PB95-208641       | A03        |
| **Project Title** | Definition and Prevention of Infant Macrosomia |
| **Investigator**  | Norman Kretchmer, M.D., Ph.D.  
| | University of California at San Francisco  
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| MCJ060546      | PB92-136191       | A06        |
| **Project Title** | Pesticide Exposure and Pregnancy Outcome |
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                              University of California at San Francisco  
                              San Francisco, CA |
| MCJ060551      | PB89-215636       | A07        |
| **Project Title**  | Infant Mortality among Indochinese Refugees in San Diego County |
| **Investigator**  | John R. Weeks, Ph.D.  
                              Rubén G. Rumbaut, Ph.D.  
                              International Population Center  
                              San Diego, CA |
| MCJ060564      | PB95-208633       | A05        |
| **Project Title**  | Risk Taking Behavior in Adolescents: Impact of Puberty |
| **Investigator**  | Charles E. Irwin, Jr., M.D.  
                              University of California at San Francisco  
                              San Francisco, CA |
| MCJ060570      |                  |            |
| **Project Title**  | Collaborative Study of the Effects of HIV on Development of Hemophilic Children |
| **Investigator**  | Edward D. Gomperts, M.D., M.Sc.  
                              Children’s Hospital of Los Angeles  
                              Los Angeles, CA |
| MCJ060573      | PB93-179992       | A03        |
| **Project Title**  | Laboratory Evaluation of Jaundiced Newborns: A Reevaluation |
| **Investigator**  | Thomas B. Newman, M.D., M.P.H.  
                              University of California at San Francisco  
                              San Francisco, CA |
| MCJ060580      | PB95-203899       | A03        |
| **Project Title**  | Physiologic Risk Assessments to Predict Preterm Birth |
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- Can Mothers Identify the Seriously Ill Febrile Child?
- Nutrition Services in Perinatal Care
- Alternative Dietary Practices and Nutritional Abuses in Pregnancy: Proceedings of a Workshop
- Alternative Dietary Practices and Nutritional Abuse in Pregnancy: Summary Report
- Research Issues in the Assessment of Birth Settings

**Investigator**
- E. B. Thoman
  University of Connecticut
  Storrs, CT
- Paul L. McCarthy, M.D.
  Yale University Medical School
  New Haven, CT
- Myrtle L. Brown
  National Research Council
  Washington, DC
- Myrtle L. Brown
  National Academy of Sciences
  Washington, DC
- Enriquetta Bond
  National Academy of Sciences, Institute of Medicine
  Washington, DC
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**Project Title**
Feasibility and Effectiveness of Obtaining Consent for Neonatal Screening

**Investigator**
Ruth R. Faden, Ph.D., M.P.H.
The Johns Hopkins University
Baltimore, MD

| MCR240418      | PB81-188526       | A05        |

**Project Title**
Interdisciplinary Research on Physical Rehabilitation

**Investigator**
Michael F. Cataldo
John F. Kennedy Institute
Baltimore, MD

| MCR240421      | PB86-150596       | A11        |

**Project Title**
Assessment of the Impact of the IPO Project

**Investigator**
Donna M. Strobino
The Johns Hopkins University
Baltimore, MD

| MCR240422      | PB83-163550       | A08        |

**Project Title**
Research Study to Improve Teenage Contraception Practices

**Investigator**
Theodore M. King
The Johns Hopkins University
Baltimore, MD

| MCR240426      | PB83-163857       | A10        |

**Project Title**
Family Economic Impacts of Children’s Handicaps

**Investigator**
David S. Salkever
The Johns Hopkins University
Baltimore, MD

| MCR240436      | PB84-200708       | A07        |

**Project Title**
Education, Consent, and Counseling in Alpha-Fetoprotein: An Evaluation Study

**Investigator**
Ruth R. Faden, Ph.D., M.P.H.
The Johns Hopkins University
Baltimore, MD
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<td>Lewis H. Margolis, M.D., M.P.H. University of Michigan Ann Arbor, MiChapel Hill, NC 27599-7400</td>
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University of Michigan  
Ann Arbor, MI |
| MCJ260554      | PB92-135573       | A05        |
| **Project Title** | Improving Memory of Educable Mentally Retarded Children |
| **Investigator** | Hilary H. Ratner, Ph.D.  
Wayne State University  
Detroit, MI |
| MCJ260560      | PB92-135532       | A02        |
| **Project Title** | Anthropomorphic Standards for the Evaluation of Growth and Nutritional Status |
| **Investigator** | Roberto A. Frisancho, Ph.D.  
University of Michigan  
Ann Arbor, MI |
| MCR270416      | PB84-199942       | A07        |
| **Project Title** | Early Maladaptation: A Prospective-Transcational Study |
| **Investigator** | B. Egeland  
University of Minnesota  
Minneapolis, MN |
| MCR270439      | PB84-200658       | A15        |
| **Project Title** | Causal Model for Nurse Turnover in NICU's |
| **Investigator** | M. L. Duxbury  
University of Minnesota  
Minneapolis, MN |
| MCR280438      | PB83-162693       | A06        |
| **Project Title** | Drug Utilization among AFDC Children |
| **Investigator** | Mickey C. Smith  
University of Mississippi  
University, MS |
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| **Investigator** | Margaret R. Hammerschlag, M.D.  
State University of New York  
Brooklyn, NY |
| MCJ360524     | PB87-199014      | A03        |
| **Project Title** | Assessment of Diagnostic Tests for Chlamydia |
| **Investigator** | Sally S. Hipp, Ph.D.  
Yangsook Han, M.A.  
New York State Department of Health  
Albany, NY |
| MCJ360528     | PB89-220917      | A08        |
| **Project Title** | A Longitudinal Study of Service Usage by a Rubella Cohort |
| **Investigator** | Patricia R. Cohen, Ph.D.  
Research Foundation for Mental Hygiene, Inc.  
New York, NY |
| MCJ360534     | PB90-147992      | A05        |
| **Project Title** | Neonatal Outcome and Weight Gain of Black Adolescents |
| **Investigator** | Elizabeth R. McAnarney, M.D.  
University of Rochester  
Rochester, NY |
| MCJ360539     | PB95-106704      | A08        |
| **Project Title** | Outcome Evaluation of a Pediatric Health Care Model |
| **Investigator** | Jack Elinson, Ph.D.  
Penny Liberatos, M.A., Ph.D.  
Medical and Health Research Association of New York City, Inc.  
New York, NY |
| MCJ360540     | PB94-218633      | A03        |
| **Project Title** | Determinants of Adverse Outcome Among Toddlers of Adolescent Mothers |
| **Investigator** | Gail A. Wasserman, Ph.D.  
Research Foundation for Mental Hygiene, Inc.  
New York, NY |
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New York State Department of Health  
Albany, NY |
| MCJ360544      | PB95-227666        | A03        |
| **Project Title** | Relationship Between Infant Feeding and Infections |
| **Investigator** | David H. Rubin, M.D.  
Albert Einstein College of Medicine  
Bronx, NY |
| MCJ360571      | PB94-106127        | A11        |
| **Project Title** | Multidimensional Health Status Index for Infants |
| **Investigator** | Kenneth M. McConnochie, M.D., M.P.H.  
Klaus J. Roghmann, Ph.D.  
Rochester General Hospital  
Rochester, NY |
| MCJ360601      | PB97-155071        | A04        |
| **Project Title** | Body Composition in Pregnant Women |
| **Investigator** | Sally Ann Lederman, Ph.D.  
Columbia University  
New York, NY |
| MCR370424      | PB83-162743        | A12        |
| **Project Title** | Controlled Evaluation of Regional Perinatal Care in North Carolina |
| **Investigator** | Earl Siegel  
University of North Carolina  
Chapel Hill, NC |
| MCR370427      | PB83-163642        | A09        |
| **Project Title** | Simultaneous Screening of Child Health and Development: Test Development and Concurrent Validity |
| **Investigator** | Raymond A. Sturmer, M.D.  
Duke University  
Durham, NC |
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| | Cincinnati, OH |
| MCJ390520     | PB87-160396      | A07        |
| **Project Title** | Socioeconomic Correlates of Infant Mortality |
| **Investigator** | Edward G. Stockwell, Ph.D.  
| | Bowling Green State University  
| | Bowling Green, OH |
| MCJ390548     | PB90-147471      | A11        |
| **Project Title** | Improving Auditory Testing of Multihandicapped Children |
| **Investigator** | Donald P. Gans, Ph.D.  
| | Karen Derk Gans, Ph.D.  
| | Kent State University  
| | Kent, OH |
| MCJ390557     | PB92-135557      | A03        |
| **Project Title** | Prediction of Outcome of Early Intervention in Failure to Thrive |
| **Investigator** | Dennis D. Drotar, Ph.D.  
| | Case Western Reserve University  
| | Cleveland, OH |
| MCJ390629     | PB95-231916      | A08        |
| **Project Title** | Infant Mortality and Socioeconomic Status |
| **Investigator** | Edward G. Stockwell, Ph.D.  
| | Bowling Green State University  
| | Bowling Green, OH |
| MCR420385     | PB83-162735      | A04        |
| **Project Title** | Neonatal Screening for Congenital Hypothyroidism |
| **Investigator** | Thomas P. Foley  
| | University of Pittsburgh  
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| MCJ480566      | PB92-135813        | A03        | Sickle Cell Anemia: DNA for Newborn Screening Followup | Edward R. B. McCabe, M.D., Ph.D. 
University of California at Los Angeles 
Los Angeles, CA |
| MCJ500541      | PB92-136076        | A06        | Listening Partners: Psychosocial Competence and Prevention | Lynne A. Bond, Ph.D. 
Mary Field Belenky, Ed.D. 
University of Vermont 
Burlington, VT 05405 |
| MCR510454      | PB84 -199975       | A03        | Proposal to Screen Third Grade Children for Seizures | F. E. Dreifuss 
University of Virginia 
Charlottesville, VA |
| MCJ530048      | PB87-160370        | A03        | Aspirin and Acetaminophen Use by Pregnant Women and Subsequent Child IQ, Attention Decrements, Height, Weight, and Head Circumference | Ann P. Streissguth, Ph.D. 
University of Washington 
Seattle, WA |
| MCR530348      | PB82-140740        | A12        | Premature Infant Refocus | Kathryn E. Barnard 
University of Washington 
Seattle, WA |
| MCR530351      | PB83-162669        | A08        | Measures to Predict Child Abuse: A Validation Study | Mildren A. Disbrow 
University of Washington 
Seattle, WA |
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**MCR530411**  PB81-247579  A08

**Project Title**  Prenatal Correlates of Hyperactivity

**Investigator**  Sharon Landesman-Dwyer  
University of Washington  
Seattle, WA

**MCR530414**  PB84-200716  A02

**Project Title**  Intervention with High Frequency Crying (Colic)

**Investigator**  T. S. Hyde  
University of Washington  
Seattle, WA

**MCR530431**  PB84-200724  A03

**Project Title**  Prematurity, Mother-Infant Interaction, and Language

**Investigator**  Keith A. Crnic  
University of Washington  
Seattle, WA

**MCJ530513**  PB88-174420  A10

**Project Title**  Adaptation in Families of Children with Special Needs

**Investigator**  Steven P. Schinke, Ph.D.  
Columbia University  
New York, NY

**MCJ530517**  PB95-208641  A03

**Project Title**  Familial Adaptation to Developmentally Delayed Children

**Investigator**  Mark T. Greenberg, Ph.D.  
University of Washington  
Seattle, WA

**MCJ530535**  PB92-139039  A04

**Project Title**  Mothering in Adolescence: Factors Related to Infant Security

**Investigator**  Susan J. Spieker, Ph.D.  
University of Washington  
Seattle, WA
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Healthy People 2000 Objectives\textsuperscript{1} Addressed by Completed Projects 1994–96

Physical Activity and Fitness:

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

Nutrition:

2.1* Reduce coronary heart disease deaths to no more than 100 per 100,000 people.
2.3* Reduce overweight to a prevalence of no more than 20 percent among people aged 20 and older and no more than 15 percent among adolescents aged 12 through 19.
2.4 Reduce growth retardation among low-income children aged 5 and younger to less than 10 percent.
2.5* Reduce dietary fat intake to an average of 30 percent of calories or less and average saturated fat intake to less than 10 percent of calories among people aged 2 and older.
2.7* Increase to at least 50 percent the proportion of overweight people aged 12 and older who have adopted sound dietary practices combined with regular physical activity to attain an appropriate body weight.
2.8 Increase calcium intake so at least 50 percent of youth aged 12 through 24 and 50 percent of pregnant and lactating women consume 3 or more servings daily of foods rich in calcium, and at least 50 percent of people aged 25 and older consume 2 or more servings daily.

\textsuperscript{1} For a complete list, see Healthy People 2000: National Health Promotion and Disease Prevention Objectives.

* Indicates duplicate objectives that appear in two or more priority areas.
2.9 Decrease salt and sodium intake so at least 65 percent of home meal preparers prepare foods without adding salt, at least 80 percent of people avoid using salt at the table, and at least 40 percent of adults regularly purchase foods modified or lower in sodium.

2.10 Reduce iron deficiency to less than 3 percent among children aged 1 through 4 and among women of childbearing age.

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

2.19 Increase to at least 75 percent the proportion of the Nation’s schools that provide nutrition education from preschool through 12th grade, preferably as part of quality school health education.

2.21 Increase to at least 75 percent the proportion of primary care providers who provide nutrition assessment and counseling and/or referral to qualified nutritionists or dietitians.

**Tobacco:**

3.1* Reduce coronary heart disease deaths to no more than 100 per 100,000 people.

3.5 Reduce the initiation of cigarette smoking by children and youth so that no more than 15 percent have become regular cigarette smokers by age 20.

**Alcohol and Other Drugs:**

4.5 Increase by at least 1 year the average age of first use of cigarettes, alcohol, and marijuana by adolescents aged 12 through 17.

4.6 Reduce the proportion of young people who have used alcohol, marijuana, and cocaine in the past month.

4.7 Reduce the proportion of high school seniors and college students engaging in recent occasions of heavy drinking of alcoholic beverages to no more than 28 percent of high school seniors and 32 percent of college students.

4.8 Reduce alcohol consumption by people age 14 and older to an annual average of no more than 2 gallons of ethanol per person.

4.9 Increase the proportion of high school seniors who perceive social disapproval associated with the heavy use of alcohol, occasional use of marijuana, and experimentation with cocaine.

4.10 Increase the proportion of high school seniors who associate risk of physical or psychological harm with the heavy use of alcohol, regular use of marijuana, and experimentation with cocaine.
**Family Planning:**

5.1 Reduce pregnancies among girls aged 17 and younger to no more than 50 per 1,000 adolescents.

5.2 Reduce to no more than 30 percent the proportion of all pregnancies that are unintended.

5.4* Reduce the proportion of adolescents who have engaged in sexual intercourse to no more than 15 percent by age 15 and no more than 40 percent by age 17.

5.6 Increase to at least 90 percent the proportion of sexually active, unmarried people aged 19 and younger who use contraception, especially combined method contraception that both effectively prevents pregnancy and provides barrier protection against disease.

5.7 Increase the effectiveness with which family planning methods are used, as measured by a decrease to no more than 5 percent in the proportion of couples experiencing pregnancy despite use of a contraceptive method.

5.10* Increase to at least 60 percent the proportion of primary care providers who provide age-appropriate preconception care and counseling.

**Mental Health and Mental Disorders:**

6.3 Reduce to less than 10 percent the prevalence of mental disorders among children and adolescents.

6.4 Reduce the prevalence of mental disorders (exclusive of substance abuse) among adults living in the community to less than 10.7 percent.

6.5 Reduce to less than 35 percent the proportion of people aged 18 and older who experienced adverse health effects from stress within the past year.

6.7 Increase to at least 45 percent the proportion of people with major depressive disorders who obtain treatment.

6.8 Increase to at least 20 percent the proportion of people aged 18 and older who seek help in coping with personal and emotional problems.

6.9 Decrease to no more than 5 percent the proportion of people aged 18 and older who report experiencing significant levels of stress who do not take steps to reduce or control their stress.

6.13 Increase to at least 50 percent the proportion of primary care providers who routinely review with patients their patients’ cognitive, emotional and behavioral functioning and the resources available to deal with any problems that are identified.

6.14 Increase to at least 75 percent the proportion of providers of primary care for children who include assessment of cognitive, emotional, and parent-child functioning, with appropriate counseling, referral, and followup, in their clinical practices.
Violent and Abusive Behavior:

7.4 Reverse to less than 25.2 per 1,000 children the rising incidence of maltreatment of children younger than age 18.

7.5 Reduce physical abuse directed at women by male partners to no more than 27 per 1,000 couples.

7.12 Extend protocols for routinely identifying, treating, and properly referring suicide attempters, victims of sexual assault, and victims of spouse, elder, and child abuse to at least 90 percent of hospital emergency departments.

7.14 Increase to at least 30 the number of States in which at least 50 percent of children identified as neglected or physically or sexually abused receive physical and mental evaluation with appropriate followup as a means of breaking the intergenerational cycle of abuse.

Educational and Community-Based Programs:

8.3 Achieve for all disadvantaged children and children with disabilities access to high quality and developmentally appropriate preschool programs that help prepare children for school, thereby improving their prospects with regard to school performance, problem behaviors, and mental and physical health.

8.10 Establish community health promotion programs that separately or together address at least three of the Healthy People 2000 priorities and reach at least 40 percent of each State’s population.

8.11 Increase to at least 50 percent the proportion of counties that have established culturally and linguistically appropriate community health promotion programs for racial and ethnic minority populations.

Unintentional Injuries:

9.1 Reduce deaths caused by unintentional injuries to no more than 29.3 per 100,000 people.

9.2 Reduce nonfatal unintentional injuries so that hospitalizations for this condition are no more than 754 per 100,000 people.

9.3 Reduce deaths caused by motor vehicle crashes to no more than 1.9 per 100 million vehicle miles traveled and 16.8 per 100,000 people.

9.5 Reduce drowning deaths to no more that 1.3 per 100,000 people.

9.18 Provide academic instruction on injury prevention and control, preferably as part of quality school health education, in at least 50 percent of public school systems (grades K through 12).

9.22 Extend to 50 States emergency medical services and trauma systems linking prehospital, hospital, and rehabilitation services in order to prevent trauma deaths and long-term disability.
Environmental Health:
11.1 Reduce asthma morbidity, as measured by a reduction in asthma hospitalizations to no more than 160 per 100,000 people.
11.2* Reduce the prevalence of serious mental retardation among school-aged children to no more than 2 per 1,000 children.
11.4 Reduce the prevalence of blood lead levels exceeding 15 µg/dL and 25 µg/dL among children aged 6 months through 5 years to no more than 500,000 and zero, respectively.

Maternal and Infant Health:
14.1 Reduce the infant mortality rate to no more than 7 per 1,000 live births.
14.2 Reduce the fetal death rate (20 or more weeks of gestation) to no more than 5 per 1,000 live births plus fetal deaths.
14.3 Reduce the maternal mortality rate to no more than 3.3 per 100,000 live births.
14.5 Reduce low birth weight to an incidence of no more than 5 percent of live births and very low birth weight to no more than 1 percent of live births.
14.6 Increase to at least 85 percent the proportion of mothers who achieve the minimum recommended weight gain during their pregnancies.
14.7 Reduce severe complications of pregnancy to no more than 15 per 100 deliveries.
14.9* Increase to at least 75 percent the proportion of mothers who breastfeed their babies in the early postpartum period and to at least 50 percent the proportion who continue breastfeeding until their babies are 5 to 6 months old.
14.11 Increase to at least 90 percent the proportion of all pregnant women who receive prenatal care in the first trimester of pregnancy.
14.12* Increase to at least 60 percent the proportion of primary care providers who provide age-appropriate preconception care and counseling.
14.13 Increase to at least 90 percent the proportion of women enrolled in prenatal care who are offered screening and counseling on prenatal detection of fetal abnormalities.
14.14 Increase to at least 90 percent the proportion of pregnant women and infants who receive risk-appropriate care.

Heart Disease and Stroke:
15.1* Reduce coronary heart disease deaths to no more than 100 per 100,000 people.
15.4 Increase to at least 50 percent the proportion of people with high blood pressure whose blood pressure is under control.
15.5 Increase to at least 90 percent the proportion of people with high blood pressure who are taking action to help control their blood pressure.
15.9* Reduce dietary fat intake to an average of 30 percent of calories or less and average saturated fat intake to less than 10 percent of calories among people aged 2 and older.

15.10* Reduce overweight to a prevalence of no more than 20 percent among people aged 20 and older and no more than 15 percent among adolescents aged 12 through 19.

15.11* Increase to at least 30 percent the proportion of people aged 6 and older who engage regularly, preferably daily, in light to moderate physical activity for at least 30 minutes per day.

**Cancer:**

16.7* Reduce dietary fat intake to an average of 30 percent of calories or less and average saturated fat intake to less than 10 percent of calories among people aged 2 and older.

**Diabetes and Chronic Disabling Conditions:**

17.2 Reduce to no more than 8 percent the proportion of people who experience a limitation in major activity due to chronic conditions.

17.4 Reduce to no more than 10 percent the proportion of people with asthma who experience activity limitation.

17.6 Reduce significant hearing impairment to a prevalence of no more than 82 per 1,000 people.

17.8* Reduce the prevalence of serious mental retardation in school-aged children to no more than 2 per 1,000 children.

17.12* Reduce overweight to a prevalence of no more than 20 percent among people aged 20 and older and no more than 15 percent among adolescents aged 12 through 19.

17.13* Increase to at least 30 percent the proportion of people aged 6 and older who engage regularly, preferably daily, in light to moderate physical activity for at least 30 minutes per day.

17.14 Increase to at least 40 percent the proportion of people with chronic and disabling conditions who receive formal patient education including information about community and self-help resources as an integral part of the management of their condition.

17.15 Increase to at least 80 percent the proportion of providers of primary care for children who routinely refer or screen infants and children for impairments of vision, hearing, speech, and language, and assess other developmental milestones as part of well-child care.
17.20 Increase to 50 the number of States that have service systems for children with or at risk of chronic and disabling conditions, as required by Public Law 101-239.

**HIV Infection:**

18.3* Reduce the proportion of adolescents who have engaged in sexual intercourse to no more than 15 percent by age 15 and no more than 40 percent by age 17.

**Sexually Transmitted Diseases:**

19.9* Reduce the proportion of adolescents who have engaged in sexual intercourse to no more than 15 percent by age 15 and no more than 40 percent by age 17.

**Immunization and Infectious Diseases:**

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

**Clinical Preventive Services:**

21.3 Increase to at least 95 percent the proportion of people who have a specific source of ongoing primary care coordination of their preventive and episodic health care.

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

**Surveillance and Data Systems:**

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