Summary

Statement of the Problem

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

Research Questions or Hypotheses

By following a sample of homeless and housed families for 24 months and collecting additional data over time, the study team will be able to: (1) Examine the natural course of homelessness among families and the extent to which it is chronic or episodic; (2) compare and contrast factors that increase risk of homelessness with those that prolong it; (3) examine mediating factors, especially social support resources and their effects on residential stability for homeless women and their children; (4) describe the conse-
quences of homelessness for women with respect to service utilization, victimization, and other life stressors; and (5) examine the consequences of homelessness, other risk factors, and protective factors (such as mother’s mental health) on the development, socio-emotional adaptation, and academic achievement of children over time.

**Study Design and Methods**

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

A battery of standardized measures will be used to operationally define and measure the maternal and child variables of interest. Child outcomes (including mental and physical health, socioemotional functioning, and educational achievement) will be measured using standardized instruments, including the Children’s Depression Inventory, the revised Children’s Manifest Anxiety Scale, the Child Behavior Checklist, the Diagnostic Interview Schedule for Children (DISC), and the Vineland Adaptive Behavior Scales. Mediating variables including social support, other resources, and children’s traits will be measured using the Harter Scales (parallel forms for school-age and preschool children). For school-age children, social support will be measured using “My Family and Friends,” and peer relations will be measured using the Index of Peer Relations. The Emotionality, Activity, Sociability (EAS) Temperament Scale will be used for infants and toddlers ages 4 months to 30 months. With the exception of the DISC, Kaufman Brief Intelligence Test (K-BIT), and health questions, all of the outcome measures will be administered at 12 and 24 months followup.

**Population Description and Sampling Plan**

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

**Analysis Plan**

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

Summary

Statement of the Problem

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

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

First, could deficits in component neuropsychological functions, such as attention and memory, which are important to intelligence test performance, result from lead burden? Second, are there windows of time during which children are at greater risk for long-term or specific neuropsychological deficits due to the state of the maturing nervous system at the time the child was first burdened with lead? Third, are findings dependent on the method of measuring neuropsychological outcome? Fourth, have all confounding factors been accounted for, or might lead burden coexist with other factors that could influence neuropsychological development? Specifically, do the factors of nutri-
tion and iron deficiency influence the relationship between lead burden and attention and memory?

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

Research Questions or Hypotheses

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

Study Design and Methods

All children will receive a baseline developmental assessment at 8 months of age. Children will then be seen 13 times between 12 and 48 months of age to complete the Bayley Scales of Infant Development-II or the Wechsler Preschool and Primary Scales of Intelligence, neuropsychological and experimental measures of memory, or experimental measures of attention. Different measures will be administered at each testing session to achieve six time points for developmental status, attention, and memory domain assessments.

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

Population Description and Sampling Plan

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

Analysis Plan

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

Summary

Statement of the Problem

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

Research Questions or Hypotheses

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

Study Design and Methods

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

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

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

Population Description and Sampling Plan

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

Analysis Plan

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

Analyses of continuous variables for knowledge and blood lead will be done by general linear models for correlated data (SAS procedure MIXED). This approach will allow for repeated measures when there may be partial data. Dichotomous outcomes (i.e., blood lead levels > 10 µg/dL) will be analyzed by applying the general linear model to distributions (SAS macro GLIMMIX). In addition, actuarial methods, including Kaplan-Meier nonparametric stratified survival analysis and Cox proportional hazards, will be used to assess time to an outcome.
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Costs
 Direct Costs Indirect Costs Total
Awarded Awarded
Year 1 248,324 111,746 360,070
Year 2 279,479 125,811 405,290
Year 3 283,707 130,505 414,212
Year 4 315,230 124,602 439,832
Year 5 221,596 101,934 323,530

Year 2000 Objectives
7.4

Study Design
Experimental

Time Design
Longitudinal

Care Emphasis
Interventional

Population Focus
Toddlers, Preschool Children, Parents

Race/ Ethnic Focus
African Americans

Summary

Statement of the Problem

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

Research Questions or Hypotheses

This project’s two experimental studies are designed to examine the effectiveness of a multicomponent preventive program aimed at mothers who are at high risk for child abuse. The primary goal is to create a complete set of lesson plans and stimulus materials with empirically demonstrated effectiveness that could be readily implemented at other child abuse treatment and prevention sites. The project will also examine individual differences in response to treatment (in
order to determine the psychosocial and historical characteristics of the women who benefit most from the program) and will provide initial data on the process of treatment. Such process measures include using a daily diary to track the point during treatment when affective changes occur and to examine how subjects’ reactions to treatment (e.g., motivation, relationship with staff) predict treatment response. Ultimately, such data can describe the characteristics of the subjects who benefit most from such preventive treatment.

**Study Design and Methods**

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

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

Knowledge of the child’s developmental abilities is taught directly, referenced throughout the curriculum, and reinforced through the technique of taking perspective. Beliefs and attitudes are addressed directly in the lesson Gentle but Strong Parenting, yet every lesson targets attitudes or beliefs that act as barriers to effective parenting and teaches the technique of reconstructing dysfunctional beliefs. Affective changes are addressed directly through teaching anger management, and self-regulation of affect is addressed in each lesson. The techniques of “tuning in” to the joy of parenting and planned demonstrations of physical affection from mother to child and from child to mother (“warm fuzzies”) are topics of explicit exercises every week.

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

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

Seven domains of data will be collected: Screening information, demographic and background information, premeasures and postmeasures of treatment outcome, continuous measures of treatment outcome, detailed process measures of response to treatment both within the group and during the home visit, data on social service referral and utilization, and followup data. Background information will include history of violence within family of origin and later conjugal relationships, levels of social support, and history of drug and alcohol use, including maternal substance use while pregnant with the target child. Premeasures and postmeasures include the Child Abuse Potential Inventory, Eyberg Child Behavior Inventory, Child Anger Scale, Problem-Solving Abilities, Parent Opinion
Questionnaire, Home Observation for Measurement of the Environment Inventory, and three measures developed for this study—Family Chaos: Interview and Observation, Problem Solving, and the Parental Efficacy Inventory. Also developed for this study are two structured observations of child compliance (parent control strategies and mother-child interaction) as well as a self-monitored daily diary that will be used to measure positive and negative maternal affect and to document the mother’s use of discipline over the 4 months. At the end of the first study, staff members will assist the home visitor in designing materials that can be used to improve group sessions.

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

**Population Description and Sampling Plan**

Subjects are recruited in five waves for the first study and five waves for the second study. Twelve subjects in each wave are initially assigned to the experimental group and 12 to the control group. A targeted total of 120 mothers will participate in each of the two studies. Mothers are included if they (1) are of low-income status, (2) have a target child between the ages of 18 months and 5 years, (3) use physical discipline, and (4) experience anger toward the child. The study excludes mothers who do not speak English, plan to move within the next 4 months, have more than 2 years of college education, are active clients of child protective services, or have major psychopathology or moderate-to-severe mental retardation.

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

**Analysis Plan**

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

Statement of the Problem

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

Additional progress has been made in developing molecular procedures. The investigators now consider the combination of PCR and Southern analysis of fragile X mental retardation–1 (FMR-1) status to be reliable not only for amniotic fluid samples but also for chorionic villus samples (CVS). Therefore, cytogenetic prenatal or postnatal testing for fragile X is no longer recommended. In contrast to cytogenetic laboratories and laboratory settings in which maternal cell contamination is excluded, not one instance of a false negative or false positive result has been recorded with the use of the molecular testing procedures. A summary of results through 1996 is provided in the following table.
Since several examples of “spontaneously” occurring (noninduced) fragile X chromosomes have been observed in prenatal cultures and subsequently found to be fragile X mutations, the investigators have stressed that cytogenetic laboratories continue to be aware of fragile sites. The investigators recommend that pregnant women be offered molecular testing immediately when fragile X chromosomes are observed spontaneously.

The combination protocol previously developed and employed is being improved. Additional studies are being carried out to reduce turnaround time by limiting sample size for both PCR and Southern analyses. The investigators are continuing to improve this protocol by developing a novel PCR-Southern blot procedure and demonstrating that this new procedure can significantly reduce turnaround time for the Southern analysis. In addition, the investigators have been able to show that it is possible to distinguish between full mutation samples and control prenatal samples using monoclonal antibodies. Through continued development, prenatal detection procedures will be improved so that results may be made available the same day or within 1 day of receipt of sample.

Research Questions or Hypotheses

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

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

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

Population Description and Sampling Plan

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

Analysis Plan

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

Summary

Statement of the Problem

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

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

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

Study Design and Methods

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

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

Population Description and Sampling Plan

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

Analysis Plan

For the antenatal portion of the study, the decision to breastfeed will be treated as a binary outcome (yes/no). Continuous variables will be compared between groups, by using Student’s t test (transforming any non-normal variable distributions, if necessary,
or using nonparametric methods). Categorical variables will be tested for differences by chi-square statistics, and 95 percent confidence intervals for proportions will be calculated to examine the variance of the point estimates. In addition, the effect of exposure to formula will be tested by calculating the relative risk of deciding to breastfeed, and stratified and logistic regression analyses will test for potential confounding variables in this relationship.

In the postnatal portion of the study (examining the effect of antenatal exposure to formula on breastfeeding duration), duration will be treated as a binary variable (continued breastfeeding to 6 months) and analyses will be similar to those for the antenatal portion. Duration of breastfeeding will also be treated as a continuous variable (duration in weeks). Mean differences between the two groups will be tested by Student’s t test or nonparametric methods. Time-to-event analysis (Cox proportional hazards “survival” analysis) will also test for the relative risk associated with the failure or success of breastfeeding with multivariate modeling to control for confounding variables. We will also test various models for potential effect modification by subject characteristics.
Diarrheal Illness Surveillance in Child Day Care

Summary

Statement of the Problem

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

Research Questions or Hypotheses

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

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

Population Description and Sampling Plan

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

Analysis Plan

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

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

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