Example 1

10.   SPECIFIC AIMS

More than 14% of US households are food insecure, or at risk of going hungry because of the inability to afford food. About 21% of households with children are affected, as are more than a quarter of Latino and African-American households. One in eight US households is now enrolled in the Supplemental Nutrition Assistance Program (formerly known as Food Stamps).

Economists and social scientists have spent two decades studying the measurement of hunger, its psychological impact, and its effect on food consumption patterns. Food insecure adults tend to shift dietary intake toward nutritionally-poor, energy-dense foods, which cost less calorie-for-calorie than more nutritionally-rich foods. They also tend to overconsume during episodes of food adequacy in expectation of future food shortages. These behaviors may predispose adults to the development of obesity and diet-sensitive chronic disease. My recent work has demonstrated that food insecurity is independently associated with a higher prevalence of hypertension and diabetes, and poorer diabetes self-management. However a number of crucial questions remain: *Does food insecurity predispose adults to obesity or diabetes? Does food insecurity alter self-management capacity, making diabetes management more difficult? And finally, does reducing food insecurity enable adults with diabetes to improve self-management capacity and intermediate outcomes?*

Diabetes is increasingly a disease of the poor; among US adults 50-64 years of age in California, the prevalence of diabetes is 8% among whites, 16% among blacks, and 22% among Latinos. Diabetes prevalence is twice as high among adults with less than an 8th-grade education as among those with a college education. The objective of this application is to determine whether obesity/diabetes interventions implemented in low-income settings should specifically target food insecurity. My central hypothesis, formulated on the basis of my clinical experience as a general internist at a public hospital and my subsequent preliminary research, is that food insecurity negatively impacts the prevention and control of obesity and diabetes through alterations in dietary intake and interference with self-management capacity. If this hypothesis is correct, one strategy to increase the effectiveness of obesity and diabetes prevention and control efforts in low-income communities may be to directly address food insecurity – a risk factor that has been largely overlooked and that may be causally related to socioeconomic inequalities in the incidence of obesity and diabetes. My long-term goal is to implement and disseminate interventions at the clinic and policy level that reduce the burden of obesity and diabetes in low-income communities. By pursuing the following specific aims, I will gather data essential for a formal intervention to shift dietary intake among low-income patients with diabetes toward increased fruit and vegetable consumption (to be proposed in a subsequent R01).

Aim 1: Establish the extent to which food insecurity is related to the incidence of obesity, pre-diabetes, and diabetes. To accomplish this aim, we will use longitudinal data from the NHLBI-funded Coronary Artery Risk Development in Young Adults Study (CARDIA). We hypothesize that food insecurity will be associated with unhealthy dietary intake and 5-year incidence of obesity, pre-diabetes, and diabetes.

Aim 2: Determine whether food insecurity alters response to a diabetes self-management intervention. We will use the infrastructure of an existing self-management intervention which has recruited 702 patients with diabetes receiving primary care in federally qualified health centers. We hypothesize that food insecurity will moderate participants' success with the behavioral intervention.

Aim 3: Conduct a pilot randomized controlled trial of a fruits and vegetables voucher in a population of food insecure patients with poorly-controlled diabetes. We will recruit 60 patients from a safety net clinic with a 43% rate of food insecurity. Process outcomes include success with recruitment, ability to deliver the intervention in a clinical setting, and ability to measure study outcomes. Clinical outcomes include dietary intake, change in blood pressure and glycosylated hemoglobin, and rates of hypoglycemia

In addition to establishing the importance of food insecurity as a risk factor for difficulty with obesity and diabetes prevention and management, these studies are expected to have an important impact on the design of clinical and public health interventions to shift dietary intake in low-income communities toward more healthy food alternatives. These specific aims build logically toward an R01-level intervention targeted at patients with, or at high risk of, obesity and diabetes. I am well-prepared to undertake this research, but I require continued mentorship in three critical areas to complete these projects and achieve my long-term career goals: advanced statistical techniques; nutrition epidemiology, assessment, and policy; and intervention research.   My mentorship team includes experts in each of these areas and has the breadth of expertise to help me obtain critical multidisciplinary skills.

Example 2

10.   SPECIFIC AIMS

Although the mother's breastmilk is the optimal nutrition for premature infants, many mothers of premature infants do not initiate breastmilk provision or stop soon after birth. The benefits of breastmilk for premature infants have been well described and include prevention of morbidities such as retinopathy of prematurity, necrotizing enterocolitis, and sepsis.[13-16] Breastmilk may also improve neuro-developmental outcomes, a concern for preterm infants.[17-21] Despite these benefits, many premature infants in California have either never received breastmilk or have switched to exclusive formula feeding by the time they leave the hospital.[22] Furthermore, hospital rates of breastmilk provision vary widely, ranging from 20% to 100%.

What is not known is why there is such wide variation in practice for this therapy that is widely accepted as beneficial. Although we and others have identified socio-demographic factors, such as maternal race, age, and education that are associated with decreased breastmilk provision, we do not know what leads to failure for these groups.[23-27] Without this knowledge, we will not be able to effectively intervene to promote this beneficial clinical practice, particularly in populations that are already at risk for being medically underserved. This type of knowledge cannot be gained from study of currently available administrative or clinical datasets but may be discovered through innovative primary data collection involving qualitative and survey techniques.

My long-term goal is to improve breastmilk feeding rates for premature infants on a broad scale. The _overall objective_ of this application, which is the next step in this plan, is to better understand the behavioral factors that influence the practice of breastmilk provision to premature infants. We need to have a better understanding of these factors in order to design effective quality improvement interventions. The design and testing of such an intervention will lead to attainment of my long-term goal, which is to conduct quality improvement efforts on a statewide level. The _central hypothesis_ motivating this research is that systems, clinician, and patient factors in the period immediately surrounding birth are crucial for initiation and maintenance of breastmilk feeding to premature infants. Observational studies that have shown that starting pumping within the first several hours after delivery and frequent pumping in the first several days are important factors in successful long-term breastmilk provision. This presents a unique and challenging situation in medicine, as it requires a person (the mother) to perform a difficult physical activity (breast pumping 8 times a day starting soon after delivery) for the medical benefit of another person (the baby). It also requires active education, support, and resources from clinicians and the hospital for an activity that does not provide financial benefit to the system. The _rationale_ for the proposed research is that understanding the most relevant factors for this practice, something that is currently unknown, is critical to designing the most effective quality intervention.

Aim 1: To identify <u>maternal factors</u> that promote or hinder breastmilk feeding for premature infants. There are racial and other sociodemographic disparities in breastmilk for premature infants that do not always align with breastfeeding rates for term infants. There are likely to be cultural and educational factors that are important to recognize when developing interventions to reduce disparities. We will investigate these factors through semi-structured interviews and survey methods of mothers who have recently given birth to a premature infant. This study will lead to development of specific interventions directed at high-risk groups.

Aim 2: To identify <u>clinician-level factors</u> that promote or hinder breastmilk feeding for premature infant. Early education and counseling may have an impact on a mother's choice to start pumping early and persist throughout the hospital course. By conducting focus groups with clinicians who care for the baby and mother, we will investigate the self-perceived roles of clinicians in this process and identify barriers that they face in supporting mothers' pumping for their infants. Accomplishing this aim will inform the design of an intervention that accounts for clinicians' needs in supporting mothers to provide breastmilk.

Aim 3: To identify <u>hospital-level factors</u> that promote or hinder breastmilk feeding for premature infants. Considering the wide variation in breastmilk provision rates to premature infants, there must be hospital practices that lead to success or failure. These may include resources—such as availability of equipment and lactation consultants—or education of staff on benefits of breastmilk for premature infants—or policies and procedures surrounding premature infant care. We will investigate this using a mixed-methods approach that will include qualitative research and a survey of neonatal intensive care units in California, linking the results to breastmilk provision rates.

The knowledge gained from this research will be used to design and test an intervention to promote breastmilk feeding in premature infants. Before the end of the K award, we will apply for an R03 grant to pilot the intervention at select centers. The culmination of these studies will be an R01 application to conduct an intervention trial in California hospitals.

Example 3

10.   SPECIFIC AIMS

Regular physical activity reduces the risk of being overweight, thereby reducing the risk of heart disease, stroke, hypertension, diabetes, certain cancers, and premature mortality. Approximately 50 million U.S. adults are sedentary and at high risk for chronic disease or functional limitations. Moreover, there are social disparities in the segments of the population who are sedentary. Elderly, women, ethnic minorities, and individuals with a high school education or less or with a low income are less likely to participate in recommended levels of physical activity compared to men, the young, Caucasians, and individuals with a college/graduate education or high income.

One of the objectives in "*Healthy People 2010*" is to increase the proportion of U.S. adults engaged in recommended levels of physical activity and to decrease the disparities in physical activity. Clearly, more needs to be done to engage U.S. adults in physical activities. Communication technologies that can deliver physical activity interventions that reach large numbers of U.S. adults are readily available. We need to understand how to use them effectively to develop innovative outreach and intervention strategies.

The Internet and hand-held computers have become the most common communication technologies to deliver physical activity interventions. Numerous internet-based physical activity programs have been tested in the past. The Internet based program can be disseminated to a large population with cost effective manner. However, a high attrition rate over time is the biggest problem since the subjects have to proactively log on to a website. Moreover, the subjects who participate in a web-based physical activity program tend to be from higher social economic status.

Given the problems with delivering interventions via the Internet, we need to investigate other promising communication technologies that would enable us both to deliver a physical activity intervention to large numbers of sedentary adults and to retain and motivate them to achieve their physical activity goals. With the rapidly growing use of cell phones in the United States,[12] researchers have begun to investigate the application of cell phone technologies as a means of disease self-management, particularly for chronic illnesses.[13-23] These studies have shown encouraging results, with relatively low attrition rates.[15, 19] However, the application of cell phone technologies for areas of health promotion in sedentary adults has not been studied.

We propose to assess the potential of an innovative cell phone-based intervention in a pilot randomized, controlled trial (RCT) in which 50 sedentary adults will be assigned to an intervention group or to a comparison group. Participants in both groups will receive a pedometer and a cell phone. Over a 12-week period, participants in both groups will be asked to wear a pedometer and to send their total number of steps through a cell phone diary before going to bed. However, only participants in the intervention group will receive the intervention through their cell phones via weekly video clips; they will also receive customized feedback and self-monitoring. In addition, because the pedometers can store data on the last 8 weeks, participants in both groups will be asked to bring their pedometers to the research clinic at 6 and 12 weeks to download these data. To minimize possible hurdles in using cell phones for this intervention or in wearing a pedometer daily, we will install the physical intervention program on the participants' own cell phones whenever possible, and we will have a 10-day "run-in" period in which participants who find it too difficult to wear the pedometer daily and/or use the cell phone program will be identified and will not be randomized. We propose the following specific aims.

Aim 1: To assess the acceptability of using cell phones to deliver a physical activity intervention and to collect outcome data in sedentary men and women. To achieve this aim, we will conduct 4 to 6 focus groups prior to conducting a pilot study of a randomized controlled clinical trial in sedentary men and women.

Aim 2: To provide preliminary estimates of efficacy of a cell phone-based physical activity intervention in sedentary men and women. Because we are using a randomized study design, this pilot study will provide preliminary estimates of magnitude of effect size and variance of the 12-week cell phone-based intervention in sedentary adults on the following outcomes:

2.1   The amount of physical activity (number of steps) and duration (minutes) of aerobic activity measured by a pedometer between the cell phone-based intervention and the cell phone monitoring group over the 12-week study period

2.2   The 7-day Physical Activity Recall questionnaire scores between the cell phone-based intervention group and the cell phone monitoring comparison group.

2.3   The Self-Efficacy for Physical Activity scores between the cell phone-based intervention group and the cell phone monitoring group.