**SIGNIFICANCE (*maximum 1 page*)**

**[ *Provide enough background and information on the problem to support that it is a significant problem for the community. State the overall goal(s) of the proposed research*]**

Background

*The burden of childhood obesity* - The burden of childhood obesity in American Indian (AI) communities is well-documented (1). Among 7-11 year-old children from 41 elementary schools in 7 AI communities, 29% had BMI greater than the 95th BMI percentile; the corresponding rate of overweight/obesity (BMI >95th BMI percentile) in similarly aged children in the National Health and Nutrition Examination Survey (NHANES) was 11% (2). In the Aberdeen area Indian Health Services—a service area that comprises North Dakota, South Dakota, Nebraska, and Iowa, nearly twice as many young AI children were overweight/obese than a national sample of children, with 44% and 24% of five-year old AI children with BMI >85th and >95th BMI percentiles, respectively (3). The burden of childhood obesity in AI communities continues to rise. There was a 5% increase in the prevalence of overweight/obesity among AI children aged 6-17 years during the 7 year period between 1995-1996 and 2002-2003 (3). As childhood obesity and early-onset diabetes are risk factors for many debilitating and costly diseases later in life (4, 5), it is critical to develop effective strategies to reduce overweight/obesity in children.

*Efforts to improve diet are critical to obesity prevention* - Obesity is a complex disease influenced by several factors, including physical inactivity and poor diet quality (6, 7). Importantly, the overall qualities of the AIs participants’ diets were poor. In the Strong Heart Family Study of AI, only 6% of AIs achieved 1 or 2 recommended dietary goals and 65% of AIs did not achieve any (7). Efforts to improve diet are critical to obesity prevention. Unfortunately, diet education programs have had limited success in lowering the burden of obesity among AIs on a population-level (8). This may be a result of a poor understanding of the social-contextual determinants of diet, including factors that influence families’ dietary choices/food purchasing patterns. To date, few published studies have explored factors that may influence dietary decisions and food purchases (9-14); these studies suggest price (10, 12, 14), convenience (10, 13), family food preferences (10, 14), and habit (11) as contributors to dietary decisions/food purchasing patterns.

*Dietary interventions in AI communities* - The CDC identified several point-of-purchase grocery-store interventions as evidence-based strategies for the promotion of a healthy diet (15), and a recent systematic review of published food store interventions determined placement, price and promotion as key factors that influence healthful eating (16). Only a few such interventions have been conducted in rural American Indian communities (17-19). These have promoted the purchase of healthy foods, manipulated prices, offered in-store promotions, taste-testing, and shelf-labeling (17, 18, 20). A major limitation of the interventions in AI communities to date is the quality of outcome assessment; most have assessed self-reported outcomes that are prone to recall bias, social desirability bias, and measurement error (21). The use of an objective marker of change (i.e., tracking changes in promoted foods over time using the grocery stores’ electronic sales database) may provide a solid measure of intervention success. Additionally, most food store interventions have focused on adults only. Based on communication with those on the proposed community, children (5-12 years old) regularly shop with caregivers and often have strong opinions on types of food to purchase. As such, better understanding the feasibility of a kid-friendly/family-focused grocery store intervention is warranted. Awareness of the importance of a healthy diet and access to healthy foods may not always translate into healthier food choices (22). Unfamiliarity with healthy foods (e.g., taste, cooking methods) may deter families from purchasing these items. Likewise, families, especially those with children, may be influenced by the marketing/advertising of unhealthy processed foods (23). Such factors must be considered in intervention development and implementation. As the barriers and facilitators of dietary decisions are at least in part driven by environmental, cultural, and family characteristics, the generalizability of findings from individual studies is unclear. A better understanding of the primary determinants of dietary decisions/food purchasing patterns is needed to inform the development of a culturally-appropriate obesity-prevention intervention in the community.

Goals

The overall goals of this application are to perform the formative research needed to understand what motivates family dietary choices/food purchasing patterns, and to use this information to develop a kid-friendly food-store intervention to promote healthy food choices for families in the community. This research will generate the knowledge necessary to implement a culturally-appropriate and sustainable store-based dietary intervention to increase healthy food consumption in a rural AI community with a high burden of obesity.

**APPROACH (*maximum 2 pages*)**

**[ *Provide details on how you will conduct the study. What steps will you take? Be specific. E.g. include numbers, timelines to demonstrate its feasibility, etc. Importantly, describe what comparisons, statistical tests, and/or outcomes you will use to judge success or to arrive at your conclusions.*]**

We propose the following steps to address the problem:

1. **Characterize the local food environment in the community, and what decision-making processes underly family food-purchasing patterns.** This will include: (a) an investigation of the availability, price, and variety of foods offered at retail food stores on and around the er reservation using the United States Department of Agriculture Community Food Store Survey Instrument, and (b) forming focus groups and key-informant interviews with AIs who reside in the community to determine what external (i.e., price, availability, and quality of food items) and internal (i.e., taste of foods, food knowledge/familiarity, family food preferences, convenience) factors are the primary facilitators and barriers of healthy dietary decisions.
2. **Develop a grocery store-based intervention on the reservation to promote healthy food choices for school-aged children and their families, and pilot test the feasibility and acceptability of the intervention’s components at one large centrally-located grocery store.** Details of the intervention will be based on the data collected from step 1 about families’ dietary choices/food purchasing patterns, and developed in partnership with the community and store owners. Intervention activities may include increasing kid-friendly promotions and interactive community events. Components of the intervention will be pilot tested at the primary local grocery store, and will be evaluated in terms of store-based feasibility, customer acceptance, and customer purchasing behavior.

*USDA Market Basket.* **-** We will characterize the local food environment using the USDA Food Store Survey Instrument (a.k.a. market basket). The instrument is based on the Thrifty Food Plan, and comprises 68 individual food items (24). We will determine the cost and availability of the market basket at all food stores on and within 150 miles of the community.

*Focus Groups.* - We will recruit AI families with school-aged children to take part in focus groups to inform the development of the store-based intervention. Eligibility requirements for the focus group include 1) being a primary caregiver for a school-aged child (aged 5-12 years of age), and 2) being the primary household shopper. In order to obtain well-balanced groups, staff will recruit eligible participants from a variety of local venues, including family-friendly community events/meetings, parent-teacher meetings at the local elementary school, and the local food pantry. The purpose of the first set of focus groups will be to better understand barriers and facilitators to food choices and food purchasing patterns for families with school-aged children. For instance, do price, child(ren’s) food preferences or convenience influence what sorts of foods families buy? Additionally, we will explore what types of food store interventions aimed at increasing healthy food choices would be acceptable to the community. We will use information from the focus groups to design a culturally-appropriate community-based food store intervention. We will then host another set of focus groups to better assess perceived logistical issues in the design and implementation of the proposed intervention and revise the intervention design and implementation plan accordingly. Each focus group will comprise approximately 8 participants who meet eligibility criteria and will last up to 1.5 hours. Focus groups will be performed until saturation. We anticipate 4 focus groups in total. Participants will be compensated for their time. All focus groups will be audiotaped and transcribed.

*Key-informant interviews***.** - In addition to hosting focus groups in the community, we will meet with local grocery store managers to better understand their perspective on what drives customer purchasing patterns and to discuss opportunities and challenges of designing and implementing a food store intervention for the promotion of healthy eating. The managers of local stores may have a different perspective on the primary determinants of food purchasing patterns than other community members, and their insights are essential to the development of a feasible and sustainable food store intervention. Based on the limited number of retail food stores in the area, we anticipate 8 key-informant interviews.

*Store-based intervention***.** - Evidence-based food store point-of-purchase interventions implemented in other populations include prime placement of healthy foods, educational displays, promotional giveaways, sales on healthy foods, taste-testing, and cooking demonstrations (25). At the focus groups and key-informant interviews, we will discuss the pros and cons of each of the evidence-based strategies, and explore enthusiasm for adapting/tailoring the interventions to achieve a culturally appropriate food store intervention that is inclusive of local cultural-knowledge, attitudes, and behaviors. As such, the details on the objective and design of the store-based intervention will be informed by knowledge acquired in focus groups and key-informant interviews. This information will determine what sort of intervention will be culturally-acceptable, feasible, and have the greatest impact within the community. For instance, an intervention that focuses on the taste-testing of healthy foods will be explored if families express unfamiliarity with healthy foods as a primary purchasing deterrent. Likewise, if price of healthy food items is a major constraint on the purchasing of healthy food items, we will work with the local market to put healthy foods on sale. Hands-on in-store activities will be scheduled during peak times when food is acquired, including weekend evenings and dates of supplemental nutrition assistance program benefits distribution. At a minimum, the activities that comprise the proposed intervention must meet the following criteria: (1) Long-term sustainability; (2) Innovative, practical and kid-friendly strategies to increase sales of healthy foods*;* (3)Acceptable to community values and integrity; (4)Long-term cost-effective; (5) Ability to be scaled-up over time (i.e., expanded to other grocery stores).

*Pilot Testing/Evaluation* - Once the details of the proposed intervention are finalized, we will pilot test components of the intervention to: a) determine feasibility of the activities on a day-to-day operational level within the community market; b) gauge the community’s awareness and acceptance of the intervention’s components; and c) identify challenges in implementation. Feasibility, reach, and acceptability will be evaluated using direct observation, short in-store exit interviews with customers, and interviews with store employees/managers. For instance, if cooking/taste-testing demonstrations are incorporated into the proposed intervention and pilot tested, we will document the frequency of demonstrations, the number of people who viewed the cooking demonstration or stopped by a taste-testing table, and acceptability. All short interviews with shoppers are voluntary, and we will offer a small incentive (e.g., water bottle) as a token of appreciation. If shelf labels/posters are incorporated into the intervention, we will have a staff member visit the grocery store once a week to document the presence and placement of shelf-labels/posters. As the project timeline is short, evaluating quantitative changes in diet or BMI for individual community members is beyond the scope of proposed work.However, we will track the market’s monthly purchasing spreadsheet throughout the study period. The feasibility/acceptability testing will be useful to determine if the proposed intervention’s activities can be scaled-up to a formal pilot study for a large intervention in the future.

*Statistical analysis* **-** The purpose of this work is to better understand food purchasing patterns among families with school-aged children and to assess the potential for a grocery store intervention to promote the purchase of healthy foods on the CRSR. We will conduct focus groups and key-informant interviews until saturation. We anticipate 4 focus groups and 8 key-informant interviews. All focus groups will be audiotaped, transcribed, and coded using the Atlas.ti software. A publishable manuscript will be developed based on recurring themes identified from the focus groups. Outcomes related to the feasibility of the study (e.g, community support, acceptability of intervention) will be assessed descriptively.

*Dissemination* - The community will be involved in all aspects of the proposed project. At the conclusion of the feasibility work, we will meet with the chairman to report results of the feasibility project and discuss ways to continue the project (i.e., apply for a larger grant). We will also present results of the feasibility work to the community at the conclusion of the project, as well as the Strong Heart Study STAR pilot funders. Future work will only be pursued with community support and approval.

**Timeline.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Month  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| Development of materials and IRB approvals | x | x | x |  |  |  |  |  |  |  |  |  |  |  |  |
| Focus Group Recruitment/Focus Groups & Key-Informant Interviews |  |  |  | X | X | X |  |  |  |  |  |  |  |  |  |
| Intervention Development  |  |  |  |  | X | X | X |  |  |  |  |  |  |  |  |
| Feasibility Work at the community market |  |  |  |  |  |  |  | X | X | X | X | X | X | X |  |
| Data Analysis/Dissemination |  |  |  |  |  |  |  |  |  |  |  |  |  | X | X |

*Strengths & Limitations.*- This proposal has several strengths. As there are few food-stores on the community, an intervention at the primary food store in the community will have high reach. Store-based interventions are also more likely to achieve long-term sustainability than interventions that focus on individuals (26). Working directly with the community will make possible shared responsibility/ownership over the project, and facilitate an on-going partnership.This project is not without limitations.Given the small scope of the project (1 year), we will not be able to objectively measure changes in individuals’ diet, BMI, or other cardio-metabolic risk factors.

**INVESTIGATORS (*maximum 1 page*)**

**[ *List the investigators involved, what they will do on the project, and describe their training/expertise, and how it will help the project be successful.* ]**

**XXXXX** is an Assistant Professor of Epidemiology at the University of XXXX. She will manage all aspects of the project, including the focus groups, key-informant interviews, intervention development and feasibility work. She has been actively involved with the SHS for the past nine years, and has experience in physical activity, diabetes, and nutritional epidemiology. As an AI investigator, she is interested in the development of culturally-appropriate health interventions.

**XXXXXXX** is a Professor of Epidemiology. S/he will advise on all aspects of the project, including the focus groups, key-informant interviews, intervention development and feasibility work She has extensive experience in nutritional epidemiology and the design/implementation of interventions.

**XXXXX** is the Director of the Missouri Breaks Research Institute and SHS clinic on the CRSR. She will assist field staff and investigators in assuring all aspects of the project are completed, including the focus groups, key-informant interviews, intervention development and feasibility work She has extensive experience in AI health and CBPR.

**ENVIRONMENT (1 page maximum)**

**[ *Describe where the proposed study will take place, emphasizing how the environment supports the feasibility of the project. If using existing facilities, it may help to include a letter of support or commitment that the facility is willing to provide the necessary resources for the project.* ]**

The Cheyenne River Sioux Tribe is a band of the Lakota Nation. The CRSR is the fourth largest AI reservation in the United States. Located in South Dakota, the reservation comprises 4,200 square miles. Approximately 8,000 people live on the reservation. There are 3 privately owned food outlets in Eagle Butte, 1 tribally owned store (the primary grocery store—the Lakota Thrifty Mart), and 1 USDA commodity food provider. *Please see attached letter of support for this research proposal*. The nearest grocery vendors to the north, south, east, and west of Eagle Butte are 41, 117, 121, and 41 miles away, respectively.

This project will build upon existing ties of the Cheyenne River Sioux community and the Strong Heart Study (SHS). The Cheyenne River Sioux community has been actively involved in the SHS since 1989. We will utilize the existing SHS infrastructure (i.e., SHS field center, the Missouri Breaks Industries Research, Inc, *see letter of support*) to perform the feasibility work needed to develop a store-based intervention to improve diet quality among school-aged children (aged 5-12 years of age) and their families. The feasibility of the intervention’s components will be tested at the Lakota Thrifty Mart; the store keeps detailed purchasing history (i.e., the number of food items sold and type of food), and reports more than 21,000 food transactions per month. The store stocks a wide-range of healthy foods, including fruits, vegetables and low-fat dairy products.

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