**Research Proposal**

**Title: Evaluation of Feeding Patterns of Infants and Toddlers at WIC in San Marcos, Texas**

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**Research Plan**

**Introduction/Background**

In recent decades, *pediatric overweight*, including children in two categories defined by the Centers for Disease Control [i.e., *pediatric overweight* or ‘at risk for overweight’, describes children over the 85th body mass index (BMI) percentile for age, and *pediatric obesity* or ‘overweight’, describes children over the 95th BMI percentile for age], has increased in the US to include 26% of children ages 2-5 and 37% of children ages 6-11. Mexican American (MA) children are disproportionately affected, with 33% of MA children ages 2-5 experiencing *pediatric overweight*, compared to 25% of non-Hispanic whites of the same age. This disparity is also true for older children, with 43% of MA children ages 6-11, compared to 37% of non-Hispanic white children of the same age experiencing *pediatric overweight* (1). Not only is *pediatric overweight* associated with a variety of negative health outcomes for children, including social stigmatization, glucose intolerance, hypertension, hyperlipidemia, sleep apnea, orthopedic complications, and polycystic ovary disease, but it also increases risk for obesity, metabolic syndrome, and type 2 diabetes in adulthood (2). Therefore, there is an urgent need for research addressing *pediatric overweight* in the MA population.

Consuming a balanced diet emphasizing a variety of fruits and vegetables is vital to preventing obesity and associated comorbidities (3). A critical time for establishing healthy eating behaviors is before the age of 2 years (4). The American Academy of Pediatrics recommends that ‘complementary foods’, which are foods added to the diet of breast or bottle fed infants, be introduced gradually, beginning at 6 months of age, but that timing should reflect the individual infant’s developmental stage, so that foods may be introduced between 4 and 8 months (5). Ideally, complementary foods should be nutrient dense and include developmentally appropriate vegetables, fruits, cereals and meats, but not desserts and sweetened beverages. Consumption of nutrient dense foods may not only be protective against *pediatric overweight,* but is necessary to support good health, including cognitive development (6).

In the Feeding Infants and Toddlers Study (FITS), a national cross-sectional study conducted in 2002, Mennella, et al. found that Hispanic infants were offered sweet-tasting foods at an earlier age than non-Hispanic infants, and that Hispanic infants and toddlers consumed more sweetened complementary foods and beverages compared to non-Hispanic infants and toddlers (7). This trend may contribute to a heightened preference for sweet foods (8) and to the risk for developing *pediatric obesity* (9). FITS was the first study to comprehensively characterize feeding patterns of infants and toddlers in the US, and while the researchers included a nationally representative sample of Hispanic infants and toddlers, they did not include specific at-risk populations, such as the children (70% MA) in San Marcos, TX (10). In 2003, we found that the incidence of *pediatric overweight* was greater among San Marcos school children when compared to children in Texas and the US. For example 54% of 4th graders in San Marcos schools had BMI measurements which classified them as being *overweight*, compared to 39% in Texas and 37% in the US; comparable weight disparities were also identified in older children (11).

Given the prevalence of *pediatric overweight* in San Marcos, especially when considering the increased disease risk faced by these children, it is imperative that early feeding patterns of infants and toddlers in San Marcos be investigated so that effective interventions can be developed. The San Marcos Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), which serves approximately 400 women with children per month (personal communication, WIC Director), provides an accessible sample for an investigation of early feeding patterns in children in San Marcos.

**Objectives/Specific Aims**

The aims of this study are to: (1) investigate the feeding patterns of infants and toddlers participating in WIC in San Marcos, TX; (2) compare the observed feeding patterns to those reported in the FITS study and other national studies; and (3) identify disparities in complementary feeding patterns between MA and non-Hispanic whites in San Marcos. Based on the local prevalence of *pediatric overweight*, we hypothesize that intake of sweetened foods and beverages by MA infants and toddlers in San Marcos, TX, will be greater than that reported for Hispanic infants and toddlers in the FITS study and other national studies. We also hypothesize that differences will be detected between the feeding patterns of MA and non-Hispanic white infants and toddlers, including a higher intake of sweet foods in the MA infants and toddlers an intake of sweet foods at an earlier age.

**Participant Selection**

**Study Population**

One-hundred and thirty participants of WIC in San Marcos, TX, with a child, aged 4 months-5 years, will be recruited for this study on a volunteer basis (see WIC approval letter in appendix). Each month, approximately 250 infants and toddlers are signed in to WIC in San Marcos, TX. We determined that a sample number of 130 participants recruited over a 3 months period would adequately represent the WIC population being studied (12). The infants and toddlers will be segmented into the following age groups for data analysis: 4-5 months of age, 6-11 months of age, and 12-24 months of age. Though the purpose of this study is to compare the feeding patterns of Mexican American infants and toddlers and non-Hispanic white infants and toddlers, any and all races and ethnicities will be included in this study. Both genders will be included, and state of health will not be assessed before accepting participants into the study.

**Eligibility Criteria**

Participants of WIC in San Marcos, TX, with a child aged 4 months-5 years will be eligible for this study. The researchers will require no contact with the children being studied; only caregivers of the children, usually the mother, will have contact with the researchers. Children will be studied in this research design due to the importance of assessing their feeding patterns as reported by caregivers.

**Ineligibility Criteria**

Participants with a child who is not within the age range of 4 months-5 years will be excluded. Also, only one child from each family will be invited to participate; no additional children in an already participating family will be allowed to participate because this would over-represent the feeding patterns of single respondents.

**Recruitment/Registration**

Trained researchers will recruit participants by two methods, including (1) posting flyers, and (2) by briefly introducing the project to small groups of WIC participants who are attending required nutrition classes at the San Marcos, TX, WIC location. Potential volunteers who learn about the study from flyers can call the Texas State University researchers for more information. Those who learn about the study at a nutrition class can meet with trained researchers immediately after their class. All pertinent information about the study will be detailed on the flyer or handout (see appendix). The WIC participants who respond to the active recruitment will be screened immediately in the WIC location according to the study criteria. The WIC participants who call the Texas State University researchers about the research study flyer will be screened during the initial phone call by a trained researcher.

**Protocol Details**

**Research Design and Methods**

This research study will be an investigative study of the feeding practices of MA and non-Hispanic white infants and toddlers in the San Marcos, TX, WIC population. We will follow the basic design of the FITS study, which includes a 24-hour diet recall over the telephone after recruitment and screening (13). In addition, we will ask questions from the Feeding Practices Questionnaire over the telephone to determine when certain foods were first introduced. The Feeding Practices Questionnaire contains questions from CDC questionnaire and does not need to be validated since it assesses observable data (14). Health history and demographic information will be collected as well. The evaluation of food groups and subgroups fed to infants and toddlers and the timing of introduction of foods will be assessed in this study. Participants will be given the option to speak Spanish or English during the telephone interview. Documents will be provided in English and Spanish.

**Participant Assessment**

The trained researchers will discuss the study in a private area in the WIC location with the participants who respond to active recruitment (e.g. while attending a nutrition class). The participants will be thoroughly informed about the study verbally and asked to sign a consent form (see appendix). A copy of the consent form will be given to the participant. Upon consent, participants will be given a food amount information booklet for use during the 24-hour recall (see appendix). Specifically, participants will be called by trained researchers within 72 hours of the initial meeting at a time determined for the participant’s convenience. The trained researchers will conduct telephone interviews from a private room designated for human research in the Family and Consumer Sciences Building at Texas State University. During the 30-minute telephone call, participants will be asked about food items their child consumed over the past 24 hours. If the caregiver is unable to provide information about their child’s diet record due to time away from their child, the researcher will ask permission to call the secondary childcare provider. The secondary provider will be called if permission is granted and the researcher will ask the provider questions concerning the child’s dietary intake for the past 24 hours. The researchers will also ask participants questions from the Feeding Practices Questionnaire (see appendix) over the telephone. Questions about demographic and health history information (see appendix) related to the child and caretaker will be asked as well. Immediately following the telephone session, researchers will send the participants by mail a $10 gift certificate for the HEB grocery store and a letter thanking them for participation (see appendix).

For the participants who responded to the flyer and qualify for the study, 2 copies of the consent form, and a food amount information booklet for use during the 24-hour recall, along with a postage-paid envelope designated for return of the signed consent form. The study and consent form will also be thoroughly explained to them during the initial telephone conversation. Participants will then be called within 72 hours of the initial call by trained researchers, at a time chosen for the participant’s convenience. All other protocols will be the same as for those participants recruited in person.

**Data**

Data collected from the 24-hour recall will categorize food items fed to infants and toddlers into main groups and subgroups. Data fields of groups and subgroups will include milk (breast milk, infant formula, cow’s milk, soy milk, and other milks), grains and grain products (infant cereals, past, bread, rice, and other grains), vegetables (100% vegetable juice, baby food vegetables, starchy and non-starchy vegetables), fruits (100% juice, fresh fruits, canned fruits, baby food fruits), meats (animal sources, beans, peas, nuts, cheese, yogurt, and eggs), mixed dishes (dishes which include a grain and protein source, sometimes mixed with vegetables), sweets (pastries, sweetened beverages, desserts, candy, and other sweet foods), and salty snacks (chips, popcorn, and other salty snacks). The subgroups will be categorized by method of preparation and other factors specific to each main group. The total servings of food items reported in the 24-hour recall will be counted in each group and subgroup. The timing of introduction of these foods will also be assessed in the Feeding Practices Questionnaire. Participants will be asked about the timing of introduction of these food groups. These data will be categorized by age in months of first introduction. Questions about breastfeeding practices on the questionnaire will be categorized according to breastfeeding, when/if breastfeeding stopped (age in months), or never breastfed. Questions included on the demographic and health history forms will be utilized to group data according to ethnic groups and household characteristics and correlated to groups of specific feeding practices. Data collection from 130 participants will occur within 3 months, as estimated by the San Marcos, TX, WIC director.

Confidentiality Authorized persons from Texas State University and the Institutional Review Board have the legal right to review participants’ research records and will protect the confidentiality of those records to the extent permitted by law. Research records will not be released without authorized consent from the participant unless required by law or a court order. All data will be de-identified and only the Principal Investigators will know the code. If the results of this research are published, presented at scientific meeting or summarized for WIC, the participants’ identities will not be disclosed. All research data and documents will be kept in a locked file cabinet in a locked room in the Family and Consumer Sciences Building. Only the identified researchers will have keys to the file cabinets. All digital data will be kept on secured computers located within the Family and Consumer Sciences Building and will require a password to access the information. Only the identified researchers will have passwords to access the digital data. Once the data is analyzed for research purposes, it will be shredded and discarded at Texas State University.

**Statistical Design & Analysis**

We will analyze the 24-hour intake data using the Nutrition Data System for Research (NDS-R, version 2008, University of Minnesota Nutrition Coordinating Center, Minneapolis) which uses the multiple-pass method for 24-hour recalls. A graduate student researcher will attend a 2-day formal training session on the NDS-R application and train all interviewers prior to conducting phone interviews. This software application categorizes food intake into various main food groups and subgroups. We will conduct statistical analysis using the Statistical Package for the Social Sciences (SPSS, version 16.0, 2007), and report descriptive statistics of the food groups and subgroups, such as the percentage of the age/ethnicity group who consumed each food group (e.g. sweetened beverages), most frequently consumed food items (e.g. french fries), age of first introduction of certain food groups, and breastfeeding practices. From these analyses, we will be able to report practices, compare them to the national trends found in FITS and other national studies, and test for differences between MA and non-Hispanic white infants and toddlers by using calculated percentages and standard errors in SPSS at 95% and 99% confidence intervals.

**Informed Consent Document**

See appendix.

**Risks/Benefits**

No known risks are involved in this study other than possible apprehension and slight anxiety in disclosing personal information. The participants will be assured that all information collected will be kept private and confidential and that it will not be shared with WIC or any other agency or individual.

Participants will be informed that they are participating in an investigative study that will further help create interventions for those at risk. Those who participate will be offered a $10 gift grocery store certificate as an incentive for completing the study. Publication of the results of this project will contribute a unique perspective to the literature because it will indicate whether complementary feeding practices of San Marcos children are similar to those of Hispanic populations reported in the FITS study. Furthermore, results can be used to design future interventions to improve feeding practices for this population. Given the obesity epidemic plaguing the US population and especially the Hispanic population, results of this research may be significant.

**Student Investigator/Requestor**

This will be thesis work for two graduate students. The MS in Human Nutrition at Texas State was launched in Fall 2008, and this project will support the thesis research of graduate students enrolled in the program and provide a new line of investigation for Dr. Crixell. While Dr. Crixell has researched the child nutrition programs in Texas, conducted weight management research with MA women in San Marcos, and collaborated with WIC through student internships, this will be her first investigation of the use of complementary foods in MA infants. Dr. Crixell has successfully completed CITI training (see appendix).

Undergraduate students registered for NUTR 4101, an independent research course, will aid in recruitment and data collection after thorough training with the Principal Investigator and graduate students.

**Appendix**

* WIC Approval Letter
* Recruitment Flyer in English and Spanish
* Screening form
* Consent Form Reading Comprehension Level Explanation
* Consent Form in English
* Consent Form in Spanish
* Food Amount Booklet
* Feeding Practices Questionnaire
* Demographic Form
* Health History Form
* Thank You Letter in English
* Thank You Letter in Spanish
* CITI Training Certificate (Dr. Crixell)

**Funding**

Funding by a federal agency is not being provided. Application for a Research Enhancement Program grant at Texas State University is under review.

**This proposal has also been submitted to the Texas Department of State Health Services Institutional Review Board for review and approval on December 24th, 2008.**

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