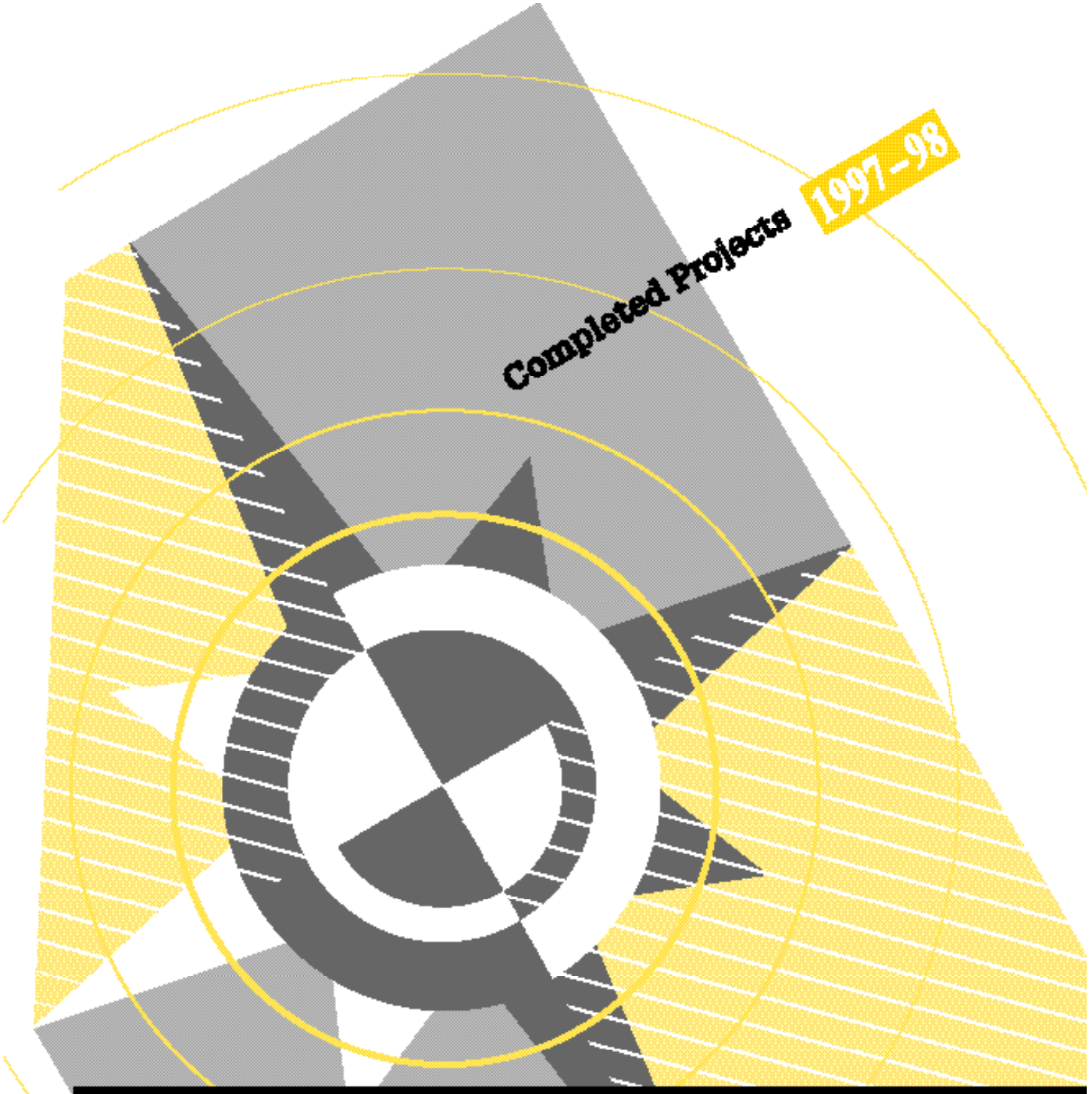

Maternal and Child Health
RESEARCH PROGRAM

HRSA

Maternal and Child Health
RESEARCH PROGRAM

Completed Projects 1997-98

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

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Table of Contents

Preface

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 sixth 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 1997–98.

The research projects in this book are arranged alphabetically by project name. This edition 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.

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
December 2000

Project Classification Guide

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

Healthy People 2000 Objectives

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

Study Design

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

Time Design

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

Care Emphasis

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

Population Focus

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

Race/Ethnic Focus

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

Completed
PROJECTS ABSTRACTS

Adverse Effect of Cow Milk in Infants

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Project Number MCJ-190808

NTIS Number PB2000-106683

Project Period 10/1/1995-9/30/1998

Costs	Awarded	Requested
Year 1	$119,520	$145,656
Year 2	$124,191	$151,360
Year 3	$129,000	$157,292
Year 4		
Year 5		
Year 6		

Year 2000 Objectives
2.4, 2.10

Study Design
Experimental

Time Design
Longitudinal

Care Emphasis
Interventional

Population Focus
Infants

Race/Ethnic Focus
No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Although the prevalence of iron deficiency in the United States has decreased over the past decade, iron deficiency continues to be the leading nutritional deficiency of infants and children. Unless there is a substantial increase in whole body iron during the first year of life, the rapid expansion of the hemoglobin mass will deplete body iron stores. When iron deficiency is severe enough to cause anemia, a considerable body of evidence, both in animal models and humans, suggests that cognitive development is likely to be impaired.
Infants should be breastfed or fed infant formulas until one year of age, and cow milk should not be fed, according to current recommendations by the American Academy of Pediatrics and by the Institute of Medicine. Less than 10% of infants in the United States are breastfed at 10 months of age. After 9 or 10 months of age, the major choice for most families is between cow milk and infant formula. Although cow milk is considerably less expensive than infant formulas, its use has declined over the years. In 1991 in the United States 55% of 10-month-old infants were fed fresh fluid cow milk, and at 12 months of age the percentage was 80%. By 1997 the percentage of 12-month-old infants who were fed cow milk had dropped to 39%. Insistence on avoidance of cow milk in the diet of older infants should be based on sound evidence of adverse effects of such feeding. Until recently, authoritative sources such as the Committee on Nutrition of the American Academy of Pediatrics

condoned, with some provisos, the feeding of cow milk to older infants. The new recommendations from 1992 are based on newer, semi-quantitative information, epidemiologic data and theoretical considerations, which suggest that the feeding of cow milk is one of the most important, if not the most important, determinant of iron nutritional status in infants and toddlers. The present project sought data supporting that notion because if adverse effects of feeding cow milk are in reality trivial, we should, on the basis of economic considerations, condone the feeding of cow milk to older infants. However, if adverse effects are medically important, efforts should continue to promote avoidance of cow milk feeding until after 1 year of age.
This application sought to broaden our understanding of the adverse effects of cow milk on iron nutriture by providing data on the effect of cow milk on bioavailability of iron from the infant's diet (Question 1) and on the prevalence and severity of cow milk-induced intestinal blood loss (Question 2). Because cow milk is currently fed almost exclusively to older and not to young infants, the study involved infants between 6 and 12 months of age.

Research Questions or Hypotheses

This project consisted of two parts, each devoted to answering a specific question:
Question 1 asked to what extent the feeding of cow milk inhibits the absorption of non-heme iron from the diet. To answer this question, we tested the study hypothesis that iron is better absorbed from the diet when infant formula is fed than when cow milk is fed. The incorporation of 58Fe into erythrocytes, expressed as a percentage of orally administered label, was used as a surrogate for iron absorption. Iron absorption was also determined directly with the use of 4-day stool collections made with the use of disposable diapers.
Question 2 asked what are the medical consequences of cow milk-provoked intestinal blood loss? Specifically, exactly how much blood do infants lose? Is blood loss associated with clinical signs and symptoms, and does it have adverse effects on iron nutritional status. The study hypothesis was that infants lose more fecal blood when they are fed cow milk than when they are fed formula, that blood loss is associated with clinical symptoms and leads to deterioration of iron nutritional status.

Study Design and Methods

To answer the Question 1, normal infants aged 9 to 11 months were studied in a crossover design. Erythrocyte incorporation of the stable isotope, 58Fe, was determined, as was iron absorption determined as intake minus 96-hr excretion of an ingested dose of 58Fe. In each infant, iron absorption was determined twice, once while being fed cow milk and once while being fed formula. The order of study was random by predetermined sequence, using sealed envelopes. 58Fe, a stable, nonradioactive isotope, was given with test meals over 3 days.
The study was relatively demanding on the parents, who were required to bring the baby to our Metabolic Unit for three consecutive days on two separate occasions, plus several other visits. We enrolled 22 infants and all completed the study as planned. We calculated that 22 infants in a crossover design were necessary to detect a difference of 0.75 SD. The assigned feeding (cow milk or formula) was fed for 28 days, with ingestion of the isotopically labeled meals (beikost followed by milk or formula) beginning in each case on day 15. On the 29th day, the feeding was changed to the alternate feeding, which was fed for 28 days with isotope ingestion again beginning after 15 days. Infants came to the metabolic unit for ingestion of the 58Fe-labeled meals, which contained each 0.115 mg of 58Fe in the form of ferrous sulfate. A blood sample (approximately 1 ml) was obtained by heel stick using the disposable Tenderfoot spring-loaded device just before and 28 days after ingestion of the dose. Stool collections were obtained during the first 96 hours after ingestion of the first labeled meal.
To answer Question 2, two studies were carried out. In Study A, 32 infants were enrolled at 252 days, placed on a milk -based formula for 4 weeks and then fed cow milk for 12 weeks. Thirty-one infants completed the study. Spot stools were collected at frequent intervals and 96-hour stool collections were performed on five occasions in most infants. Fecal hemoglobin was determined with a quantitative method (HemoQuant test). Feeding-related infant behavior and stool characteristics were closely monitored. Iron nutritional status was followed and related to fecal blood loss.
In Study B, 39 infants were enrolled at 196 days of age, fed formula for 4 weeks and then cow milk for 8 weeks. Thirty-four infants completed the study as planned. Twenty-nine infants were enrolled at 336 days of age, fed formula for 4 weeks followed by cow milk for 8 weeks. All but one infant completed the study as planned. In each group of infants spot fecal specimens were obtained at frequent intervals and analyzed for hemoglobin concentration. As in Study A, infant behavior,

stool characteristics and indicators of iron nutritional status were determined at frequent intervals.

Findings

Question 1:
Twenty-two infants were recruited into this demanding study and all completed the study as planned. Thus, a total of 44 iron absorption studies were completed. Each study included administration of 58Fe -labeled test meals on 3 consecutive days, collection of feces for 96 hours, and determination of erythrocyte incorporation of 58Fe four weeks later. There was thus direct determination of iron absorption as well as erythrocyte incorporation of iron, a widely used surrogate for iron absorption. Because specimens of only 4 subjects have been completely analyzed to date, no conclusions can be drawn yet with regard to the question asked, i.e., does cow m~lk inhibit iron absorption. However, one conclusion can be drawn, namely that erythrocyte incorporation of absorbed 58Fe is far less than the 80-100% reported for adult subjects. This confirms observations made by our group in much younger infants.
Question 2:
In two separate studies a total of 100 infants were enrolled, of whom 93 completed the studies as planned. In Study A, infants fed cow milk starting at 280 days of age showed a statistically significant increase in stool hemoglobin concentration as well as daily hemoglobin excretion. As is characteristic of cow milk-induced blood loss in younger infants, some infants showed an increase and others did not. However, the cow milk-induced blood loss was altogether trivial in magnitude. During baseline and in non-responders, daily fecal hemoglobin excretion was about 12 mg/day, equivalent to a loss of iron of 0.042 mg/day. In responders during cow milk feeding, hemoglobin loss rose to a mean of 16.5 mg/day, equivalent to a loss of iron of 0.057 mg/day. These losses have to be considered nutritionally and clinically unimportant. There was no association between blood loss and infant behavior or iron status.
In Study B, infants were fed cow milk starting at 224 days of age or at 364 days of age. Baseline fecal hemoglobin concentration was higher than previously observed in younger infants, especially at 364 days of age. During cow milk feeding, there was a significant increase in fecal hemoglobin excretion at 224 days of age, but it was much less intense than previously observed in younger infants. At 364 days of age there was no measurable response to cow milk. No association between fecal blood loss and infant behavior was uncovered, and there was no effect on iron nutritional status.
Together, the results of these two studies lead to the conclusion that cow milk-induced fecal blood loss, which is very pronounced in young infants, diminishes in intensity during the second 6 months of life and ceases by 12 months of age.

Recommendations

The present studies establish that cow milk-induced blood loss gradually disappears during the second 6 months of life. This means that fecal blood loss is most likely not the main cause of the poor iron nutritional status that is associated with cow milk feeding. Whether that cause is impairment of dietary iron absorption by cow milk remains to be established. Regardless of the mechanism involved, the fact that cow milk feeding clearly affects iron nutritional status negatively, plus concern about the high potential renal solute load of cow milk, argue in favor of continuing the general recommendation that cow milk not be fed during the first year of life. However, during the last 3 months of the first year of life, the concerns about cow milk diminish to the point where the advantages of cow milk (high protein and calcium content, low cost) may begin to outweigh the disadvantages.

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Jiang T, Romero E, Vinco A, Frantz JA, Ziegler EE. 1997. Cow milk feeding and gastrointestinal blood loss in older infants. *Abstracts of the 16th International Congress*.

Articles

Jiang T, Jeter JM, Nelson SE, Ziegler EE. 2000. Intestinal blood loss during cow milk feeding in older infants: Quantitative measurements. *Archives of Pediatrics and Adolescent Medicine* 154:673-678.

Jiang T, Jeter JM, Nelson SE, Ziegler EE. 2000. Intestinal blood loss during cow milk feeding in older infants; quantitative measurements. *Archives of Pediatrics and Adolescent Medicine* 154(7):673-678.

Ziegler EE, Jiang T, Romero E, Vinco A, Frantz JA, Nelson SE. 1999. Cow's milk and intestinal blood loss in late infancy. *Journal of Pediatrics* 135(6):720-726.

Presentations

Ziegler E. 2000. *Adverse effects of cow milk in infants*. Presented at the 30th Research Roundtable, Maternal and Child Health Bureau, Rockville, MD.

Antenatal Formula Distribution: Effect on Breastfeeding

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Project Number MCJ-360648

NTIS Number

Project Period 10/1/1994-9/30/1997

Costs	Awarded	Requested
Year 1	$117,305	$137,994
Year 2	$99,295	$129,798
Year 3	$18,459	$21,716
Year 4		
Year 5		
Year 6		

Year 2000 Objectives
2.10, 2.11, 14.9

Study Design
Experimental

Time Design
Longitudinal

Care Emphasis
Interventional

Population Focus
Infants, Neonates, Pregnant Women, Non Pregnant Women

Race/Ethnic Focus
No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Breastmilk is acknowledged as the optimal way to nourish an infant. In the early 1990's infant formula manufacturers initiated marketing practices involving the distribution of attractively packaged formula advertising, samples and free formula offers through obstetrical offices. These infant feeding materials are widely used in obstetrical offices to educate expectant women about infant feeding. The involved companies state that the materials and formula samples are provided as a patient service, designed to support breastfeeding, but also to promote the use of a safe alternative when breastfeeding is not chosen. The use of commercially produced educational materials and formula samples by hospitals in the postpartum period, however, has been shown to be detrimental to breastfeeding. In formulating this study we believed there was reason to hypothesize that their antepartum use might be equally detrimental.

Research Questions or Hypotheses

The main purpose of this research was to test the following hypotheses: The distribution of commercial infant formula promotion materials to pregnant women by obstetricians when compared to non-commercial infant feeding materials that conform to the World Health Organization code of marketing for breastmilk substitutes:

1. Decreases breastfeeding initiation rates
2. Increases rates of early breastfeeding cessation (a) peripartum (before hospital discharge); and (b) before 2 weeks
3. Decreases the duration of full exclusive, full almost exclusive, and partial breastfeeding
4. Decreases the chance of a mother attaining her personal goal for breastfeeding duration

Study Design And Methods

A randomized, investigator blinded, clinical trial was conducted to evaluate effects of antenatal distribution of commercial formula promotion materials as compared to non-commercial infant feeding educational materials on breastfeeding initiation, duration and other relevant infant feeding outcomes. Subjects were randomly assigned to receive either a commercial formula or non-commercial pack as part of the prenatal education materials at their first prenatal visit. Interviews during postpartum hospitalization and chart reviews were used to evaluate the effect of the intervention on breastfeeding initiation. The postnatal study, in which breastfeeding women received serial telephone interviews over the next six months, evaluated the effects of the intervention on breastfeeding duration, and chances of attaining personal breastfeeding goals. Sub-group analyses were conducted for four groups of at risk women (low education, primiparous, cesarean delivery and those with uncertain goals or breastfeeding goals of $\leq$12 weeks).

Study Sample and/or Population

Pregnant women (n=547) were randomized to the study at their first prenatal obstetrical visit. Due to pregnancy loss, relocation, or exclusion (medical complications of pregnancy), 19% of the cohort did not present for delivery. At delivery, 311 breastfeeding and 133 formula feeding women were identified (n=444). Of the 311 breastfeeding women, 15 (2.7%) refused follow-up, and 17 (3.1%) were excluded due to incomplete data or maternal or infant birth complications (n=15). Postnatal losses to the breastfeeding cohort were minimal (n=11, 2%).

Findings

Sociodemographic characteristics of the 444 women who completed the prenatal phase of the study did not vary between intervention groups for age, education, parity, ethnicity, delivery mode, previous breastfeeding experience, plans to return to work, breastfeeding goals and infant gestational age or birth weight. Subjects were largely White (94%), privately insured (97%), and planned to return to work within 6 months (60%).

Of 311 women who chose to breastfeed, 43% had uncertain or goals for breastfeeding of £ 12 weeks. First-time breastfeeders, primiparas, and women with plans to return to work within 6 months were significantly more likely to have uncertain or breastfeeding goals of £ 12 weeks. Most multiparous women who chose to breastfeed had previously breastfed a child (92%).

The small difference (1.4%) in breastfeeding initiation between the two groups was not statistically significant, suggesting no effect of the intervention on women's choice of an infant feeding method. Two specific times, breastfeeding cessation prior to hospital discharge and < 2 weeks postpartum, were used to assess effects of the intervention on early breastfeeding cessation. Peripartum breastfeeding cessation (in-hospital) was significantly higher in the commercial group. Relative risks for early cessation were higher (RR 5.83, P=.02) in the commercial group.

Early breastfeeding termination (< 2 weeks) was higher in the commercial group across all categories of breastfeeding with findings approaching statistical significance for overall and exclusive breastfeeding in unadjusted analyses. After adjustment for potential confounders (maternal age, planned return to work, previous breastfeeding experience, marital status and socioeconomic status) results for both overall (OR 1.91,P=.04) and exclusive (OR 1.65,p=.04) breastfeeding were statistically significant; results for full breastfeeding were suggestive(OR 1.66,P=.052). Sub-group analyses demonstrated that women with low or uncertain breastfeeding goals had significantly increased risks for breastfeeding cessation at 2 weeks when exposed to the commercial intervention [overall (RR 1.55, P=.02).

Small declines in mean and median long term breastfeeding duration were noted in all categories of breastfeeding among women exposed to formula promotion packs. None of these differences, however, reached statistical significance. Differences

in breastfeeding duration among primiparas, women of low educational attainment and women who underwent cesarean delivery did not demonstrate significant effects due to the intervention. Sub-group analyses, however, demonstrated statistically and clinically significant declines in duration as a result of the commercial intervention among women with undefined or breastfeeding goals of £ 12 weeks. In this group, (43% of breastfeeding women), women in the commercial group experienced an average decline of 35 days in overall, 20 days in full and 11 days in exclusive breastfeeding duration. The intervention did not affect the likelihood of women attaining their personal breastfeeding goals.

Recommendations

This study demonstrates that the distribution of formula company educational materials and samples by obstetricians adversely affects breastfeeding duration. While we saw no evidence to suggest a significant effect on choice of infant feeding method, this study confirms that breastfeeding duration is adversely affected by the distribution of such items. The likelihood that a woman will terminate breastfeeding prior to hospital discharge is approximately five fold higher for women prenatally exposed to commercial formula materials and cessation in the first 2 weeks postpartum is increased. Women with uncertain or goals for breastfeeding of £ 12 weeks also experienced clinically significant declines in breastfeeding duration. The breastfeeding success of substantial numbers of women is placed at risk by the widespread use of formula promotion materials in obstetrical offices. We believe these findings support the elimination of commercial formula promotion products from prenatal settings. The prenatal use of such materials is counterproductive to our nation's health goals, as exposed women may experience significant declines in breastfeeding duration. Physicians must ensure that patient educational materials clearly and unequivocally support breastfeeding as optimal for both mother's and baby's health.

Products To Date

Abstracts

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Howard CR, Howard FM, Andresen E, Lawrence RA, deBlieck EA, Weitzman M. 1997. Does formula advertising during pregnancy affect breastfeeding initiation or duration? *Ambulatory Child Health* 3:180 (Abstract).

Howard CR, Howard FM, Lanphear BP, et al. 1997. Does early pacifier use negatively influence breastfeeding duration? *Ambulatory Child Health* 3:180 (Abstract).

Articles

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Presentations

Howard CR. 1995. *Breastfeeding education during prenatal care.* Presented at the Ambulatory Pediatric Association, San Diego, CA.

Howard CR. 1995. *Breastfeeding education during prenatal care.* Presented at the Child Health 2000, Vancouver, British Columbia, Canada.

Howard CR. 1997. *Do pacifiers interfere with successful breastfeeding?* Presented at the National Meeting of the Academy of Breastfeeding Medicine, Boston, MA.

Howard CR. 1997. *Does formula advertising during pregnancy affect breastfeeding initiation or duration?* Presented at the National Meeting Academy of Breastfeeding Medicine, Boston, MA.

Howard, CR. 1997. *Does pacifier use interfere with successful breastfeeding?* Presented at the Townsend Teaching Day in Neonatal Medicine, Rochester, NY.

Howard CR. 1997. *Does formula advertising during pregnancy affect breastfeeding initiation or duration?* Presented at the Pediatric Academic Societies Annual Meeting, Washington, DC.

Howard CR. 1997. *Does early pacificer use negatively influence breastfeeding duration?* Presented at the Pediatric Academic Societies Annual Meeting, Washington, DC.

Howard CR. 1996. *Employer support for breastfeeding.* Presented at the Ambulatory Pediatric Association, Washington, DC.

Changes in Supplemental Security Income for Children

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Project Number MCH-250634

NTIS Number PB99-145674

Project Period 10/1/1993-9/30/1996

Costs	Awarded	Requested
Year 1	N/A	$288,655
Year 2	$243,204	$292,813
Year 3	$201,602	$280,417
Year 4		
Year 5		
Year 6		

Year 2000 Objectives
No Stated Healthy People Objectives

Study Design
Quasi Experimental

Time Design
Mixed

Care Emphasis
Noninterventional

Population Focus
Infants, Toddlers, Preschool-age children, School-age children, Adolescents (not pregnancy related)

Race/Ethnic Focus
No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

The Supplemental Security Income program for children and adolescents has undergone major expansion in the past several years, reflecting at least three main policy changes: a) the publication of new guidelines for determining childhood disability due to mental impairments, b) new guidelines for determining childhood disability in general (the "Zebley"' regulation), and c) major efforts by the Social Security Administration to identify children with disabilities. In February 1990, the US Supreme Court (in Sullivan V Zebley) struck down the then current guidelines for determining childhood disability, ruling that those guidelines were too restrictive and discriminated against children. The Court required the Social Security Administration to develop new and broader disability guidelines, including an assessment of the child's functional abilities. Prior to the Supreme Court decision, to follow an earlier (1985) revision of adult mental impairment listings, the Social Security Administration had begun revisions of the listings of childhood mental impairment. This revision (published in late 1990) made more explicit several childhood categories and added attention deficit/hyperactivity disorder (ADHD) as a new listing. The new mental impairments listing also required assessment of the severity of the mental impairment, mainly by assessing its impact on the child's functioning in several domains, including social and

educational.
These new regulations helped to expand the numbers of US children receiving disability payments and also their access to Medicaid. (In all but 10 states, SSI eligibility brings automatic or easier enrollment in Medicaid, even where household income may be higher than required by the states usual Medicaid criteria.) From 1989 to 1994, the numbers of child and adolescent SSI recipients have almost tripled, from about 275,000 to over 900,000. Direct cash benefits and associated health insurance (Medicaid) expenditures have grown accordingly, with cash benefits alone currently at about $5 billion. Yet, remarkably little is known about the childhood SSI population, their clinical characteristics, variations in their use of Medicaid services, or the persistence of utilization patterns over time.
Despite a commonly prevailing lay view that many children with disabilities are doomed to die in childhood or to lead non-productive lives dependent on public institutions, the reality is quite different. The large majority (90% or higher) of children with developmental or physical disabilities will survive to young adulthood, although with varying degrees of physical and psychological morbidity. Although some children may require significant attendant care and remain in a highly dependent state as they enter adulthood, there is ample evidence that the large majority of these children and adoles-cents can make an effective transition to adulthood and become active and productive members of society . Similarly, state Medicaid officials often view the population of childhood SSI recipients as generating very high costs, although data from 984 (pre-Zebley) indicate a relatively low median expenditure among these children despite high mean expenditures. In Michigan, for example, only 9% of recipients used 70% of Medicaid expenditures for childhood SSI recipients.

Research Questions or Hypotheses

This research program was developed to document further the growing numbers of children and adolescents receiving SSI benefits and examine 1) variations in access to SSI programs by state; 2) changes over time among child and adolescent SSI recipients, both in the types of conditions that they have and in their utilization of services, and 3) particularly high utilizing SSI recipients to understand better their use of resources and to define options for cost savings.

Study Design and Methods

The project analyzed state level poverty., program generosity, and health status indicators to predict state enrollment in SSI in 1989 and 1992.
The second part of the project analyzed Medicaid data from five states (Maryland, Georgia, Tennessee, Michigan, and California). We used Medicaid enrollment files and claims data for four years (1989-1992) for five states (California, Georgia, Maryland, Michigan, and Tennessee) to estimate changes in rates of key diagnoses from before to after the major changes in program policy. These years included the key program policy changes, and the data therefore allow examination of their associations with the clinical conditions that newly-eligible children had. We defined three time periods during the four study years: July 1989 to June 1990 (time 1, prior to the changes in policy), July 1990 to June 1991 (time 2, during program changes), and July 1991 to June 1 992 (time 3, after the policy changes). We included claims data up to December 1992 so as to have a six-month window following first SSI enrollment to identify any claims for a chronic condition. We used a broad general classification of childhood conditions as chronic, based on a previously published categorization of ICD-9 codes, and then separated these conditions into primary physical, mental health, or mental retardation groups. We also developed algorithms to identify children with two specific diagnoses of interest (asthma and ADHD) in the Medicaid data files.
We first determined numbers and demographic characteristics of total new enrollees by state during each time period. We then determined numbers of new enrollees with chronic conditions in each time period and rates for physical, mental health, and mental retardation categories and for asthma and ADHD. For children and adolescents who enrolled in time 1, we also determined the numbers with chronic conditions when including claims from all months following enrollment. We finally calculated changes in relative proportions of each diagnosis or diagnostic group over tune.
We also computed the average expenditures by state arid Medicaid eligibility group (SSI or non-SS1 Medicaid) for the whole sample and separately for children with high and non-high Medicaid expenditures. We calculated the percent of total expenditures accounted for by the high expenditure children by multiplying the number of children with high expenditures by the average Medicaid expenditure for high expenditure children and dividing the resulting number by the average cost for all children multiplied by the total number of children (again, by state and Medicaid eligibility group).
We also calculated rates of previous Medicaid enrollment by state for each time period to determine how these rates changed

during the study. We then determined whether a SSI child had a chronic health condition which led to one or more Medicaid claims at any time from July 1989 through December 1992. Classification of conditions as chronic came from previously published categorizations of ICD-9 codes. This approach is conservative, insofar as a child might have a chronic health condition for which treatment was sought, but the claim might be labeled with another diagnosis or purpose for visit. We used a life table approach to estimate frequency of a chronic condition claim if the child had had SSI enrollment throughout the study years.

Findings

Poverty accounts for a majority of the variation in SSI state enrollment although it is less predictive in 1992 than in 1989. Few other indicators, such as of health status, had major association with enrollment. We found little evidence of major variations across states in enrollment patterns once we controlled for poverty status.
The Medicaid analyses document growth in specific conditions, most notably asthma and mental health conditions other than mental retardation. Children with all types of conditions had substantial growth in numbers during the study period, although the growth was particularly marked for asthma and ADHD and less so for mental retardation. About 45% of new enrollees had had no previous Medicaid coverage during the study period, although the likelihood of previous Medicaid enrollment prior to 881 benefits increased from about 40% in 1989 to 60% in 1992. Children with Medicaid claims for chronic conditions were more likely to have had Medicaid prior to their SSI enrollment
Nearly all high expenditure children (whether on SSI or not) use either long-term care or hospitals, which are the sources of high expenditures in general for children. The approximately 10% of SSI children who had total Medicaid expenditures over $10,000 in 1992 accounted for well over 2/3 of all 581 expenditures for children in these states in this year. Although the SSI population includes a number of children with high expenditures, expenditures are relatively modest for children with SSI once high expenditure children are excluded, averaging about twice the expenditures of non-SSI Medicaid children.

Recommendations

These several related studies provide major new information on the characteristics and changing health and utilization patterns of children and adolescents who receive disability benefits from the SSI program, along with Medicaid and access to Title V programs for Children with Special Health Care Needs. The data help to describe the population in ways that can help Title V planning. They also demonstrate that, even within the SSI population, a small percentage accounts for a large proportion of expenditures. Improved care coordination focused on these children could better use scarce Medicaid resources. Further research should examine the family implications of these changing patterns, how families use their benefits, how varied public programs intersect to improve the outcomes for children with disabilities and their households. Many of these finding and recommendations fit well also with the recommendations of the National Commission on Childhood Disability.

Products To Date

Articles

Kuhlthau K, Perrin JM, Ettner SL, McLaughlin TJ, Gortmaker SL. 1998. High-expenditure children with supplemental security income. *Pediatrics* 102(3):610-615.

Perrin JM, Ettner SL, McLaughlin TJ, Gortmaker SL, Bloom SR, Kuhlthau K. 1998. State variations in supplemental security income enrollment for children and adolescents. *American Journal of Public Health* 88(6):928-931.

Development of Monitoring Methods for Perinatal Outcomes

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Project Number MCJ-240639

NTIS Number PB99-158032

Project Period 4/1/1994-12/31/1997

Costs	Awarded	Requested
Year 1	$49,864	$62,330
Year 2	$42,083	$61,886
Year 3	$50,786	$63,483
Year 4		
Year 5		
Year 6		

Year 2000 Objectives
14.1, 14.5

Study Design
Observational

Time Design
Longitudinal

Care Emphasis
Noninterventional

Population Focus
Neonates, Infants

Race/Ethnic Focus
No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Of the many purposes for surveillance, monitoring of perinatal events at the national level primarily encompass detecting epidemics, and providing quantitative estimates of the magnitude of morbidity and mortality. If surveillance efforts were expanded to smaller jurisdictions such as cities or communities, the purposes of monitoring could be extend to include describing and identifying local factors related to adverse perinatal outcome occurrence, and evaluating local control and prevention programs and activities. Monitoring rare health events such as adverse perinatal outcomes, however, presents program planners and researchers with a challenging task. Despite decades of experience with monitoring national or state-wide rates of infant morbidity and mortality in the U.S., no adequate methods are available to monitor short-term changes in perinatal events in areas such as counties, cities or even smaller areas such as census tracts. Because there are few infant deaths in these areas distinguishing random fluctuations from actual increases or decreases in infant mortality over time is difficult.
Quality assurance methods are an overlooked source of efficient monitoring techniques. These methods were developed

several decades ago for use in industry to monitor assembly line processes and to detect unacceptably high numbers of 'defective' or nonconforming products. There are hundreds of industrial quality assurance methods but only a few seem applicable to the surveillance needs specific to public health. Several methods were investigated as part of this project. Monitoring efforts rarely include a spatial component. Moreover, when spatial analyses are used, rarely are they applied with the intent of providing guidance to the content of public health programs and interventions. Consideration of their spatial distribution is important for several reasons. First, most adverse health outcomes are heterogeneous with respect to their distribution across space. It is also of interest to know if characteristics of areas are wholly or partially explain the spatial variation or if there is spatial variation present independent of the area characteristics. If characteristics of areas that describe the shared environment explain spatial variability, we may want to know if any of these area-level factors might be candidates for intervention. Finally, spatial variability can be broken down into 'global' and 'local' correlation. Global variability or heterogeneity measures the extent to which outcomes have similar v~ues over the whole region of interest while local variability or clustering describes how correlated outcomes are within smaller neighboring areas (e.g., whether occurrence of an outcome is dependent upon neighboring census tracts). When studying outcomes spatially, knowing the relative presence and magnitude of heterogeneity ('global') and clustering ('local') can be useful for monitoring purposes and the consideration of program or intervention design.

Research Questions or Hypotheses

Aim 1: To assess the utility of using industrial quality improvement techniques to monitor short-term changes in perinatal outcomes in small geographic areas such as cities, census tracts or census block groups.
Aim 2: To assess the utility of using spatial stochastic process techniques as a means for monitoring perinatal outcomes.

Study Design and Methods

To fulfill the first aim of this project, modifications of industrial quality assurance techniques were employed. After considering several candidates, we focussed on modifications of the cumulative summary (CUSUM) quality assurance method to examine changes in rates of perinatal outcomes for geographic areas such as cities and neighborhoods (clusters of census tracts). We used computerized birth and certificates as our source of data to examine the following outcomes: smoking during pregnancy, initiation of prenatal care, very low birth weight, low birth weight, infant deaths including neonatal and postneonatal mortality. To ensure the reliable performance of the methods we developed, we used simulated data for which parameters and underlying distributions were known. One product is a set of computer programs which can be used to create CUSUM charts for the monitoring of any type of health data.
For the second aim, we applied methods of Composite Likelihood estimation procedures to assess the global and local spatial variability of four perinatal outcomes: very low birth weight, low birth weight, all infant deaths and infant deaths due to SIDS and perinatal infections. For the development of this method, we also relied heavily on simulations. We employed regression methods to explain the global and local variability of these outcomes with a set of social and behavioral covariates. Covariates with intervention potential were given high priority in terms of inclusion in final models. Information yielded with this method included (1) knowledge about the global and local spatial distribution of outcomes, (2) information on which factors with intervention potential are most closely linked to the local spatial variability of outcomes and (3) the factors which most likely would have the greatest impact on reducing adverse outcomes.

Findings

CUSUM, as a monitoring method, performed well for the outcomes examined, especially when supplemental criteria, average run length, was used. CUSUM performed better for larger geographic areas (e.g., city as a whole) and for low but not rare prevalence outcomes (e.g., late or no prenatal care). However, even for smaller geographic areas, CUSUM was able to detect substantial changes in rates that were not apparent via other means of detecting trends or visual inspection of the data. For the spatial analyses, average month of prenatal care initiation was found to be an important explanatory variable for global variability. These methods also suggest that variables which explain local variability, such as month of prenatal care initiation, should be good candidates for public health community based interventions as improvements on these factors in a given region is likely to impact and improve the outcome Status in areas immediately surrounding intervention

communities.

Recommendations

Monitoring perinatal Outcomes in small geographic areas such as cities and communities within cities is feasible. Such activities should be useful for targeting interventions. Methods of quality assurance could be used to identify changing rates of outcomes and possibly deploying and targeting interventions as necessary. Methods of spatial monitoring could be used to identify factors associated with local variability in Outcomes and which would serve as good intervention candidates.

Products To Date

Articles

O'Campo P, Guyer B. 1999. Innovative methods for monitoring perinatal health outcomes in cities and in smaller geographic areas. *American Journal of Public Health* 89(11):1667-72.

Presentations

O'Campo P. 1996. *Innovative methods for monitoring rare public health outcomes.* Presented at the Department of Maternal and Child Health, Baltimore, MD.

O'Campo P. 1999. *Development of monitoring methods for perinatal ooutcomes.* Presented at the 27th Research Roundtable, Maternal and Child Health Bureau, Rockville, MD.

O'Campo P, Ju X. 1995. *Monitoring methods for use in surveillance and monitoring of perinatal outcomes.* Presented at the Annual Meeting of the American Statistical Association, Orlando, FL.

Free Beta and hCG in Screening for Down Syndrome

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Foundation for Blood Research

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Project Number MCJ-230802

NTIS Number PB98-126642

Project Period 3/3/1995-2/28/1997

Costs	Awarded	Requested
Year 1	$113,364	$133,370
Year 2	$33,713	$39,640
Year 3		
Year 4		
Year 5		
Year 6		

Year 2000 Objectives
No Stated Healthy People Objectives

Study Design
Observational

Time Design
Mixed

Care Emphasis
Noninterventional

Population Focus
Pregnant women (not otherwise defined as adolescents)

Race/Ethnic Focus
African Americans, Asians–Chinese, Asians–Filipinos, Asians-All Others, Hispanics-All others

Summary

Statement of the Problem

Approximately two-thirds of the 4.1 million annual pregnancies in the US are screened prenatally for fetal Down syndrome. Most women are screened using alpha-fetoprotein (AFP), unconjugated estriol (uE3), and human chorionic gonadotropin (hCG). An estimated 60-70% of cases of Down syndrome can be detected with an initial positive rate of 5 to 8% with the three-marker combination. The single best marker is hCG, a dimer (intact hCG) consisting of an a subunit (common to other glycoproteins) and a Beta subunit (unique to hCG). Both intact hCG and the free Beta-subunit are present in the blood, but in the second trimester of pregnancy more than 99% of hCG in maternal serum circulates as a whole molecule, and only approximately 0.5% is present as the free Beta-subunit. In 1990, it was reported that measurements of just the free Beta-subunit alone could increase detection of Down syndrome by as much as 20% as compared to the use of conventional hCG assays. However, hCG measurements were not performed on the sample set, which precluded a direct comparison of the two markers. Since that initial report, studies which have directly compared free Beta-subunit measurements with hCG have reached varying conclusions, ranging from a loss of 1% to a gain of 9% in the Down syndrome detection rate. The studies reporting the largest gains had either a flaw in study design or mathematical errors. Even assuming that the use of the free Beta-subunit measurements provide some advantage over hCG, a potential problem is that the free Beta-subunit is spontaneously generated in vitro by dissociation of whole molecule hCG, even at ambient temperatures. This phenomenon

could counterbalance any small advantage that might be gained by using the free Beta-subunit assays if specimens were to experience elevated temperatures or shipment delays.

In spite of these problems, there is a widespread perception that use of the free Beta-subunit measurements in place of other types of hCG assays will yield a significant gain in screening performance. Introduction of free Beta-subunit as a screening marker has been blocked because the FDA has not yet licensed kits for clinical use. Unlike the situation with hCG, the screening performance of the free Beta-subunit has not been reliably defined. The present study was designed to minimize or eliminate these problems by directly comparing the relative performance of the free Beta-subunit and hCG measurements, both univariately and in combination with other markers, using serum specimens and clinical information from a well characterized population with complete ascertainment of outcome.

Research Questions or Hypotheses

This study had four goals which were to: 1) Accurately define how effectively the free beta-subunit of hCG measurements identify risk for fetal Down syndrome in the second trimester of pregnancy as compared to conventional hCG assays, both univariately and in combination with AFP and uE3; 2) Determine the effect of time and temperature on the spontaneous generation of the free beta-subunit in stored blood samples; 3) Determine the affect of race/ethnicity, maternal weight, maternal smoking, and method of gestational dating on the free b-subunit measurements; and 4) Define a set of parameters (log mean, log standard deviation, correlation coefficients) that will allow laboratories to calculate Down syndrome risks using free beta-subunit measurements and other markers.

Study Design and Methods

The estimates of screening performance were based on multivariate modeling from 52 cases of Down syndrome and 5,065 pregnancies from an earlier study. As part of that study, measurements of AFP, uE3, and hCG were performed on all of the sera under routine operating conditions, and serum aliquots were frozen for future studies. Karyotypes were obtained for all of the pregnancies. The stored sera were thawed and assayed for the free beta-subunit and hCG over a period of one year. The hCG measurements were repeated simultaneously with the free beta-subunit measurements so that a direct comparison could be made between the two analytes treated and assayed under identical conditions.

The measurements were used to calculate a set of population parameters for the free beta-subunit and hCG measurements. These parameters, along with the parameters determined for AFP and uE3 from the earlier study, were used to calculate detection and false positive rates for free beta-subunit compared to hCG, both alone and in combination with other markers. The research team also sought to accurately define the increase in the free beta-subunit analyte values to be expected from the in vitro dissociation of hCG for specimens collected and stored under varying conditions of times and temperatures. This was investigated by determining the increase in the free beta-subunit under specified conditions of time and temperature using fresh maternal serum specimens from ten pregnant women. The resulting values were then fitted to an Arrhenius equation, which permitted prediction of increases in the free beta-subunit for any combination of time and temperature.

Findings

The hCG and free beta-subunit measurements were highly correlated in both unaffected and Down syndrome pregnancies (0.889 and 0.876). This high correlation indicated that any advantage of free beta-subunit over hCG measurements must be small. Observed detection rates at any given false positive rate were similar for hCG and free beta-subunit when analyzed as a single marker. At false positive rates of 3%, 5%, and 7%, hCG measurements detected 27%, 35%, and 42% of the Down syndrome pregnancies. The corresponding detection rates for free beta-subunit were 27%, 33%, and 40%. At all three false positive rates, the observed detection rates for hCG and free b-subunit were very similar.

Population parameters were derived for free beta-subunit and hCG from probability plots. These parameters were used for

modeling Down syndrome screening performance, since modeling can provide a more accurate estimate of screening performance than direct observation by smoothing statistical irregularities. Screening performance was consistently better with hCG than with free beta-subunit and improved when biparietal diameter measurements were used. At a 5% false positive rate, the detection rate for hCG in combination with maternal age and AFP was higher than when free beta-subunit was substituted for hCG (62 versus 57 percent). Addling uE3 measurements to either of the double marker combinations yielded about a 5% increase in detection when dating was by last menstrual period and about 7% when dating was by biparietal diameter.

Six published studies provided values for the same population parameters used in the current study, which allowed modeling to be performed. Using modeling allowed the research team to use the same underlying maternal age distribution, with other modeling-related features held constant. At a 5% false positive rate, the change in detection resulting from substituting the free beta-subunit for hCG measurements in combination with AFP and maternal age ranged from a loss of 8% to a gain of 6%, with a median change of 0%. The current study showed a loss in detection of 5%. The modeled detection rates for each of the combinations of markers were remarkably consistent between the various studies, ranging from 54 to 62% for free beta-subunit and 55 to 62% when hCG measurements were used.

Arrhenius analysis of the effect of time and temperature studies on the concentration of free beta-subunit showed little or no change in concentration over a three day period at 4°C or at 15°C. At 20°C and 25°C, the increases in free beta-subunit concentrations were about 2% and 7% per day, respectively. At higher temperatures, such as might be experienced with ambient temperature on a summer day, concentrations increase significantly, even after one day (eg. a 38% increase at 30°C). Free beta-subunit measurements decreased with increasing maternal weight similarly to that reported for hCG. The effect of race and ethnicity was also similar to that of hCG (5% higher for African Americans, 8% higher for Asians, and 10% lower for Hispanics). Findings were also similar for free beta-subunit and hCG for diabetic status (no significant difference) and maternal smoking (20% lower).

Data from this study and others indicated that hCG and the free beta-subunit provide essentially equivalent screening performance. Free beta-subunit concentrations increased by 5-7% per day at room temperature and at much higher rates at elevated temperatures. Special handling is therefore necessary if free beta-subunit measurements are to be used for screening if sera experience elevated temperatures or long delays in shipping. The effects of variables that influence free beta-subunit measurements were very similar to that found for hCG.
All of the approximately 2.5 million women being screened for fetal Down syndrome nationally are potential candidates for screening using free beta-subunit assays Screening programs have an obligation to provide the best combinations of marker(s) to pregnant women. However, results from this study, in combination with other published studies, indicated that substitution of the free beta-subunit for hCG measurements in either a double or triple marker combination provided equivalent screening performance.

Based on these findings, laboratories should be free to choose either free beta-subunit or hCG measurements and should expect to achieve similar Down syndrome screening performance. Each laboratory's decision could be based on other factors such as assay availability, cost, ease of assay, and turn-around time. However, stability data indicated that increases in the free beta-subunit concentrations can be significant for samples exposed to elevated temperatures or long shipping times. Increases in free beta-subunit would raise the false positive rate, thereby increasing the number of women requiring amniocentesis to achieve any given detection rate. Laboratories need to be aware that special precautions are necessary if free beta-subunit is to be used for screening.

Products To Date

Articles

Knight, GJ, Palomaki, GE, Neveux LM, Fodor KK, Haddow JE. 1998. hCG and the free beta-subunit as screening tests for down syndrome. *Prenatal Diagnosis* 18:235-245.

Presentations

Knight G. 1998. *Free-beta and hCG in screening for down syndrome.* Presented at the 19th Research Roundtable, Maternal and Child Health Bureau, Rockville, MD.

Palomaki GE, Knight GJ, Fodor KK, Haddow JE. 1996. *Second trimester screening performance of free beta-subunit versus hCG on a population with complete ascertainment of outcome.* Presented at the 46th Annual Meeting of the American Society of Human Genetics, San Francisco, CA.

Functional Assessment of Children

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Project Number MCJ-360646

NTIS Number PB99-109225

Project Period 10/1/1994-9/30/1997

Costs	Awarded	Requested
Year 1	$73,100	N/A
Year 2	$68,825	N/A
Year 3		
Year 4		
Year 5		
Year 6		

Year 2000 Objectives
No Stated Healthy People Objectives

Study Design
Quasi Experimental

Time Design
Mixed

Care Emphasis
Noninterventional

Population Focus
Preschool-age children with developmental disabilities

Race/Ethnic Focus
No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Over the past decade there has been an effort to expand the type of outcome measures used in examining the effectiveness of intervention programs for children with developmental disabilities and their families. A broadening of the range and type of assessment procedures is necessary to meet the requirements of PL 99-457, the Individuals with Disabilities Education Act (PL 101 -476), and the Americans with Disabilities Act. The broadening of assessment options demands the development of strategies to evaluate impairment, disability and handicap across the life span . The Functional Independence Measure for Children (WeeFIM addresses the broad area of functional independence in children and provides the basis for longitudinal follow-up. The WeeFIM instrument builds on the conceptual and organizational for-mat of the Functional Independence Measure for adults. The WeeFIM instrument is designed to examine the amount of assistance required in self-care, sphincter control, transfers, locomotion, communication and social cognition. The WeeFIM instrument may be administered by observation or interview. Key characteristics of the WeeFIM instrument are its focus on a minimal essential data set, and the emphasis on consistent actual performance and discipline free observations in diverse settings. The utility of the WeeFIM instrument in tracking short-term outcomes and recovery of function is dependent on the demonstration of adequate

reliability and validity. The purpose of this research investigation was to comprehensively examine the psychometric characteristics of the WeeFIM instrument on a large sample of children with developmental disabilities.

Research Questions or Hypotheses

This study tested the following hypotheses.
Hypothesis 1. The inter-rater reliability of the WeeFIM will be adequate for children with a disability ranging from 12 to 84 months of age. Adequate reliability is defined as an intraclass correlation coefficient (ICC) of .80 or greater across two or more raters.
Hypothesis 2. The test-retest reliability of the WeeFIM will be adequate for children with a disability ranging from 12 to 84 months of age. Adequate test-retest reliability is defined as an ICC of .80 or greater.
Hypothesis 3. The concurrent validity for the WeeFIM and the Battelle Developmental Inventory Screening Test will be high for children with a disability ranging from 12 to 84 months. High concurrent validity is defined as a Pearson product moment correlation of 0.85 or greater.
Hypothesis 4. The concurrent validity for the WeeFIM and the Vineland Adaptive Behavior Scales will be high for children with a disability ranging from 12 to 84 months of age. High concurrent validity is defined as a Pearson product moment correlation of 0.85 or greater.
Hypothesis 5. The results of the reliability analysis will be the same when the data are analyzed using traditional ordinal level item scaling and when the data are analyzed after being transformed into logit scores using Rasch analysis procedures.
Hypothesis 6. The results of the validity analysis will be the same when the data are analyzed using traditional ordinal level item scaling and when the data are analyzed after being transformed into logit scores using Rasch analysis procedures.

Study Design and Methods

The study used a prospective design in which three assessment instruments were administered to 205 children with a disability. The study was conducted in two phases. In phases I information on interrater and test-retest reliability was collected. The time between interviews was manipulated. The two interviews were separated by a short interval (3-7 days) or a long interval (20-30 days). The time interval was counter balanced within the raters (same versus different) so a similar number of interviews were included in each design cell.
The design of the concurrent validity study paralleled the reliability investigation described in Phase 1. Within a period of one to six weeks following the initial administration of the WeeFIM, 10 1 randomly selected children from the original sample (N = 205) were administered the Battelle Developmental Inventory Screening Test. The BDIST was administered to each child at the facility in which he or she received early childhood services. In order to reduce the possibility of rater bias, the examiner who administered the Battelle Developmental Inventory Screening Test was not the same rater who collected information on the WeeFIM.
A similar procedure was followed to collect concurrent validity information on the Vineland Adaptive Behavior Scales. The Vineland was administered to 104 children not administered the BDIST . The Vineland Adaptive Behavior Scales is a survey instrument and was administered to the child's parent or teacher. The Vineland was administered to the same parent (or teacher) who was interviewed using the WeeFIM. As with the Battelle Developmental Inventory Screening Test, the Vineland was administered by one of the trained raters within a period of one to six weeks following the administration of the initial WeeFIM.

Findings

Reliability. Kappa values for individual WeeFIM items ranged from 0.44 to 0.82. Intraclass correlation (ICC) coefficients ranges from 0.73 to 0.98. Total WeeFIM ICC values were greater than 0.95 for both interrater and test retest reliability analyses.
Validity. Correlations (rho) among subscales for the WeeFIM, BDIST, and VABS ranged from 0.42 to 0.92. Correlations for total scores ranged from 0.72 to 0.94.
Moderator Variables. Analyses of potential moderator variables found no statistically significant relationship between age and severity of disability, or socioeconomic status and severity of disability. WeeFIM ratings were highly correlated with

age. The correlations were strongest for those WeeFIM subscales rating gross and fine motor skills. Correlations with socioeconomic status and WeeFIM ratings were low ranging from 0.03 to 0. 18.
Rasch Analysis. All WeeFIM ratings were converted to Rasch Measures. Reliability values computed with Rasch measures were almost identical to those obtained with raw WeeFIM ratings. The correlation between raw WeeFIM total ratings and Rasch total ratings was 0.98.

Conclusions and Recommendations

The WeeFIM ratings for the 205 children with developmental disabilities participating in this investigation were consistent across raters and time. The three instruments provided information regarding performance in motor, self-care, communication, cognitive and social skills. The WeeFIM instrument requires less administration time and provides information directly relevant to evaluating functional outcomes for children with disabilities and their families.
The results suggest that the WeeFlM, BDIST and the VABS are measuring similar skill areas. Whether specific skills are subsets of the same construct is not clear from the information collected in this investigation. This study was not designed to examine the construct validity of the WeeFIM. The WeeFIM is designed to assess the construct of functional independence in children and is based on the conceptual framework of the World Health Organization's International Classification of Impairments, Disabilities, and Handicaps (ICIDH). The ICIDH does not form the conceptual foundation of either the Battelle Developmental Inventory Screening Test or the Vineland Adaptive Behavior Scales. The issue of construct validity of the instruments included in this investigation is important, but complex and beyond the scope of this investigation. Such an investigation would require an evaluation of the theoretical and conceptual distinction between developmental assessment and functional independence.
There are several practical implications contained in the results of this investigation. First, is the obvious difference in time, effort and training required to collect information using each of the instruments. The WeeFIM can be completed in approximately 15 minutes by an examiner with moderate training (approximately 4 to 5 hours). In contrast, the Vineland Adaptive Behavior Scales requires approximately one hour to administer and the examiner is expected to have a graduate degree and considerable experience in the assessment of children. The BDIST requires approximately 30 minutes to administer. A practical limitation of the BDIST is the need to administer each item in a specific order. This requirement restricts the flexibility of the BDIST, particularly with young children.
It should be noted, that the WeeFIM is not meant to replace more comprehensive assessments such as the Vineland Adaptive Behavior Scales, Battelle Developmental Inventory Screening Test, or Pediatric Evaluation of Disability Index. The results of this investigation, nonetheless, suggest that similar basic information can be obtained from the WeeFIM, although the level of detail obtained using the WeeFIM will be less than that provided by more comprehensive assessments. The information obtained using the WeeFIM instrument was consistent across raters and time.
The second practical implication of the findings concerns the value of the information as perceived by rehabilitation professionals, educators, developmental clinicians, parents, and policy makers. There is a tendency, particularly in educational settings, to emphasize functional skills used in daily living as goals in program planning. Frequently there is disagreement between medical or rehabilitation professionals and educators in approaches to assessment and program planning. Medical professionals have traditionally performed assessments focused on determining underlying physical or neurologic impairment or etiology. Educators are generally less interested in underlying etiology and more concerned with practical limitations related to classroom performance.
The results of the current investigation suggest that information collected from a developmental instrument used widely by clinicians, that is, the Battelle Developmental Inventory Screening Test, is very similar to data provided by an assessment that focuses on functional independence. This information may help to reduce some of the tension that frequently exists between medical or rehabilitation professionals and educators. The WeeFIM instrument provides results that are similar to those contained in a developmental assessment (BDIST), but presents the findings in the context of functional skills acceptable to educators and relevant to parents and other family members. Information on functional outcomes is also of value to educators and parents in documenting change over time or planning intervention programs.

Products To Date

Abstracts

Msall ME, Ottenbacher K, Duffy L, et al. 1996. Reliability and validity of the WeeFIM in children with

neurodevelopmental disabilities. *Pediatric Research* 392:378A.

Msall ME, Ottenbacher K, Duffy L, et al. 1996. Reliability and validity of WeeFIM in children with neurodevelopmental disabilities. *Developmental Medicine and Child Neurology* 3874:90.

Ottenbacher KJ, Msall ME, Lyon N, Duffy LC, Braun S, Granger C. 1996. Reliability of the functional independence measure for children (WeeFIM). *Archives of Physical Medicine and Rehabilitation* 77:833.

Articles

Msall ME, Rogers BT, Ripstein H, et al. 1997. Measures of functional outcomes in children with cerebral palsy. *Mental Retardation and Developmental Disabilities Research Reviews* 3:1-10.

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Ottenbacher KJ, Msall ME, Lyon N, Duffy LC, Granger CV, Braun S. 1999. Measuring developmental and functional status in children with disabilities. *Developmental Medicine and Child Neurology* 41(3):186-194.

Ottenbacher KJ, Msall ME, Lyon N, Duffy LC, Ziviani J, Braun S, Granger CV, Braun S. 2000. Functional assessment and care of children with neurodevelopmental disabilities. *American Journal of Physical Medicine and Rehabilitation* 79(2):114-123.

Ottenbacher KJ, Taylor E, Msall ME, Braun SL, Lane SJ, Granger CV, Lyons N, Duffy LC. 1996. Stability and equivalence reliability of the functional independence measure for children (WeeFIM). *Developmental Medicine and Child Neurology* 38:907-916.

Sperle P, Ottenbacher KJ, Braun SL, Lane SJ, Nochajski S. 1997. Equivalence reliability of the functional independence measure of children (WeeFIM) administration methods. *American Journal of Occupational Therapy* 51:35-41.

Vohr B, Msall ME. 1997. Neuropsychological and functional outcomes of very low birth weight infants. *Seminars in Perinatology* 21:202-220.

Presentations

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Indicators of Maternity Care in Medicaid Managed Care

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Project Period 10/1/1994-3/31/1998

Costs	Awarded	Requested
Year 1	$139,099	$213,999
Year 2	$125,076	$213,805
Year 3	$127,306	$230,891
Year 4		
Year 5		
Year 6		

Year 2000 Objectives
14.5

Study Design
Observational

Time Design
Cross Sectional

Care Emphasis
Noninterventional

Population Focus
Low-income, pregnant women and their newborn infants

Race/Ethnic Focus
African Americans, Hispanics, White (non-Hispanic)

Summary

Statement of the Problem

Establishing the quality of maternity care is an important problem for all women, and particularly for low-income women who experience a disproportionate share of the poor outcomes of pregnancy. In recent years Medicaid has become the predominant purchaser of maternity care services for low-income pregnant women, and managed care is becoming the predominant system through which the women obtain the services. Therefore, many states are turning to Medicaid managed care in order to assure that low-income women receive quality maternity care. To evaluate the quality of care, indicators of adequate service performance are critical.

The federal Health Care Financing Administration, which is responsible for the Medicaid program, is developing indicators to assess the quality of performance of the personal health care services that Medicaid-eligible women receive in managed care plans. The Medicaid program, however, does not have indicators for the maternity care support services that have been developed through the years with Title V Maternal and Child Health Bureau funding: psychosocial, nutrition and health education services. Two of the challenges that remain in developing indicators for these services are both translating maternity care guidelines into measures of adequate performance, and validating such measures with data acquired from

actual service delivery to Medicaid-eligible women.
The purpose of this study was to develop and test indicators of quality performance of psychosocial, nutrition and health education support services in maternity care for Medicaid-eligible women that could be adapted for use by Medicaid managed care plans.

Research Questions or Hypotheses

After defining and evaluating indicators for adequate performance of psychosocial, nutrition and health education services, we tested the validity of the indicators by investigating the following four questions: 1) Is adequate performance as measured by the indicators associated with improved birth outcomes? 2) Is adequate performance more strongly associated with improved outcomes in women with high risks for the outcomes? 3) Does adequate performance vary among different types of providers and practice settings in ways that help explain variation in their outcomes? 4) Does adequate performance help explain variation in the outcomes among individual women and individual practice sites?

Study Design and Methods

Our criteria in establishing indicators for psychosocial, nutrition and health education services were that they: 1) be tied as closely as possible to federal and California guidelines for the services; 2) require as little subjective judgment as possible; 3) be relevant to as broad a population as possible; and 4) have a measurable hypothesized effect on health outcomes.
We defined the performance indicators based on the guideline that every woman should receive psychosocial, nutrition and health education assessments for risks and strengths at least once each trimester that they are in prenatal care. First, we created specific indicators of adequate performance for psychosocial, nutrition and health education services, and then a combined indicator for all three service areas. We then combined these three indicators into one indicator with four levels of adequacy.
We next evaluated the face validity, data reliability and availability, and construct validity for the performance indicators using ambulatory care medical records information.
Finally, to test the construct validity of the indicators, we developed multivariate, multilevel models, and tested the associations of the performance indicators with the risk-adjusted birth outcomes.

Study Sample and/or Population

The study sample of 3,467 women was originally generated for an evaluation of the birth outcomes comprehensive perinatal services for Medicaid-eligible women in California. The sample consisted of consecutive births in a stratified random sample of 27 prenatal care sites of five different practice setting types (community clinic, public health department clinic, physician office, public hospital clinic, private hospital clinic). Women who met the following three criteria were included in the study: 1) Medicaid was a payer source for their prenatal care; 2) the births to those women were singleton live births between July 1989 and December 1990; and 3) the mother had at least one obstetric visit and one assessment for psychosocial, nutrition or health education risks before birth.

Findings

The support service indicators developed in this study met the most commonly applied criteria for performance indicators: they were associated with risk-adjusted health outcomes, and they were associated in a dose-response manner. Adequate performance of psychosocial, nutrition and health education services was not only associated with significantly better risk-adjusted birth outcomes, but the more areas in which the services were adequate, the better the risk-adjusted outcomes (demonstrated by the indicator that combined performance in all three areas). The strength of the associations of the performance indicators with the outcomes were substantial (two-fold effects in relative odds ratios). These associations were robust in different analytical models and test samples. When the temporal relationship and biological plausibility of the association of the performance of support service risk assessments with improved outcomes are added to these findings, there is a preponderance of evidence that the indicators meet the criteria for indicating effectiveness of a prenatal intervention.

Recommendation

We recommend that the combined indicator for the adequate numbers of support service assessments be adapted for use in Medicaid managed care plans. The combined indicator includes information on how many of the three areas (psychosocial, nutrition and health education) received an assessment of the women's risk for each trimester (or part thereof) in which they received prenatal care. In California an indicator for obstetric risk assessment has just been used for the first time in a quality assessment of Medicaid managed care plans by an External Quality Review Organization.

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Lactose Intolerance in African-American Pregnant Women

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Project Number MCJ-240632

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Project Period 10/1/1993-9/30/1996

Costs	Awarded	Requested
Year 1	N/A	$159,709
Year 2	$154,907	$193,634
Year 3	$105,590	$146,653
Year 4		
Year 5		
Year 6		

Year 2000 Objectives
No Stated Healthy People Objectives

Study Design
Quasi Experimental

Time Design
Longitudinal

Care Emphasis
Noninterventional

Population Focus
Pregnant women (not otherwise defined as adolescents), Nonpregnant women (not otherwise identified as adolescents)

Race/Ethnic Focus
African Americans

Summary

Statement of the Problem

Many population groups may not comfortably consume milk due to lactose and milk intolerance. Low lactase levels are reported in the majority of African-American, Hispanic, Asian and Native American adults; as well as 10- 15% of Caucasian adults (Rush. 1988). Despite a vast literature on lactose intolerance, there are only two published reports on lactose intolerance and pregnancy. The study of pregnant Guatemalan women raises important questions regarding changes in ability to digest lactose as pregnancy progresses and its impact on milk consumption. The 1990 Institute of Medicine report on Nutrition During Pregnancy underscores the importance of these questions. The report notes, that "lactose intolerance among pregnant black women may result in their subsequent avoidance of milk".
Many population groups may not comfortably consume milk due to lactose and milk intolerance. Low lactase levels are reported in the majority of African-American. Hispanic, Asian and Native American adults; as well as 10-15% of Caucasian adults (Rush. 1988). Despite a vast literature on lactose intolerance, there are only two published reports on lactose intolerance and pregnancy. The more recent study of pregnant Guatemalan women, raises important questions regarding changes in ability to digest lactose as pregnancy progresses and its impact on milk consumption. The 1990 Institute of

Medicine report on Nutrition During Pregnancy underscores the importance of these questions. The report notes, that "lactose intolerance among pregnant black women may result in their subsequent avoidance of milk". The report points out that the Villar study of lactose intolerance in pregnant Guatemalan women is the only study currently available upon which to predicate nutrition recommendation and inform policy decisions. The IOM review suggests that a decrease in dairy product consumption as a result of the much higher prevalence of lactose intolerance among blacks, may be the reason why women may not consume some of the dairy products supplied by WIC. There is no data on lactose status among pregnant African-American women, their digestion of lactose, milk tolerance and associated nutritional patterns.

Research Questions or Hypotheses

This study examined two broad areas of interest. The first explored lactose digestion and changes which may occur during pregnancy and its effect on usual levels of milk consumption. The second sought to improve our understanding of the association between lactose digestion and dietary practices and intake. Data obtained would permit more appropriately targeted health and nutrition recommendations, food supplementation, education and counseling to women prenatally.
We have investigated lactose absorption and any changes that occur during pregnancy and its effect on milk consumption. Data were obtained on a) lactose digestion during three discrete time periods. early pregnancy (13-16 weeks), late pregnancy (30-35 weeks) and postpartum (8 weeks); b) changes in lactose digestion status as pregnancy progressed; c) the digestion of usual levels of lactose contained in milk; and d) the presence or absence of symptoms with milk ingestion. This study also examined lactose digestion status and its association with dietary patterns and intake. Data was obtained on: a) dairy product consumption patterns, b) historical information on the diet, c) dietary intake information during early and late pregnancy and eight weeks post-partum, and d) estimates of nutritional adequacy. This study protocol was approved by the Johns Hopkins Committee on Human Research.
Specifically, we hypothesized: 1) Milk tolerance in African-American pregnant women is not related to lactose digestion and does not change between the early and late stages of pregnancy and does not differ from lactose digestion and milk tolerance in non-pregnant AfricanAmericanwomen. 2) Lactose digestion and milk tolerance are not associated with milk and milk product consumption, and dietary patterns and practices, in early and late pregnancy and eight weeks post-partum in African-American women and does not differ from non-pregnant AfricanAmerican women. Flatulence was the only symptom reported at a statistically significantly different level between the tolerant and intolerant controls.

Study Design and Methods

This is a quasi-experimental study which provides for a longitudinal study of lactose status; as measured by the breath hydrogen tests , and compared at three key intervals I) the 13th to 16th weeks of pregnancy (early), 2) the 32nd to35th weeks of pregnancy (late) and 3) at 8 weeks post-partum. The design provides for the study of a similar group of non-pregnant control women, independently studied at a single point in time. In addition, the cohort of pregnant women will be compared to themselves at the early, late, and post-partum periods.
The study design will permit exploration of each of the following objectives of this study: 1) lactose status and milk tolerance during pregnancy; a) the change, if any, in lactose status during the early and late stages of pregnancy, b) comparison of lactose status during pregnancy with non-pregnant controls, c) status at 8 weeks post-partum, d) comparisons between lactose status and the digestion of unmodified milk, e) digestion of a similar quantity of pre-hydrolyzed lactose containing milk, f) reported milk drinking patterns prior to or during the pregnancy and post-paratum period, and g) the reported presence or absence of symptoms.
Three types of dietary data were collected and analyzed for this study: 24-hour recall, modified diet history and Block Food Frequency Questionnaire. Each of these data sources were designed to address different study questions. The 24 hour recall, the most comprehensive and precise measures of nutrient composition of the diet, was used for the following purposes:
1. To nutrient intake at each of the three measurement periods for both study subjects and controls.
2. To compare nutrient intake during the stages of pregnancy and the early postpartum period with nutrient intake of non-pregnant controls.
3. To determine the relationship between nutrient intake and nutrient adequacy by comparing nutrient intake with 70% of the Recommended Dietary Allowances (1989)
4. To determine adequacy of intake of two key nutrients - folate and vitamin B6.
In a sub analysis by body mass index, the data were used to determine whether women with low body mass index also had

low nutrient intake.

Findings

Lactose absorption status (as determined by a breath hydrogen rise >20 ppm) does not significantly change throughout pregnancy and the post-partum period. This finding is different than reported by Villar et al. and more recently by Szilagyi, et al. which proposed a physiologic adaptation which improves the efficiency of intestinal lactose hydrolysis during pregnancy. However, our study indicates that many of the pregnant women have their peak hydrogen rise after four hours. Therefore, limiting breath hydrogen testing to four hours as reported by Villar, et al can misclassify women as lactose absorbers. Prevalence rates of lactose intolerance in pregnant subjects and non-pregnant controls are similar to previous reports of African American young women (4, 9). Approximately, 20% of the women regardless of lactose tolerance status reported symptoms (bloating, diarrhea, flatulence and/or abdominal pain)

In general the quality of nutrient intake for this sample of women does not meet the Dietary Guidelines. Their diets are too high in sodium and fat and too low in fiber, folate and other key nutrients important to pregnancy outcome like calcium and zinc. Diets with this profile are not conducive to protection against the onset of chronic diseases such as coronary heart disease, high blood pressure and some forms of cancer.

The food frequency questionnaire developed by Block (1986) was used to assess usual dietary pattern historically, and the consumption of specific combinations of foods in order to evaluate calcium intake. One question for this study was whether lactose intolerance would change food consumption patterns such that dairy foods were omitted and other foods rich in calcium were consumed to compensate. The Calcium Rich Foods - Food Frequency Questionnaire was developed to assess the extent to which this sample of women during pregnancy and the early postpartum period used other foods with a calcium content > or =75 mg. There were basically no differences in food consumption patterns for calcium rich foods by lactose tolerance status in this sample.

When compared with controls, nutrient intake during pregnancy was higher for all nutrients, though the difference was significant only for calcium . When comparing controls with women during the early postpartum period, nutrient intake was greater for protein, iron, zinc. vitamin A, and total kcalories but similar for fiber, thiamin, riboflavin, vitamin B 6, copper caffeine, vitamin C, folate, magnesium and calcium. These differences were not statistically significance and in some cases the differences were very small.

Another approach to evaluating nutrient adequacy is to assess the proportion of women who consumed 70% of the Recommended Dietary Allowance (RDA, 1989). When the sample was divided by lactose tolerance status, based on findings from the breath hydrogen evaluation, there were differences by stage of pregnancy. Lactose intolerant women during early pregnancy were significantly less likely to have intakes that were deficient (<70% of the RDA) for vitamins C and A, thiamin. riboflavin, vitamin B 12, and niacin but more likely than intolerant controls to have intakes that were deficient (<70% of the RDA) in folate, iron, zinc and sodium. Lactose intolerant women during early pregnancy were also more likely to consume a lower percent of calories from fat. During late pregnancy folate was the only nutrient where a larger proportion of the women did not consume 70% of the RDA when compared with the intolerant non-pregnant controls.

Several sub-analyses were done to assess nutrient associations. The purpose of this subanalysis was to examine the relationship between low body mass index (BMI) [weight (kg)/height (M2)] and the adequacy of nutrient intake during pregnancy at three time periods - early pregnancy (13 - 16 weeks), late pregnancy (30 - 35 weeks) and 8 weeks postpartum. Folate was especially low among women with low BMI (150 mcg versus 255 mcg for women with BMI between 20 - 27.3 and 250 mcg for women with BMI greater than 27.3). Fiber intake was 7.5 g for women with low BMI, 13.5 g for women with BMI between 20 - 27.3 and I I mg for women with BMI greater than 27.3. The only area where the intake was high for women with low BMI was percent of kcalories from fat.

An additional sub-analysis was done to evaluate the association between WIC food supplementation and folate and vitamin B6 intake by comparing the amount of these nutrients in the diet of pregnant women at enrollment in the WIC Program, during late pregnancy and again at eight weeks postpartum

Recommendations

1. Health care providers instructing African American women on optimal dietary patterns during pregnancy need to be mindful of their high rate of lactose and milk intolerance.
2. While considering lactose status of the client, health care professionals in all clinical settings as well as WIC needed to have a united approach to helping pregnant women achieve weight gain through adequate food intake based on nutrition counseling and monitoring.

3. Since protein foods are often high in fat, while considering lactose status of the client, nutrition counseling should focus on helping pregnant women lower their protein intake to recommended levels and make sure that protein intake is from low fat foods to protect against high fat intake and increased risk for cardiovascular disease and some forms of cancer. while considering lactose status of the client.
4. The intake of iron rich foods should continue to be monitored and nutrition counseling directed toward encouraging the intake of iron rich foods.
5. Clinical practitioners with the assistance of WIC and other federally funded food and nutrition programs should monitor compliance with iron supplementation.

Conclusion

This study corroborates the increase in intestinal transit time found during pregnancy. Peak hydrogen breath values occurred at 5 hours during early and late pregnancy. However, already by eight weeks post-partum, peak values occurred at 4 hours as in the control group. This study indicates that the prevalence of lactose intolerance for pregnant African-American women is similar to non-pregnant African-American women and similar to previous prevalence reports in adult African-Americans. There was no change in the tolerance of lactose noted during pregnancy in these women. However, there were fewer symptoms reported by the pregnant women. Despite a fairly high occurrence of lactose intolerance as determined by breath hydrogen, symptoms were reported by approximately 20% of women. The prevalence of lactose intolerance in pregnant African American women irrespective of pregnancy status, or the stage of pregnancy parallels the prevalence of lactose intolerance reported in adult African-Americans. Intolerance as measured by breath hydrogen response to 240ml of milk reinforces the Institute of Medicine's concern with milk intolerance among pregnant African American women. Health care providers instructing African American women on the optimal dietary pattern during pregnancy need to be mindful of the high rate of lactose and milk intolerance. Symptoms may be unevenly reported by pregnant African American women and do not represent a reliable guide to milk tolerance. Health care providers should discuss with the pregnant woman, her ability to tolerate milk and should educate her as to food options, other than milk, which provide calcium and protein.

Maternal Psychosocial Factors and Use of Well-Child Care

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NTIS Number PB99-110843

Project Period 10/1/1994-9/30/1996

Costs	Awarded	Requested
Year 1	$130,404	N/A
Year 2	$116,300	N/A
Year 3		
Year 4		
Year 5		
Year 6		

Year 2000 Objectives
No Stated Healthy People Objectives

Study Design
Observational

Time Design
Longitudinal

Care Emphasis
Noninterventional

Population Focus
Infants, Toddlers, Preschool-age children, Pregnant women (not otherwise defined as adolescents), Nonpregnant women (not otherwise defined as adolescents)

Race/Ethnic Focus
African Americans

Summary

Statement of the Problem

There is consensus among the medical, public health and public policy communities that preventive health care is of great importance to infants and preschool age children. Preventive health care is the source of immunizations against preventable diseases; developmental assessment; screening for elevated blood lead levels, perceptual disorders and other conditions; anticipatory guidance; and other services. Despite this, many children, especially those of lower socioeconomic status, or who are members of minority groups, do not receive recommended levels of preventive care and immunizations in the preschool period.

The lack of immunizations is a major public health problem, and has led to resend measles outbreaks in the inner cities. It also suggests deficient participation in other preventive services.

A beneficial approach to increasing use of preventive care by young children might be to focus upon early identification of infants who are at increased risk of subsequent lack of adequate preventive care and immunizations. Specific factors associated with poor health care outcomes among low income children might serve as signals for early identification of those infants and children who would most benefit from special efforts to involve them in preventive care.

There is reason to believe that selected maternal psychosocial factors and use of prenatal care may be associated with subsequent participation in preventive health care by young children. The maternal psychosocial factors include maternal exposure to stressors and depressive symptoms. By examining the relationship between these psvchosocial factors, as well as maternal use of prenatal care, it may be possible to develop interventions targeted at specific "high risk" populations of mothers and children to increase use of preventive care among young children.

Research Questions or Hypotheses

The objective of the research described in this report was to evaluate the associations between maternal exposure to stressors, depressive symptoms, and use of prenatal care with use of well-child care and immunizations in the first two years of life.

Study Design and Methods

The data for this study were derived in part from a prior longitudinal study of maternal psychosocial factors and pregnancy outcomes. Women were enrolled in the prior study at several hospital-based prenatal clinics, and at enrollment completed a baseline questionnaire about psychosocial factors, including depressive symptoms and exposure to stressors. For the current study, women who enrolled at one of the sites were located and interviewed by telephone about sources of pediatric care used by the infants during the first two years of life. Subsequently, the pediatric records of each child were reviewed to obtain information about use of well-child care and immunizations during the first two years of life.
Overall, 87.9 percent of the infants were up-to-date on immunizations at twelve months and 52.6 percent were up-to-date on well-child visits at twelve months. The median number of well-child visits in the first year of life for the children in the sample was five. At 24-months of age, 74.0 percent were up-to-date on immunizations and 48.6 percent on visits.

Findings

The majority of children (82.9%) had only pediatric provider in the first year of life. About half of the children used a large hospital-based primary care center with a long-standing interest in promoting appropriate use of well-child care. Fewer than 2 percent of the children had no source of pediatric care.
None of the independent variables of interest (i.e., maternal exposure to stressors, depressive symptoms or trimester of enrollment in prenatal care) was associated with any of the dependent variables. However, maternal prenatal behaviors were associated with use of well-child care during the first two years of life, Smoking, for example, was associated with being up-to-date on visits at 12 to 24 months of age.
These results suggest that certain maternal behaviors, smoking and drug use during pregnancy, are significantly associated with lack of completion of recommended well-child care and immunizations during the first year of life.
It is apparent that harmful patterns of health behaviors during the prenatal period continue after childbirth. The prenatal period provides an important time to intervene with women to enhance pregnancy outcomes as well as infant health and use of well-child care and immunizations.
Completion of recommended immunizations and well-child care in this sample of children is actually higher than in many samples. Since the sample of children is primarily of lower socioeconomic status and Black, we would expect the level of immunizations to be much lower. The high use of well-child care and immunizations is due in part to the high level of enrollment in pediatric primary care by the children in the sample.
Our results suggest both individual patient factors and health care system factors that are amenable to intervention to increase use of well-child care and immunizations in communities. Efforts directed by findings such as ours can go beyond removal of financial barriers to enhance use of important preventive services by infants.

Prevention of Medication Compliance Problems in Children with Juvenile Rheumatoid Arthritis

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NTIS Number PB99-107229

Project Period 5/1/1992-9/30/1996

Costs	Awarded	Requested
Year 1	N/A	$177,076
Year 2	N/A	$101,723
Year 3	$77,521	$109,308
Year 4	$60,000	$127,862
Year 5		
Year 6		

Year 2000 Objectives
17.2, 17.14

Study Design
Experimental

Time Design
Longitudinal

Care Emphasis
Interventional

Population Focus
Toddlers, Preschool-age children, School-age children, Adolescents (not pregnancy related)

Race/Ethnic Focus
No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

When patients fail to improve medically, one plausible explanation is that they were not sufficiently adherent to derive therapeutic benefits from prescribed treatments. Estimates are that about 50% of children and adolescents sufficiently adhere to medical regimens for chronic diseases (Rapoff & Barnard, 1991; Varni & Wallander, 1984).
Juvenile rheumatoid arthritis (JRA) is a chronic childhood disease that responds well to daily non-steroidal anti-inflammatory medications (NSAIDS) which are prescribed over a period of months or even years (Cassidy & Petty, 1995). Two separate studies have found that only 55% of patients with JRA adhere adequately to medication regimens, as measured by serum salicylate levels (Litt & Cuskey, 198 1; Litt, Cuskey, & Rosenberg, 1982).
Non-adherence to medical regimens can be costly from a therapeutic and cost-effectiveness perspective. Non-adherent patients may not realize the full benefits of therapy and experience more disease-related activity limitations and disability (Rapoff & B amard, 199 1). Non-adherence can also result in overuse of health care resources and add unnecessary expenses for families of chronically ill children and for society in general, in the form of increase insurance premiums and taxes to cover these health care costs (Rapoff & Barnard, 1991; Smith, 1985).

Research Questions or Hypotheses

1. To experimentally demonstrate that a nursing-administered adherence intervention will be superior to an attention-placebo control condition in improving and maintaining adherence to medications among children and adolescents who were newly diagnosed with JRA.
2. Patients exposed to the adherence intervention will have less disease activity and limitations and lower health care costs compared to the control group.

Study Design and Methods

Patients were matched by age and type of JRA and then randomly assigned to the experimental or (attention-placebo) control group. Patients and parents in the experimental group were given verbal, written, and audiovisual information from the nurse about adherence improvement strategies, including prompting, monitoring, positive reinforcement, and discipline techniques. Control group patients and parents were given verbal, written, and audiovisual information about JRA and recommended treatments by the nurse, but no specific information about adherence improvement strategies. Patients and parents in both groups received their respective interventions during a 30 minute clinic visit and were then telephoned by the nurse biweekly for two months and then monthly for 10 months. The content of the phone calls centered around the information presented during the initial clinic visit presentation.
Dependent variables included: adherence (measured by an electronic monitor that records the date and time when pill containers are opened), disease activity (global severity rating, number of active joints, and morning stiffness obtained by the rheumatologists during clinic visits), activity limitations (as rated by parents using the Child Health Assessment Questionnaire), direct medical costs (charges for physicians' fees, lab work, eye exams, x-rays, and hospitalizations as determined from medical records), and indirect costs (out-of-pocket expenses, including transportation to the clinic, parking, food, lodging, income loss by parents, child care, and medications as recorded by parents).
The primary statistical strategy was analysis of covariance for repeated measures (ANCOVA; using baseline adherence as the covariate) with follow-up multiple comparisons (Duncans). Data were aggregated by quarters (as varying amounts of data were missing for patients during some weeks) and group means were determined for each quarter to analyze between-group differences. Because we had daily adherence data on patients, we also examined individual patient trends in each group using time series analysis. The primary hypothesis was that patients in the experimental group would have higher adherence than the control group. Secondary hypotheses were that patients in the experimental group would have lower disease activity, limitations, and health care costs compared to the control group.

Findings

A total of 54 patients were entered into the study and had some useable data over the one year period required for participation (N=29 in the experimental group and N= 25 in the control group). Mean age of the sample was 7.8 years (range=2-16 years). Seventy-four percent (N=40) were female and the mean SES level was 45.75 (range = 15-64), corresponding to "medium business, minor professional, technical" social strata (Hollingshead, 1975). About half of the sample (52%) had poly-articular JRA, while 3 1 % had pauci-articular and 17% systemic-onset JRA. There were no significant differences on demographic and baseline dependent measures between the groups (with the exception of significantly more siblings in the control group).
Regarding adherence results, ANCOVA for repeated measures showed a significant group (p=.016) and group by time interaction (p=.047) and follow-up multiple comparisons showed significantly higher adherence (p=<0 I) in the experimental group compared to the control group during quarters two (75% vs.47%), three (68% vs. 45%), and four (67% vs. 42%), but not in quarter one (68% vs. 59%).
ANCOVA and follow-up multiple comparisons yielded no significant differences between groups on the disease activity, activity limitations, or direct and indirect health care costs.

Time series analysis modeled four types of trends for individual patients in each group relative to their baseline adherence levels (p values set at <05): (1) significant increase in adherence; (2) significant decrease in adherence; (3) gradual increase in adherence; and (4) increase but gradual decrease in adherence. This analysis included 29 experimental and 20 control patients. Of those patients who evidenced a significant trend (10 experimental patients and 6 control patients), 60% of experimental patients and 50% of control patients either showed a significant increase in adherence (trend # 1) or a gradual increase in adherence (trend # 3) relative to their own baseline adherence levels.
Overall, these results support the primary hypothesis that the intervention would be effective in improving and maintaining adherence relative to an attention-placebo control condition. However, the secondary hypotheses were not supported, as there were no differences, as predicted, in disease activity, activity limitations, or health care costs.

Recommendations

In general, efforts need to continue to develop and test interventions for improving adherence to regimens for chronic diseases. Much of the adherence literature is concerned with identifying correlates or predictors of adherence but there are relatively few intervention studies (Rapoff & Barnard, 1991). In addition, assessments of disease and health status outcomes (including quality of life measures) and health care costs should be part of adherence intervention studies in order to determine the potential clinical and economic effects of improved adherence. Patients may need to be monitored over more extended periods of time then was done in this study (e.g., 3 to 5 years) to allow for health and economic benefits to accrue following an effective adherence intervention.
A question to be addressed in future studies is when adherence problems (on average) emerge following diagnosis of a chronic disease. Adherence data on the control group in this study would suggest that adherence starts to drop some three to four months after monitoring adherence in newly diagnosed patients with JRA. A previous study with children and adolescents with diabetes found that nonadherence surfaced about 3.5 years after diagnosis for 30% of the patients (Kovacs, Goldston, Obrosky, & Iyengar 1992). If this type of information could be obtained for most of the major chronic illnesses, it would help to identify when efforts to improve adherence might be optimally employed.
Chronically ill children and adolescents who have low adherence and poor disease/health outcomes would likely benefit most from intensive efforts to improve adherence. Future studies should monitor adherence and disease/health outcomes for a large sample of patients and experimentally validate (either through between-subject or single-subject designs) strategies for improving adherence on those patients who evidence low adherence and poor outcomes. Also, interventions need to be feasible for use in clinical settings which necessitates utilizing existing team members (such as nurses) to implement interventions.
A preventive approach could also be pursued. Written and audiovisual materials can be developed which focus on adherence enhancement strategies and these materials could be part of routine educational programs for chronically ill children and their families. Future studies could then evaluate the effect of these educational programs on adherence and disease/health outcomes and health care costs.
Because of the relatively small numbers of patients with any particular chronic health condition, multisite investigations are needed to accrue adequate sample sizes and to enhance generalizability of results obtained from adherence intervention studies. This would also be more cost-effective for funding agencies such as MCH.

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Recovery from Traumatic Brain Injury in Children

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Costs	Awarded	Requested
Year 1	N/A	$312,914
Year 2	N/A	$388,261
Year 3	N/A	$420,254
Year 4	$206,379	$425,752
Year 5	$168,612	$387,327
Year 6		

Year 2000 Objectives
No Stated Healthy People Objectives

Study Design
Quasi Experimental

Time Design
Longitudinal

Care Emphasis
Noninterventional

Population Focus
School-Age Children,
Parents/Families/Mothers/Fathers

Race/Ethnic Focus
No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Children who sustain moderate-to-severe traumatic brain injury (TBI) are at high risk for a variety of long-term neurobehavioral sequelae. Serious TBI in a child is also an enormously stressful event for the family. Families are faced with a heavy burden of care and have to make immediate emotional adjustments, especially in cases in which injury has affected the child's behavior or cognitive abilities. Family resources may be stretched and schools are frequently ill-prepared to meet the child's special needs. Clinical follow-up of children also suggests that family dysfunction may lead to persistent behavior and learning problems in spite of cognitive recovery. Unfortunately, there have been few efforts to examine the impact of pediatric TBI on families in a more systematic fashion, or to determine if the extent of the child's recovery is influenced by the post-injury family environment.

Research Questions or Hypotheses

The primary objectives of the project were to test two hypotheses regarding sequelae of TBI for children and their families:
1. Moderate-to-severe TBI adversely affects the family social environment and leads to more parental psychological distress than traumatic orthopedic injuries not involving insult to the central nervous system (CNS). Due to the persistence of cognitive and behavioral sequelae of TBI, we hypothesized that these differences would be apparent throughout the first year following injury. The impact of both types of injuries on families were also hypothesized to vary with sociodemographic status, concurrent family stressors and resources, and parental coping strategies.
2. Post-injury family characteristics predict outcomes at 6 and 12 months after injury for children with TBI, even after injury severity and pre-injury child and family status are taken into account. Family variables were also hypothesized to predict changes in outcomes across follow-up. Although family factors were hypothesized to predict outcomes for children with either TBI or orthopedic injuries, the more negative family consequences of TBI were expected to contribute to group differences in sequelae.
Further goals were: (1) to examine the effects of brain insult and family factors on different types of child outcomes (e.g., behavior versus cognitive functioning); (2) to increase understanding of factors that contribute to the emergence of behavior disorders following brain insults in children; (3) to survey the impact of orthopedic trauma on children and their families; (4) to discover ways that families are affected by and cope with both forms of injury; and (5) to recognize factors that place individual children and families at high or low risk for adverse consequences. Clarification of risk and resistance factors is of special value in identifying high-risk children, documenting the relevance of family interventions in the rehabilitation process, and improving health care delivery following traumatic childhood injuries.

Study Design and Methods

The study design involved prospective follow-up assessments of family functioning and child outcomes in children with moderate and severe TBI. Assessments were conducted soon after the injury (baseline) and at 6- and 12-month follow-ups. Children with orthopedic injuries not associated with insult to the central nervous system were recruited as the comparison group. The latter group served to control for the hospitalization experiences and for background factors associated with proneness to accidental injury.
Pre-injury child behavior and school performance were estimated from parent and teacher ratings completed at study entry. Assessments of child outcomes included tests of neuropsychological abilities and academic achievement, follow-up ratings of behavior and school performance, and determination of post-injury educational treatment. Families of children in the TBI and orthopedic injury groups were compared in terms of parent ratings of the impact of injury on the family, family functioning, and parent psychological distress. Additional family measures included sociodemographic status, concurrent family stressors and resources, and parent coping strategies.
Data analyses included comparisons of the three groups on measures of child and family status. Additional analyses were conducted to identify correlates of individual changes over time (growth modeling), to identify predictors of child and family outcomes, and to determine if pre- or post-injury family status was related to recovery of function following TBI.

Study Sample and/or Population

Participants were 6- to 12-year-old children prospectively recruited during their hospitalization for traumatic brain or orthopedic injuries. Recruitment criteria included the presence of a moderate or severe TBI or of an orthopedic injury not involving head injury that required at least 1 overnight stay in the hospital. Severe TBI was defined based on a Glasgow Coma Scale (GCS) score of 8 or less, and moderate TBI was defined in terms of a GCS score of 9-12 or a higher GCS score accompanied by an neurological or neuroimaging abnormality or a loss of consciousness of at least 15 minutes. To be considered for participation, children had to be living in a primarily English-speaking household, without previous histories of neurological disorder or child abuse.
Recruitment took place over a 4-year period, with a final sample of 53 children with severe TBI, 56 with moderate TBI, and 80 with orthopedic injuries. The children were recruited from 4 hospitals in central and northern Ohio. The sample comprised 127 males and 62 females. Participants included 129 whites and 60 African Americans. Altogether, 27 families dropped out of the study prior to completing the 12-month follow-ups.

Findings

Group comparisons revealed that families of children severe TBI reported more injury-related family stress and burden than children in the orthopedic injury group. Injury-related burden was present for all three groups initially after injury, but diminished less over time in the severe TBI group. Families of children with severe TBI also reported higher levels of psychological distress over the follow-up period. Higher levels of injury-related family stress and burden were associated with greater family stress and fewer social resources prior to injury. Family consequences were additionally associated with the use of maladaptive strategies for coping with the child's injury.

Consistent with previous studies of childhood TBI, children with TBI had poorer outcomes of injury than children with orthopedic injury. Children with severe TBI experienced the most adverse outcomes. Preliminary findings indicated that these children performed more poorly than children in the orthopedic group on several neuropsychological measures. Children with severe TBI were also more likely to require special education following injury and were at greater risk for developing new behavior problems post injury.

The results of this study were also consistent with the hypothesis that there is a relationship between child and family outcomes of TBI. Higher levels of injury-related family stress and dysfunction were associated with more adverse behavior and cognitive outcomes in the child. Even more critically, the adverse consequences of severe TBI relative to orthopedic injury were related to the degree of stress and dysfunction reported by the family. Specifically, the effects of severe TBI on school performance, behavior, and cognitive abilities were greater for children from stressed or dysfunctional families than for children from healthier family environments. Although the nature of the association between child and family outcomes requires further study, the latter findings provide the clearest support to date for family influences on recovery from childhood TBI.

Recommendations

The proposed study provides valuable new information regarding the impact of orthopedic trauma on children and their families. The findings not only document the negative impact of traumatic injuries in children on their families, but also help to delineate the nature and sources of negative family impact. Study results additionally demonstrate that pre- and post-injury family status is, in fact, associated with the child's longer-term recovery. The major implication of these findings is that treatment of childhood traumatic injuries is likely to be facilitated by attending to both child and family needs.

The present results suggest a number of specific ways to reduce child and family morbidity of traumatic childhood injuries:

1. The family impact of injury can be reliably assessed using methods such as the Family Injury of Burden Interview. This measure is sensitive to the difficulties experienced by families following a traumatic childhood injury. It is also useful in delineating specific family needs and thus in directing clinical interventions. In view of evidence that we can not count on parents to express their emotional needs, reduction in family morbidity is likely to require a system of anticipatory guidance and routine follow-ups. We can not rely on the families themselves to initiate contacts for assistance.
2. It is possible to identify children and families at highest risk for adverse consequences of injury, and hence to target the families most in need of careful follow-up and more intensive interventions. Risk status for families is related to the severity of the child's injury, pre-existing family stresses, and family coping styles. Risk factors contributing to poorer child outcomes include injury severity, pre-existing family dysfunction and stress, poor family adaptation to the injury, developmental or behavior problems prior to injury, and evidence of neurobehavioral symptoms soon after injury. Findings from the present study suggest that the ultimate outcome for the child is determined by several of these factors operating in conjunction with one another, rather than by a single overriding factor such as injury severity.
3. The list of neurobehavioral symptoms developed as part of the project was a particularly good predictor of adverse child and family outcomes. This or similar symptom checklists hold substantial promise as means for identifying children most in need of careful follow-up and comprehensive post-injury assessments.
4. There are psychosocial and family consequences of orthopedic trauma, hence children with traumatic injuries not involving brain insult per se are also in need of clinical follow-up and family interventions.

Children with TBI frequently have periods of protracted recovery involving substantial delays in school re-entry. Furthermore, there is a lack of uniformity of approaches to assisting the child in school reintegration and in treatment of academic and behavior problems. Many high-risk children receive little if any special consideration. These findings suggest a need for increased appreciation by schools of the problems and needs of children with TBI, and creation and implementation of educational policies with regard to educational programming for these students.

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Regulatory Disorders and Developmental Outcomes

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Costs	Awarded	Requested
Year 1	$110,312	$161,056
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Year 3	$126,492	$209,741
Year 4	$122,076	$224,909
Year 5	$121,171	$200,916
Year 6		

Year 2000 Objectives
6.3, 6.14

Study Design
Quasi Experimental

Time Design
Longitudinal

Care Emphasis
Noninterventional

Population Focus
Infants, Toddlers, Preschool-age children

Race/Ethnic Focus
No Stated Racial/Ethnic Focus

Summary

Statement of the Problem

Many children who develop behavioral and emotional disorders are not identified until they enter school. It is hypothesized that these disorders have measurable antecedents during infancy. Specifically, it is proposed that 9-month-old infants with regulatory disorders, manifested by problems in the areas of self-consoling, attention, response to changes in routine, sleeping, feeding and sensory reactivity, will differ from normal peers at 9, 24, and 36 months. The regulatory disordered infants will exhibit deficits in sensory processing, cognitive processing, psychophysiological reactivity, and emotional regulation. In addition, it is hypothesized that social-environmental risk factors (e.g.,low SES, parent stress) will contribute to the outcome risk of infants with regulatory disorders.

In order to test the stated hypotheses, 80 regulatory disordered infants and 80 SES-matched normal peers will be assessed at 9 months and followed at 24 and 36 months of age. A comprehensive battery will be administered at each assessment point and will include measures in the four domains outlined above. Mothers will complete questionnaires on child temperament, child behavior problems, parenting stress, and demographic information. At 36 months, children will receive an evaluation to assess behavioral and emotional difficulties.

If successful, the assessment strategies employed in this study will have immediate application in identifying infants at greatest risk for severe behavioral and emotional disorders. Moreover, the research will provide insight into the etiology of these processes. This knowledge will aid clinical researchers in developing effective early identification and preventive strategies to address infant vulnerabilities. Thus, the overall goal of the project is to identify, during infancy, measurable precursors of severe behavioral and emotional disorders.

Research Questions or Hypotheses

This study tested the following hypotheses related to the prediction of infants who will develop behavioral and emotional problems by three years of age.
A) Infants with regulatory disorders are at risk for deficits in sensory and cognitive processing, psychophysiological reactivity, emotional regulation, and mental health outcome.
B) Regulatory-disordered infants with greater symptoms are at greater risk for behavioral and emotional disorders, in addition to the above deficits.
C) Social-environmental risk factors contribute to the outcome risk of infants with regulatory disorders.

Study Design and Methods

171 infants/children and their families participated in the longitudinal research study. The participants included 74 normally developing infants, 76 infants with regulatory disorders (21 with mild and 55 with moderate to severe regulatory disorders), and 21 toddlers with pervasive developmental disorders. The sample was predominantly (95%) Caucasian and middle-class (mean Hollingshead SES index = 55). Children were recruited via fliers to parents and professionals or via clinical referral. All children in the normal and RD samples were full-term, normal birth weight, healthy infants with no cognitive or motor impairments. Children in the mild RD sample exhibited two of the five symptoms of regulatory disorders while children in the moderate RD sample exhibited three or more symptoms. Symptoms included: sleep disturbance, difficulties self-consoling, feeding difficulties, distress with change in routine, and distress to routine sensory challenges. Children in the PDD sample were classified using the DSM-IV criteria.
Children were seen for assessments during the first year of life, and again at 2 years and 3 years of age. During the first assessment, infants were tested with the Bayley Scales of Infant Development (Bayley, 1993), the Test of Sensory Functioning in Infants (TSFI, DeGangi & Greenspan, 1989), the Test of Attention in Infants (TAI, DeGangi, 1995). In addition, the Infant-Toddler Symptom Checklist (DeGangi, Poisson, Sickel, & Wiener, 1995) was administered to all children. Parents completed the Infant Characteristics Questionnaire(ICQ, Bates, 1984) and the Parenting Stress Index (PSI, Abidin, 1986). Finally, children were observed during a mother-child play interaction and measures of heart rate variability were obtained from EKG data collected during baseline and testing conditions.
During the 2-year assessments, parents again completed the ICQ and PSI instruments along with the Child Behavior Checklist (CBC, Achenbach, 1989). And during the 3-year assessments, parents completed the CBC and PSI as well as the Dimensions of Temperament Scale (Lerner, 1989). The Sensorimotor History Questionnaire for Preschoolers was administered as were the Bayley Scales of Infant Development. In addition, a preliminary clinical diagnosis at 3 years was conducted by two independent child psychiatrists blind to the group classification of the subjects.
From the various measures collected in this longitudinal study, we are able to address questions regarding precursors of preschool emotional and behavioral problems.

Findings

In the investigation of the first hypothesis, infants with regulatory disorders were more likely to exhibit deficits in several areas of behavioral development as compared with their normal peers. There were no group differences in psychophysiological measures. And while behavior problems tend to dissipate over time in normal infants, they are exacerbated in infants with regulatory disorders. By the time they are 3 years of age, children who manifested moderate to severe RD symptoms in infancy, are now exhibiting behaviors which meet DSM-IV criteria for behavioral/emotional problems. Infants with regulatory disorders did not exhibit

In the investigation of the second hypothesis, severity of disorder played a significant role in the prediction of deficits from early regulatory disorder symptoms. Infants in the mild regulatory disorder sample (exhibiting only 2 of the 5 symptoms) were not significantly different from their normal peers on most assessments, while the infants with moderate to severe regulatory disorders did perform significantly more poorly than normals on most assessments.
In the investigation of the third hypothesis, family socioeconomic status did not have a significant influence on the emergence of social behavioral and/or emotional problems in preschoolers.
In predicting preschool diagnoses, symptoms of poor regulation in infancy provided early markers of later problems. Almost _ of the sample (4 of 10) of infants with mild regulatory disorders and nearly all of the sample (21 of 22) of infants with moderate to severe regulatory disorders, manifested behaviors indicative of severe behavioral/emotional disorders at 3 years.
Finally, males with regulatory disorder symptoms exhibit different patterns of approach behavior in response to maternal approach in mother-child play interactions than do females with RD symptoms or male or female controls at 2 years of age. From this finding we can conclude that the sample of infants with regulatory disorders is heterogeneous and that RD males and females exhibit different behavioral manifestations.

Recommendations

The research supports the importance of early identification of infants with regulatory problems. A relationship between early symptoms of regulatory disorders and severe preschool behavioral and emotional problems was established.
Further, our findings strongly suggest that a moderate regulatory disorder during infancy should be redefined as follows:
1. In order for regulatory disorder to exist, the child should have both:
poor self-regulation (e.g. irritability, inconsolability, demandingness, and poor self-calming), and movement and/or tactile hypersensitivities
2. The coupling of a regulatory disorder with the following symptoms: inattention, problems with visual processing, and poor emotional/behavioral control predisposes the child for developmental delay in addition to the regulatory disorder.
3. The coupling of a regulatory disorder with feeding problems predisposes the child for relational problems.
Finally, our findings suggest that regulatory problems with sleep are prevalent among children with mild regulatory problems and are not critical to later development. Many of the children in the mild RD group exhibited sleep problems as one of their two problem areas. Because the mild RD group did not differ from normal children on process variables and did not display severe behavioral or emotional problems at 3 years of age, we suggest that sleep problems should not be included as a symptom in the diagnosis of a regulatory disorder.

Products To Date

Abstracts

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SUBJECT INDEX

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