



**Introduction to the HIV Nutrition Project (HNP):
Increasing Animal Source Foods (ASF)
in Diets of HIV-infected Kenyan Women and Their Children**

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Many of the 28 million people with human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) estimated to be living in sub-Saharan Africa also suffer from malnutrition. Reproductive-aged women, their infants and young children are among the most vulnerable to malnutrition and progression of HIV to AIDS. As seen in eastern and southern Africa, mortality is increased in the malnourished. The HIV Nutrition Project (HNP) researchers will be evaluating the effect of protein quality and micronutrients found in meat on the health and nutritional well-being of women living with HIV in rural Kenya and the health and development of their children. By means of a randomized nutrition feeding intervention, the study will determine if meat in the diets of HIV-infected women and their children (1) protects the immune system and prevents severe infection, (2) prevents the loss of lean body mass, enhancing the quality of life among these drug naïve women and enabling women to carry out their activities of daily living, and (3) supports the growth and development of their vulnerable children when compared to those given supplements with the same amount of energy, but with either soya or wheat protein. The intervention food with beef protein provides significantly more vitamin B12, lysine and bio-available iron and zinc when compared to the soya and wheat supplements. Deficiencies of these nutrients may hasten HIV disease progression.

Background

Effects of HIV on the human system. With the stress of a chronic infection like HIV (human immunodeficiency virus), the immune system becomes severely compromised and loses its ability to resist infection. Disease progression from HIV to AIDS (acquired immunodeficiency syndrome) is defined and monitored by the level of CD4 lymphocytes, HIV viral load, the loss of lean body mass and the incidence of co-infections like tuberculosis, pneumonia and fungal infections. The micronutrient status of the body also declines with HIV. For example, decreases in serum selenium, vitamins B12, A and zinc correlate with disease progression from HIV to AIDS.

Supportive information from other populations. The HIV Nutrition Project (HNP) focuses on the impact of animal source foods (ASF), with incorporation of beef, into the diets of HIV-infected women and their infected and affected children in Kenya, who, because of economic constraints, subsist mostly on plant-based diets and do not have the benefit of varied diets that include sufficient ASF or access to nutrition supplements. Results from the Global Livestock Collaborative Research Support Program (GL-CRSP) Child Nutrition Project (CNP) conducted in Embu, Kenya showed that primary school-aged children who were provided beef added to a snack at school experienced significant increases in arm muscle area, vitamin B12 status, physical activity and cognitive

development when compared to similar children who were provided milk with the snack, oil with the snack or no snack. In rural Pakistan and China, families who were provided-lysine supplemented wheat flour showed improved immune function compared to similar families provided with wheat flour that was not supplemented. In India, lysine requirements were shown to be increased by 50% due to parasite infestation in malnourished men. It is well recognized that zinc supplementation reduces diarrhea and pneumonia in children in the developing world. Iron deficiency anemia, common in African women of reproductive age and their infants and young children, has a negative impact on immune function, cognitive development, physical activity and growth.

Patient population. The study population of women receives medical care at the Turbo Rural Health Center, one of the 19 clinics that have been established by the Academic Model Providing Access To Healthcare (AMPATH) program. The United States Agency for International Development (USAID)-AMPATH Partnership operates under the joint direction of Moi Teaching and Referral Hospital and the Moi University and Indiana University Schools of Medicine and cares for over 79,000 HIV-infected adults and children at 19 clinics in rural and urban areas in Kenya. About 50% of AMPATH patients do not yet require treatment with antiretroviral drugs therapy (ART).

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Specific Objectives

Preliminary evidence suggests that improved nutrition early in HIV infection may delay progression to AIDS and delay the initiation or improve the effectiveness of antiretroviral drug therapy. However, there are few studies that evaluate how to optimize food-based interventions in HIV-infected individuals. Evaluations of the role of ASF, which are known to provide nutrients that support maintenance of lean tissue, child growth and development, and immune function, are lacking.

The study's central hypothesis is that drug naïve HIV-infected women and their children in rural Kenya who are provided a meat-containing supplement will have improved nutritional, clinical and functional outcomes, growth and development in children and ability to carry out tasks of daily living in women compared to those given isocaloric supplements with soya and wheat. Researchers plan to test this central hypothesis and accomplish the overall objective by pursuing the following objectives that will provide a comprehensive assessment of the impact of meat supplementation.

Objective 1: Measure the impact of meat supplements on overall health, micronutrient status, body composition and growth in children, and progression of infection in drug naïve HIV-infected Kenyan women and their children in a rural setting in western Kenya.

The hypothesis is that meat in the diet, possibly due to the amounts of lysine and vitamin B12 and the enhanced bio-availability of iron and zinc, results in improved clinical outcomes, weight gain, lean body mass, resistance to opportunistic infections, growth and development in children and ability to carry out normal tasks of daily living in women. This objective will be accomplished by means of a randomized clinical trial in which researchers compare the effect of a meat-based supplement versus isocaloric soya and wheat-based supplements on the above outcomes.

Objective 2: Contribute to improved methodology for monitoring of changes in body composition and strength of HIV-infected women and children in field settings in rural Kenya.

The hypothesis is that accurate estimates of lean body mass and strength in HIV-infected women and children can be easily obtained in field settings in rural Kenya. This objective will be accomplished by comparing bioimpedance analysis (BIA) methodology with arm muscle area calculated from triceps skin fold and mid-arm circumference measures. Additional estimates of body composition will be calculated using skin fold and circumference measures from other body sites incorporated into standardized equations. Reliable measures of anthropometry are labor intensive

and require staff who are specially trained in obtaining these. Therefore, identifying easier methods that are just as reliable, such as BIA, are needed.

Potential outcomes of this research include: (1) a food-based solution utilizing meat supplementation that will improve the overall health and nutritional well being of HIV-infected and affected women and children in rural Kenya and that will also slow declines in CD4 lymphocytes in drug naïve HIV-infected women who are asymptomatic and whose counts are not yet sufficiently low to warrant the initiation of ART, and (2) feasible assessment tools that will accurately monitor changes in body composition and strength in women and children will prove useful for improved patient assessment, care and continued research in rural settings in Kenya.

Methods

Study design. This is a three arm randomized design where 225 HIV-infected rural Kenyan mothers with a CD4 between 400 and 700 and with no coexisting opportunistic and other serious infections receive, with their index child, a nutrition biscuit supplement daily (five days/week) for 18 months. After this phase, the mother and child will then be followed for six months. These women are not yet ill enough to warrant treatment with antiretroviral drugs, and therefore a food intervention may keep them healthy longer and delay the need for drugs. Their children, between the ages of six months to five years, are those who are not infected with HIV and who also are free from opportunistic or other serious infections. Directly observed treatment (DOT) is used to assure adherence and to quantify intake. A DOT field worker delivers the supplement daily and brings any leftovers to a central location for quantification. Women and their children are randomized to receive either biscuits with added beef, added soya flour or wheat flour. The supplement provides:

Women: ~ 540 calories/day - beef, soya and wheat groups and ~ 21 g protein/day (beef and soya groups) and ~ 8 g protein/day (wheat group); the total supplement varies ~ 110 – 120 g/day depending on the product (beef, soya or wheat).

Children 1-5 years: ~ 360 calories/day - beef, soya and wheat groups and ~ 14 g protein/day (beef and soya groups) and ~ 5 g protein/day (wheat group); the total supplement varies ~ 72 – 80 g/day depending on the product (beef, soya or wheat).

Children 0.5-1 year: ~ 180 calories/day - beef, soya and wheat groups and ~ 7 g protein/day (beef and soya groups) and ~ 2.5 g protein/day (wheat group); the total supplement varies ~ 36 - 40 g/day depending on the product (beef, soya or wheat).

Intervention Food. Through continuous collaboration, the research team developed the intervention foods to be basic biscuits made with wheat flour. Dried beef or soya flour is added to the recipe. Boiled water can be added for porridge consistency for young children and those with difficulty chewing. The beef biscuits provide women and children with significantly greater amounts of lysine, vitamin B12, bio-available zinc and iron than those in the soya or wheat groups.

Outcome measures. Repeated measurements of women and children, collected over the course of two years by trained enumerators, include: estimates of lean body mass and muscle strength (women and children older than three years); immune function (CD3/CD4/CD8 lymphocytes); infection/inflammation (c-reactive protein, alpha 1-acid glycoprotein); skin tests for delayed cutaneous hypersensitivity using candida, tubercullin and tetanus skin test antigens; overall health, nutrient, energy and protein intakes (food frequency, 24-hour recall, food security); micronutrient status (iron, zinc, vitamins B12 and A, and selenium); quality of life; usual activity of women; and growth, development and activity of children.

Statistical analysis. Using SAS (Statistical Analysis Software) and other statistical programs researchers will investigate, through longitudinal models, whether the decline in CD4 counts and other longitudinally assessed markers is less steep with one intervention versus the others. Baseline indices of immune function and nutrition status will be used as co-variables. Intervention group, gender in children and age will be used as grouping factors. A multivariate Cox proportional hazards model that is adjusted for relevant factors will test the food group effect on significant morbidity. Inter-household association will be taken into account.

Researchers will fit longitudinal non-linear mixed models to describe the rates of growth and development among children belonging to the intervention program versus all other children. The term "mixed" refers to the fact that investigators will include both population and individual-subject factors in the model definition. For example, each child will be allowed by the statistical model to have its individual rate of growth and its individual starting (baseline) point. This flexibility will allow the model to be much more realistic in reflecting the heterogeneity in the anthropometric and cognitive development data. The population part of the model will consist of factors that affect the entire subject population in the same manner (e.g., treatment group).

Practical Implications

The primary goal of the HIV Nutrition Project is to determine if meat as a component in the diet will protect

the immune system, prevent severe infection and loss of body mass and enhance the quality of life of HIV-infected rural Kenyan women who are not yet experiencing the nutritional and metabolic challenges associated with advanced HIV infection (full blown AIDS), as well as protect the growth and development of their children who are certainly affected and may be infected by HIV.

The findings from this project may have implications for the development of initiatives that are either sustainable and/or subsidized by the local, regional and/or global economies, which ensure that all individuals infected with the human immunodeficiency virus have access to foods providing sufficient quantity and quality of nutrients needed to optimize health and well being. The knowledge gained may significantly impact other populations at high risk for decreased immune function and nutritional status, as found in those with tuberculosis and malaria.

Further Reading

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The GL-CRSP HIV Nutrition Project (HNP) is evaluating the effect of protein quality and micronutrients in meat on the health and nutritional well-being of women living with HIV in rural Kenya and the health and development of their children by means of a randomized nutrition feeding intervention. The project is led by Dr. Judith Ernst, Indiana University. Email: jernst@iupui.edu.



The Global Livestock CRSP is comprised of multidisciplinary, collaborative projects focused on human nutrition, economic growth, environment and policy related to animal agriculture and linked by a global theme of risk in a changing environment. The program is active in East and West Africa, Central Asia and Latin America.

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