

EVALUATING A NUTRITION ASSISTANCE AND EDUCATION
PROGRAM IN THE DOMINICAN REPUBLIC

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ABSTRACT

Introduction: The Dominican Ranks 79th in the world for high rates of under five year mortality at 33 deaths per 1000 live births. The Ninos Primeros en Salud (NPS) in Consuelo, DR has an extensive Nutrition Program for children 0-5 years to address food insecurity and malnutrition with nutrition education, regular weight checks, home visits, micronutrient supplementation and supplemental food packages in an attempt to decrease mortality amount 0-5 year olds.

Objectives: The primary aim of this study was to compare the two groups (nutrition intervention group and healthy reference group) to determine if there were differences in demographic characteristics among children receiving care at NPS. The secondary aim was to evaluate the Nutrition Program at NPS during the first nine months of the program by observing changes in wasting, weight for height z-score (WHZ), weight for age z-score (WAZ) and height for age z-score (HAZ) in children participating in the nutrition intervention program compared to the healthy reference group. The tertiary aim was to determine if there were differences in outcomes of wasting and WAZ in the Nutrition intervention group in relation to household size

Study Design: Observational study with propensity score frequency matching in healthy reference group. Baseline and up to nine months follow up data were examined on all patients being seen at NPS (n=75) consisting of age, weight, height and birth weight.. Baseline and monthly follow up was also collected on patients enrolled in the nutrition program (n=53) with monthly data consisting of weight, height, age and number living in household. All data were de-identified.

Results: The intervention group and healthy reference group differed only in age and birth weight at baseline after matching. The intervention group showed statistically significant improvement in all three areas of weight anthropometric measurements (i.e. wasting, WAZ and WHZ) from pre intervention to post intervention when compared to the healthy reference group. Both the intervention and reference group showed statistically significant decreases in HAZ, with the intervention group showing a decrease in HAZ compared to the healthy reference group. The intervention group also showed significant worsening in measure of stunting over the follow up period. Outcomes measurements of wasting and WAZ did not differ based on household size.

Conclusions: The intervention was successful in increasing the weight of malnourished children. However, it appears that the intervention had no positive effect on increasing linear growth. Further investigation is needed to determine the impact of the nutrition intervention on malnutrition, specifically linear growth.

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CHAPTER 1

INTRODUCTION

Globally, malnutrition is the most important risk factor for illness and death among children, contributing to over fifty percent of all childhood deaths (Blossner & de Onis 2005; Black, Morris & Bryce, 2003). Malnutrition can be defined as either under nutrition or over nutrition (often manifesting as obesity but with poor diet quality), for the purposes of this document malnutrition will include only under nutrition, most often due to a diet that does not provide adequate calories, protein and/or micronutrients for adequate growth (United Nations Children Fund [UNICEF], 2006; Blossner & de Onis, 2005). Malnutrition can manifest in two distinct ways, acute and chronic, often referred to as wasting and stunting, respectively, in the literature. Acute malnutrition is commonly identified when a child presents as underweight; acute malnutrition can be mild, moderate or severe and is directly related to the child's current height compared to their current weight (Waterlow, Buzina, Keller, Lane, Nichaman & Tanner, 1977). Chronic malnutrition occurs when a child is not reaching their height potential due to long term inadequate malnutrition which results in decreased height for age; children who are chronically malnourished can present at a normal weight for height or be of low weight for height (World Health Organization [WHO], 1986).

Over thirty percent of all mortality in children is directly due to malnutrition (Waddell, 2010). The World Health Organization has shown that since 1990 malnutrition rates are falling, most recent worldwide estimates show that children who are underweight has declined from 27% to 18% of children (Waddell, 2010). However, 186 million children worldwide continue to be malnourished (Waddell, 2010; Blossner & de

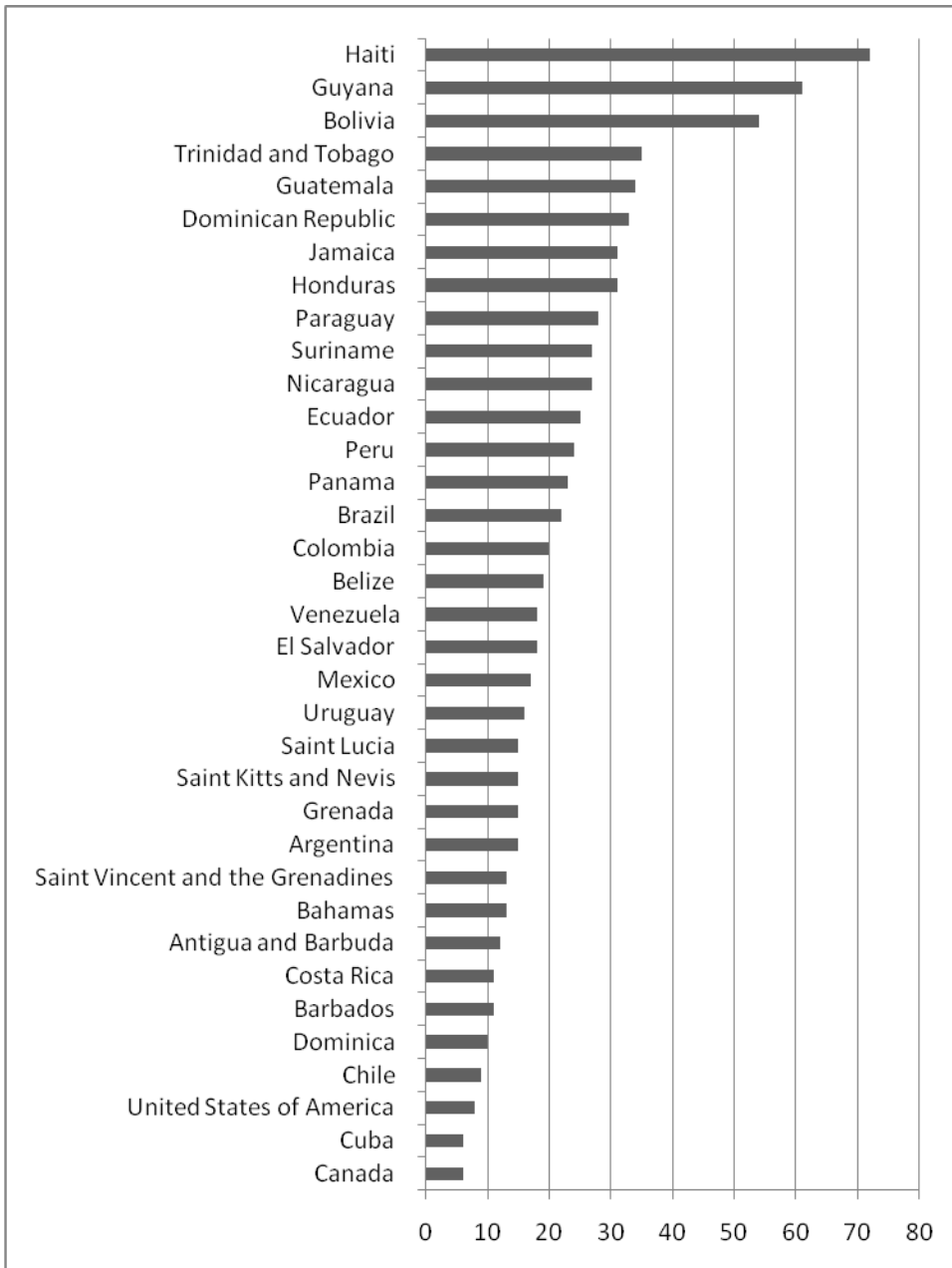
Onis, 2005). Malnutrition is a complex, multifaceted issue where not only is access to high quality food important but living conditions, sanitation, healthcare access, family size and culture are all contributing factors. While malnutrition alone is a leading cause of death, malnutrition is also a risk factor for infectious agents that have high mortality rates among children such as diarrhea, pneumonia, measles and malaria (Caulfield, de Onis, Blossner & Black, 2004).

One of the Millennium Development goals established by United Nations is to reduce the under five years of age mortality by two thirds, the current rate of mortality being 65 per 1000 live births (Sachs, 2005; WHO, 2010). A second Millennium Development goal is to halve the percentage of people who suffer from hunger by 2015, currently 1.2 billion people suffer from hunger worldwide (Sachs, 2005). Both of these goals are dependent on decreasing malnutrition in children. Children under five years are an important target of malnutrition for two reasons. First, they are the most vulnerable group because during these early childhood years, individuals have the highest nutritional requirements than at any other time in life due to the rapid rate of growth and development (Blossner & de Onis, 2005). Second, children under five years are at an increased risk of morbidity and mortality when malnourished compared to older children and adults (Waddell, 2010).

Many Latin American and Caribbean countries rank high in terms of the proportion of malnourished children when compared to other regions in the world (Economic Commission for Latin America and the Caribbean [ECLAC], 2006). Approximately 30% of the Latin American and Caribbean countries are ranked in the bottom half for under-five mortality. While the majority of European and North

American countries rank in the top 75% due their low rates of under five mortality (UNICEF, 2010). For the WHO category Region of the Americas (AMR) the Dominican Republic is in the bottom half for under five mortality at 33 deaths per 1000 live births (WHO, 2010). Table 1 shows the rates of under five mortality for the entire AMR region.

Table 1: WHO Region of the Americas (AMR) Probability of Dying at age 5 per 1000 live births



Adapted from WHO 2010, Part I, Table 2, pg 24.

In the Dominican Republic, 7% of children under age five are underweight and over 18% exhibit chronic malnutrition in the form of stunting (UNICEF, 2010; Waddell, 2010). When these figures are compared to the United States, the burdens of malnutrition in the Dominican Republic are dramatically higher. For example, the United State's rate of under five mortality is only 8 per 1000 live births and has over five times less children under five that are underweight (1.3%) compared to the Dominican Republic (7%) (Waddell, 2010).

The risk factors for malnutrition in children 0-5 years of age often differ depending on location. In Latin America and the Caribbean the following risk factors have been shown to contribute to childhood malnutrition; poor economic situation (poverty), inadequate maternal nutrition and education, low breastfeeding rates, low birth weight and lack of access to potable water (Weisstraub & Ayara, 2008;ECLAC, 2006), (Hobcraft, 1993). First, it has been widely shown that living in poverty, defined as \$2 US dollars per day or less, is a principle cause of malnutrition (World Hunger, 2010; World Bank, 2009). Second, maternal education is also linked directly to increased malnutrition in children, but also to decreased breastfeeding rates, poor maternal nutrition and low birth weight. This demonstrates the multifaceted way one risk factor, maternal education, will contribute to childhood malnutrition in multiple ways (UNICEF, 2008). Third, there is a higher prevalence of malnutrition in children who have never been breastfed when compared to children who have been breastfed (Mahgoub, Nnyepi & Bandeke, 2006). Also, infants who are malnourished and not breast fed are far more likely to die than infants who are not malnourished and not breast fed (Briend, Wojtyniak & Rowland,

1988). Globally, birth weight of an infant can greatly impact the chances of malnutrition during the first five years of life. Infants born at low birth weights (less than 2500 grams at birth) are born malnourished, require additional macronutrients and micronutrients at birth to catch up in growth to their normal birth weight peers. In addition, low birth weight infants experience growth retardation at increased rates (Ramakrishnan, 2003).

The Dominican Republic ranks poorly in most of the described risk factors for childhood malnutrition even when compared to other Latin America and Caribbean countries. Currently the Dominican Republic has 12% of the population living under \$2 per day (World Bank, 2009). Children born to mothers with no formal education in the Dominican are twice as likely to experience chronic malnutrition compared to mothers with some form of secondary education (Hobcraft, 1993). In the Dominican Republic, only 9% of infants are exclusively breastfed to 6 months of age and over 10% of the population is never breastfed, while 33% of infants in the United States are exclusively breastfed to 6 months of age (UNICEF, 2010; McDowell, Wang & Kennedy-Stephenson, 2008). Lastly, 28% of the population in the Dominican does not have access to potable water. Without safe drinking water and sanitation, infectious diseases, especially diarrhea, drastically increase which may lead to a higher prevalence of malnutrition and mortality (UNICEF, 2010; WHO 2000).

The consequences of malnutrition are multiple and range in severity from rashes to death. One of the most importance consequences of malnutrition is that underweight status decreases immunity; this is most often what leads to death in children (Black, Morris & Bryce, 2003). Children who are malnourished are at an increased risk of lowered immunity and have a higher rate of diagnosis of infectious diseases compared to

older populations who are underweight, showing that children's nutritional status has an increased burden on poor health outcomes (Black, et al., 2003). Caulfield showed that not only is malnutrition a direct cause of death in children but that malnutrition causes 60% of the deaths in children from diarrhea, 52% of deaths from pneumonia, 45% deaths from measles and 57% of deaths from malaria. Thus, over one-half of all deaths of children between 0-5 years of age are caused by malnutrition (Caulfield, et al., 2004).

Malnutrition causes several other conditions, other than mortality, that can have lifelong effects on the child. Children who are malnourished show a slow rate of growth in their brain with studies showing that the changes to the brain as a result of malnutrition are similar to those seen among mentally challenged children (Benitez-Bribiesca, De la Rosa-Alvarez & Mansilla-Olvaes, 1999). Also, children who are malnourished exhibit behavioral changes such as irritability, anxiety and unresponsiveness; they have been shown to experience developmental delays, delayed motor skills and permanent cognitive deficits (Blossner & de Onis, 2005; Mendez & Adair, 1999; Heywood, Marshall & Heywood, 1991). The high prevalence, multiple risk factors and severe consequences of acute and chronic malnutrition demonstrate that effective public health programs are needed to reduce the impact of malnutrition, particularly among children aged 0-5 years of age living in areas with high rates of infant mortality.

CHAPTER 2

LITERATURE REVIEW

The reduction of malnutrition in children and the prevention of future cases of malnutrition is a major priority for many countries and Non Government Organizations (NGOs). In particular, one of the Millennium Development Goal is to reduce mortality among children under five by two thirds by 2015 (Sachs, 2005). In order for this goal to be met, interventions and programs aimed at reducing malnutrition in children less than five years of age need to be implemented, continued and evaluated in countries with a high prevalence of malnutrition and in countries at risk of increased rates of malnutrition. Research has shown that community-based programs to address malnutrition are effective, both in cost and outcomes, and are also the choice for most organizations because they allow for greater coverage area and increased sustainability (Deconinck, Swindale, Grant, & Navarro-Colorado, 2008). The International community has developed standards in order for community-based malnutrition reduction programs to be implemented, effective, sustainable and evaluated (CORE Group, 2010). This chapter will review nutrition program outcomes and the public health impact for three main models of pediatric malnutrition intervention programs; nutrition educational based programs, supplemental food based programs, and programs that combine both education and food supplementation. The goals of all programs reviewed are to reduce the prevalence, incidence and severity of malnutrition in children less than five years of age in developing countries.

The CORE Group, along with the United States Agency for International Development (USAID), Save the Children, Academy for Educational Development

(AED) and Food and Nutrition Technical Assistance (FANTA), has developed a guide book to assist in the design, implementation and evaluation of community based programs aimed at reducing childhood malnutrition (2010). The guidelines review key areas that programs should focus on after initial needs assessment data have been collected. These areas include reducing the percentage of children experiencing malnutrition, increasing breastfeeding rates, and decreasing micronutrient deficiencies (CORE, 2010). UNICEF has added to these three key areas an additional five areas including: appropriate, adequate and safe complimentary feeding for infants, addressing maternal nutrition, therapeutic feeding for severe acute malnutrition (SAM), targeting HIV infected individuals, and nutrition and obesity awareness (Schultink & Arabi, 2009). When possible these programs should be coupled with existing policies and services in the country. The CORE Group guidelines review ways for programs to use cross cutting approaches to achieve results. The approaches include services such as; home visits, community health workers, point of service counseling, increasing production and consumption of food, fortifying food and regular growth monitoring and promotion (CORE Group, 2010). Lastly, the group recommends that all programs should have regular monitoring and evaluation for costs, continued feasibility and effectiveness (CORE group, 2010). UNICEF also recommends that benchmarks for nutrition programs should be implemented at the start of the program and evaluated regularly for timeliness and greatest effectiveness (Schultink & Arabi, 2009).

I. Nutrition Education Based Programs

Nutrition Education-based programs are popular programming options due to their low cost and rapid implementation (Christian, 2006). These programs seek to

improve child growth through targeting nutrition education to caregivers, and therefore decrease malnutrition. Most often the education is aimed at mothers or female caregivers and covers the following topic; exclusive breastfeeding, complimentary feeding, feeding during illnesses, food hygiene and sanitation (Christian, 2006). In a meta-analysis of programs using nutrition education it was shown that there is limited outcomes evidence to the effectiveness of such interventions in reducing malnutrition (Ashworth & Ferguson, 2009). In the meta-analysis only a few studies reported outcomes, from the programs that did report outcomes there was wide variance of success from 1.5 to 10 g/kg/day weight gain among children presenting with malnutrition (Ashworth & Ferguson, 2009). Both Bhutta et al. and Harrison reported similar findings, but also added that nutrition education programs have been shown to be effective in improving childhood malnutrition only when implemented in areas with adequate access to food, and are most likely are not effective in populations with food insecurity or other serious constraining factors to accessing adequate and appropriate food (2008, 2010). The combined analysis of nutrition education based programs shows that these type of programs show varying levels of effectiveness and are most likely only effective in decreasing malnutrition in children when implemented in environments with access to adequate food supply.

The Senegal Nutrition Enhancement Project was a randomized control trial that evaluated the effectiveness of nutrition education programs on childhood growth (Alderman et al., 2008). The trial was conducted on children aged 0-3 years who were from the same three villages in Senegal. The children were randomized into two groups, the intervention group received nutrition education on exclusive breastfeeding,

complementary feeding and hygiene behaviors, while the control group continued to receive basic medical services already in place. The study showed that there was a significant improvement in children's weight-for-age z-score (WAZ) in the intervention group ($p = 0.02$) (Alderman et al., 2008). Of note, the intervention group also received vaccinations, deworming medications and Vitamin A supplementation. A similar study is currently underway in Santo Domingo, Dominican Republic (DR) using a Canadian-based parenting education program called Nobody's Perfect (McLennan, Leon, Haffey & Barker, 2009). Similar education material is included in this population and is aimed at reducing malnutrition in children; however no outcomes data are available at this time (McLennan, Leon, Haffey & Barker, 2009).

II. Supplemental Food Based Programs

In addition to nutrition education based programs, supplemental food based programs exist to “prevent or alleviate under nutrition through reducing the gap between actual consumption and requirements” and consist of premade food or food packages intended for a target population in the home (Christian, 2006). Home based food supplementation has been shown to improve micronutrient status and to increase linear growth and height in children aged between 6 and 36 months, therefore decreasing chronic malnutrition and risk of mortality (Harrison, 2010 and Bhutta et al., 2008). A meta-analysis of supplemental food based programs in children in developing countries showed that after five to nine months all of the programs showed significant improvement in children's WAZ (+0.25 to +0.46) and height-for-age-z-score (HAZ) (+0.04 to + 0.35) (Caulfield, Huffman, Piwoz, 1999). In addition, home based supplemental food programs have been shown to be cost effective (Christian, 2006).

It is important to note the recommendations for the food supplied in food supplementation packets for these programs. For children who are malnourished it is optimal to give energy dense food so that less amount of food will lead to greater caloric consumption and therefore weight gains (Michaelson et al., 2009). There should be adequate protein in the food supplementation packages, and if possible, the protein should be of high quality and bioavailability (Golden, 2009). Also, adequate fat or foods containing adequate fat for the target population need to be included, when possible these sources of fat should be of high quality, with good portions of essential fatty acids (Michaelson et al., 2009). It is imperative that the food is culturally acceptable, easy to prepare with equipment that is readily available in the target population, affordable, available in the community and that the food is at a low risk for contamination (Michaelson et al., 2009). Research suggests that if poor quality food is given or if food is not appropriately nutritionally dense that children will not attain catch up growth and that those children experiencing both acute and chronic malnutrition will be at a heightened risk for obesity due to lack of catch up height growth but excess weight gain (Golden, 2009). Table 1 outlines the dietary recommendations for children who are malnourished in further detail.

Table 2: Important characteristics of diets appropriate for children with moderate malnutrition

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| <p>Important characteristics of diets appropriate for children with moderate malnutrition</p> <p>High content of micronutrients, especially growth (type II) nutrients</p> <p>High energy density</p> <p>Adequate protein content</p> <p>High protein quality and availability</p> <p>Adequate fat content</p> <p>Appropriate fat quality, especially n-3/n-6 polyunsaturated fatty acid (PUFA) content</p> <p>Content of some animal-source foods</p> <p>Low content of antinutrients</p> <p>Low risk of contamination</p> <p>Acceptable taste and texture</p> <p>Culturally acceptable</p> <p>Easy to prepare</p> <p>Affordable and available</p> <p>Michaelson et al, 2009, pg S345</p> |
|--|

An important factor to consider when distributing supplemental food packages is the number of people in the household or household size. Research has shown that an increase in household size is a risk factor for children’s nutritional status living in those households (Pelto et al., 1991). Increased house hold size has been seen as risk factor for not only wasting but also for stunting (Shah et al., 2003). Lastly, even when controlling for household income, children living in larger households were more likely to have poorer diet quality, eat less animal protein and experience stunting when compared to smaller household sizes. This suggests that even extra income, in low resource areas, is not enough to protect children from poor nutrition (Pelto et al., 1991). When utilizing supplemental food packages, organizations should be aware that household size play a part in malnutrition and those resources in households are most likely shared among all household members.

The Bateye Outreach program in combination with the Children's Hospital of Philadelphia recently reported an evaluation of their food supplementation program in the DR (Parikh et al., 2010). This nutrition program was integrated through already existing routine primary care mobile clinics in the sugar cane fields (bateyes) surrounding Consuelo, DR and included all participants 18 years of age and younger. Participants who were identified as under nourished (WAZ < -1 SD using WHO criteria) received a food package every two weeks consisting of rice, oatmeal, sardines and dry milk. The analysis showed that there was a statistically significant reduction in both mild and moderate acute malnutrition ($p = 0.004$) and in mild, moderate and severe chronic malnutrition ($p = 0.006$). This study shows that a food based supplementation program, coupled with primary care, can significantly reduce childhood malnutrition in the DR (Parikh et al., 2010).

III. Combination Programs, Nutrition Education and Supplemental Food

a. National Program (WIC)

Education-based programs and food supplementation based programs can both improve nutritional status of children in different populations; however combining the two programs may be an optimal way to increase effectiveness and outcomes. Since its initiation in 1974, the Women, Infants and Children (WIC) program is the largest food supplementation program in the United States, serving 7.5 million women and children in 2002 (Black et al., 2004). WIC serves all income eligible children five years and younger and all pregnant and lactating women. The program consists of three main services; monthly vouchers for foods high in essential nutrients (infant formula, eggs, milk, cheese, cereal, tuna, fruit and vegetables), education on breastfeeding and appropriate infant

feeding practices, and referral services to primary health care for both pregnant women and children (Children's Health Watch, 2009).

To date there have been two major evaluations of the outcomes of the WIC program in the United States. In 1997, Owen & Owen showed several positive outcomes when WIC participants were compared to eligible non WIC participants including; significantly higher mean birth weight, acceleration of growth in weight and height, and significantly decreased rates of anemia in pregnant women, infants and children. More recently in 2006, Black et al., conducted a study using household level surveys and medical record audits over a three year period in six cities across the United States. The five outcomes measured were for infants ≤ 12 months and were WAZ, HAZ, overweight status, caregiver perception of infant's health status and food security of household. There was a statistically significant difference between WIC participants and eligible non-WIC participants in WAZ and HAZ ($p < 0.001$). These effects were also seen when location, race, birth weight, breastfeeding history, age, employment status, education, household subsidies, insurance status and food stamps were included in a multivariate model ($p = 0.008$ and $p = 0.003$). There was no difference in overweight status between the two groups. There was a significance difference between non WIC participants perception of their infant's health status when compared to WIC participants, so that non participants were more likely to rate their infant's health status as poor or fair as opposed to good or excellent for WIC participants ($p = 0.01$). This difference in perception remained significant when adjusted for all previously listed factors ($p = 0.004$). Lastly, non-WIC participants were more likely to be food insecure than WIC participants ($p = 0.0001$) (Black et al., 2006). Both of these evaluations of the WIC program provide

strong evidence to the multiple positive effects on children's health and nutritional status in programs that combine education and food supplementation.

b. International Programs

In the International setting a large scale randomized trial conducted in Haiti evaluated two types of nutrition programs, both with education and food supplementation components (Ruel et al., 2008). The study consisted of two groups, the recuperative group was eligible only in younger (6-23 months) and severely malnourished ($WAZ < -3$) children versus the preventative group that targeted 6-59 month old children who were eligible with $WAZ < -2$. Both groups received monthly nutrition education sessions and monthly food rations. Both groups showed significant improvement in WAZ ($p = 0.003$). An interesting outcome of this study showed that those children in the preventative group showed significantly improved outcomes when compared to the recuperative model ($p = 0.001$). These findings reveal that programs targeting mild to moderate malnourished children ($WAZ < -1$ but > -3) could have improved outcomes and that early targeting of mildly malnourished children is as important as targeting severely malnourished children (Ruel et al., 2008).

In northern Vietnam, the community empowerment and nutrition program (CENP) incorporates growth monitoring of all children under age three, daily nutrition sessions where food is provided the last two weeks of every month (the hearth approach) and educational messages to mothers about "good foods" and optimal caretaking (Schroeder et al., 2002). The program also included deworming every six months for all participants. The CENP intervention was randomly assigned to 12 communes and the differences between children receiving CENP versus those who did not were compared.

The evaluation showed that children less than 15 months of age who were in the CENP group had significantly better growth than those not enrolled, and these effects were strongest in the first six months of the program and lessened to be not statistically significant within three months of program cessation (Schroeder et al., 2002).

One additional study in Madagascar used a similar framework to the one in Vietnam, but did not measure growth outcomes, instead measured other factors known to impact childhood growth (Guyun et al., 2009). This program provided food supplementation to malnourished children, behavior change communication on optimal infant feeding, micronutrient intake and women's dietary practices in the form of events, informal meetings, public health messages and media. After five years there was significant improvement in the initiation of breastfeeding, rate of exclusive breastfeeding until 6 months of age, rate of continuation of breastfeeding to 23 months, rate of children getting recommended amount of meals per day and the rate of iron and Vitamin A supplementation (Guyun et al., 2009). All three studies, Haiti, Vietnam and Madagascar demonstrate the positive effects community based nutrition programs that combine education and food supplementation have on both growth outcomes but also behavior change outcomes in different populations. One concerning note is that positive effects are shown to rapidly decrease back to baseline in as little as three months of program cessation (Schroeder et al., 2002).

IV. Public Health Impact

The International community has placed as much emphasis on implementing programs targeting the MDG of reducing mortality and reducing childhood malnutrition as on making sure that these programs are effective. The CORE group included a final

step in the process of program implementation to include monitoring and evaluation (2010). Also, at the 2009 UNICEF meeting one of the six overarching themes was the need for greater emphasis on monitoring and evaluation of nutrition programs, specifically “filling the gap” of what should be delivered and reach the children and what actually is happening in the field (Schultink & Arabi, 2009). Monitoring and evaluation can have several positive effects that include but are not limited to; assess the quantity, quality and timeliness of project inputs, identify operational constraints and areas of concerns as they arise so that corrective measures can be instituted, determine if project is reaching intended target population, identify effects attributable to project, permit cost-effectiveness comparisons, help to increase community participation, meet donor requirements and lead to informed decisions making about future of programs (Levinson et al., 1999). An example of the impact program monitoring and evaluation can have on the population was seen when the Tamil Nadu Integrated Nutrition Project (TINP) established ongoing monitoring, longitudinal data collection and formal evaluations (Levinson et al., 1999). The group reported that these measures allowed for timely management decisions, real time knowledge of nutritional health of the target population, calculation of costs and impacts, valuable insight on characteristics of dropouts and nonparticipants and to draw conclusions on effectiveness of program in meeting short term goals and make long term impacts (Levinson et al., 1999). Lastly, an important characteristic of nutrition programs is that monitoring and evaluation can most often be incorporated with little to no cost because most data needed are already being collected for the program to function, such as WAZ, HAZ and WHZ (Levinson et al., 1999).

For all of the above mentioned reasons, the Global and International Health Department at the Children's Hospital of Philadelphia released a five year strategic plan for their health programs in the DR that included initiatives and goals that will require ongoing monitoring and evaluation of their programs. The Nutrition component of the programs in the DR have outlined initiatives to provide food supplements to all malnourished children under five years of age, reduce the percent of children with acute malnutrition and for graduates of the nutrition program to maintain normal weight for one year after exiting program. The second most important measurable goal of the entire program is to reduce malnutrition in children under the age of five from a prevalence of 25% in the barrios of Consuelo, DR to less than 5%. (Finalle & Cover, 2010)

The purpose of this study is to determine the effectiveness of the supplemental and educational nutrition program implemented in February, 2010 at the Niños Primeros en Salud (NPS) in Consuelo, DR. The primary aim is to describe the two groups (nutrition intervention group and healthy reference group) to determine if there were differences in demographic characteristics between the groups at baseline. The secondary aim is to evaluate the Nutrition Program at NPS during its first nine months by observing changes in wasting, WHZ, WAZ and HAZ in children participating in program compared to the healthy reference group. The tertiary aim is to determine if in the Nutrition intervention group there were differences in outcomes of wasting and WAZ in relation to household size.

CHAPTER 3

STUDY METHODS

I. Setting

In the Dominican Republic, the City of Consuelo is a small landlocked community 80 miles from Santo Domingo. The population of Consuelo is approximately 30,000 people, with 1600 children under the age of five years. Since November of 2009, the Global and International Health Department at The Children's Hospital of Philadelphia (CHOP) has established a flagship collaborative partnership with the Niños Primeros en Salud (NPS) community health program (in collaboration with the Centro de Salud). The NPS was the first structured and accessible health clinic to provide primary care to the children living in the barrios (neighborhoods) of Consuelo. The barrios are ten small communities in the city of Consuelo. The barrios often lack access to clean water, consistent electricity and sanitation facilities. Each barrio varies in size, make up and extent of poverty. The NPS sees children of all ages living in the barrios for primary care visits, vaccinations and primary health education. At the time of this data collection the NPS was serving 4 of the 10 barrios in Consuelo. In February 2010, an extensive Nutrition Program for children 0-5 years was added to the services provided at NPS. The Nutrition program's goal is to address food insecurity and malnutrition with nutrition education, regular weight checks, home visits, free micronutrient supplementation and supplemental food packages.

II. Study Participants

Children five years of age and younger were included in the study if they received primary health care at NPS from November 1, 2009 to November 30, 2010. Children

from four different barrios in Consuelo were included. The barrios selected for this study were the four barrios receiving primary health care services from the NPS clinic which were Villa Verde, Filiu, Catorce and Port-Au-Prince.

The Nutrition Program was initiated from the Dominican physician's screen. Children between 0-5 years of age qualified for the Nutrition Program if they were classified as having mild, moderate or severe acute malnutrition based on the World Health Organization (WHO). Length and weight measurements were recorded for each child, and nutritional status was classified by both acute and chronic malnutrition. Classification of acute malnutrition, wasting, was based on the 2005 WHO Child Growth Standards where weights-for-height-z-score (WHZ) tables were utilized. Standard deviations (SD) for WHZ on the WHO tables classified each child as normal (> -1 SD), mild (-1 to -2), moderate (-2 to -3) or severe (≤ -3) acute malnutrition. Chronic malnutrition, stunting, was classified using the percentage cut offs for actual height to median height for age and the 2005 WHO Child Growth Charts for 0-2 years, the US CDC 2000 Growth Charts for 2- 5 years of age. Each child was classified as normal ($> 94\%$), mild (90-94%), moderate (85-89%) or severe ($\leq 85\%$). Weight-for-age z-score (WAZ), height-for-age-z-score (HAZ) and WHZ were calculated using the 2005 WHO Child Growth Standards calculator. Once identified to be eligible (having any severity of acute malnutrition) for the program, the malnourished child's name were given to the NPS Nurse who enrolled them in the Nutrition program. Time from identification of acute malnutrition by doctor to receiving first intervention was approximately two weeks.

III. Study Design and Intervention

This study is designed to answer three aims. The primary aim is to describe the two groups (nutrition intervention group and healthy reference group) to determine if there were differences in demographic characteristics between the groups at baseline. The secondary aim is to evaluate the Nutrition Program at NPS during its first nine months by observing changes in wasting, WHZ, WAZ and HAZ in children participating in program compared to the healthy reference group. The tertiary aim is to determine if in the Nutrition intervention group there were differences in outcomes of wasting and WAZ in relation to household size.

An observational study design was used with a retrospective chart review. Both pre-intervention and post intervention measurements were utilized in the four different barrios, along with a reference group of the healthy weight children who were in the same location and setting as intervention group. The healthy reference group were from the same four barrios and were receiving primary care at NPS but were not eligible for the Nutrition Program (intervention) due to healthy weight status. Retrospective clinical data were obtained from the NPS program in Consuelo, DR. All data was de-identified current data. The patients eligible and enrolled in the Nutrition program from NPS clinic (n=57) were examined for outcomes in program using weight and height measurements. Duration in the program varied due to participants being enrolled at varying times from March, 2010 to November 30, 2010. All children not enrolled in the nutrition program (n=400) but being followed at NPS for primary care were used to identify a healthy weight reference group. The healthy weight reference group was randomly chosen from all four barrios (n=78) and used to compare demographic information, birth weight information and changes in anthropometric measurements.

Table 3: Study Design, Inclusion Criteria for Intervention Group and Healthy Reference Group

| Inclusion Criteria | |
|--|--|
| Healthy Reference group | Intervention Group |
| Males or females age 0 to 5 years. | Males or females age 0 to 5 years. |
| Seen for primary care at the NPS clinic at least twice between March, 2010 and November 30, 2010. Present with healthy weight | Seen for Primary care at NPS Clinic Enrolled in Nutrition Program between March, 2010 and November 30, 2010 Present with acute malnutrition using WHO Criteria |
| Have at least two primary care visits with weight and height recorded between March 2010 and November 30, 2010 | Have weight and height recorded within 1 month of enrollment date and every month in program |

a. Intervention Group

All children seen at NPS were screened by the doctor for malnutrition, when identified as malnourished; they were enrolled in the Nutrition program. The nutrition program recipients (intervention group) came in for biweekly weight checks and checkups with the Pediatrician, along with home visits from NPS Nurse monthly. The food packets were distributed monthly and included rice, oatmeal, milk, peanut butter, tuna, corn meal and calcium powder. Recipients received multivitamins, along with regular Vitamin A supplementation. The nursing home visits every month were for nutrition education, reinforcement of nutrition recommendations and to check on

children's health. Each barrio had a designated Health Promoter who worked closely with the NPS and Dominican Nurse. Health Promoters were trained to identify high risk children, report information back to the NPS Nurse, and make home visits. The Health promoters were aware of the children enrolled in the Nutrition program and helped with monitoring, along with the NPS Nurse.

In the Intervention group, pre-intervention/baseline measurements were obtained from March through November 30, 2010 at the primary care visit at NPS one to four weeks before the child enrolled in the Nutrition program. Length of time between pre and post intervention measurements differed, due to some children being enrolled in Nutrition program in March and others not being enrolled in Nutrition program until several months later. The length of time between pre and post intervention was recorded. Demographic characteristics recorded for each patient included gender, birth weight and barrio. The only demographic characteristic recorded at the post intervention was house hold size, due to this characteristic not being available at baseline. Height or length measurements were made using a portable stadiometer and weight measurements were made using hanging or digital scales. All measurements were made by the NPS Nurse, who was trained in anthropometric measuring techniques.

b. Healthy Reference Group

In the healthy reference group, baseline measurements were obtained anytime between March and October, 2010 at their primary care visits at NPS. The healthy reference group was seen at NPS for regular well child checkups every three to six months and for sick visits when needed. In both the intervention group and healthy reference group post intervention measurements were recorded between October and

November 30, 2010. Demographic characteristics recorded for each patient included gender, birth weight and barrio. Height or length measurements were made using a portable stadiometer and weight measurements were made using hanging or digital scales. All measurements were made by the NPS Nurse, who was trained in anthropometric measuring techniques.

IV. Statistical Analysis

The primary aim was to describe the two groups (nutrition intervention group and healthy reference group) to determine if there were differences in demographic characteristics between the groups at baseline. The secondary aim was to evaluate the Nutrition Program at NPS during its first nine months by observing changes in category of wasting, WHZ, WAZ and HAZ in children participating in program compared to the healthy reference group. The tertiary aim was to determine if there are differences in outcomes of wasting and WAZ only in the Nutrition intervention group in relation to household size. All analysis was conducted using SPSS version 18, with the exception of the bootstrapping method used for the secondary aim which was conducted in STATA 11.

a. Propensity Score Matching

Prior to conducting any analysis, propensity score matching was utilized. Since this was a pre-post observational study that was not randomized both groups varied at baseline. In order to correct for this variance, propensity score matching was utilized. First, the covariates of gender, age and barrio were identified. Second, a logistic regression using the causal variable (intervention =1, healthy reference =0) as the dependent variable and the above covariates created the predicted probability variable.

This predicted probability variable was utilized to match each case (intervention group) to the closest control (healthy reference group). Controls that were not matched to a case were not used in any analysis; all analyses were adjusted for propensity score matching on gender, age and barrio.

b. Primary Aim

The primary aim was to describe the two groups (nutrition intervention group and healthy reference group) to determine if there were differences in demographic characteristics between the groups at baseline.

The descriptive statistics were summarized using pre intervention (baseline) and post intervention demographic characteristics for both groups. Means, median, range and standard deviations were calculated for continuous variables (age, birth weight (BW), length of time between pre and post intervention measurements (LOT), WHZ, WAZ, and HAZ) for pre intervention and post intervention in both the intervention and healthy reference group. All continuous demographic variables were tested for normality using the Shapiro-Wilk test and plotting data in a histogram and Q-Q graph. The differences in the two groups for all continuous variables were examined using T-Test analysis (Mann-Whitney U test utilized for variables not normally distributed), p values were reported. Percentages of categorical variables (gender and barrio) were calculated for both groups at pre intervention. Percentages of the categorical variable, for categories of acute malnutrition (wasting) and chronic malnutrition (stunting) for both groups were calculated for both pre intervention and post intervention measurements. Wasting and Stunting variables were reported as yes (wasted or stunted to any degree) or no (no wasting or stunting or healthy weight or height). Differences between the groups by

categorical variables were examined using chi-squared tests and p values were reported. Lastly, the differences between pre intervention and post intervention (change) for WHZ, WAZ and HAZ for both groups were tested for normality using the Shapiro-Wilk test and were plotted for histogram and Q-Q graph of both the variables and the residuals.

c. Secondary Aim

The secondary aim was to evaluate the Nutrition Program at NPS during its first nine months by observing changes in category of wasting, WHZ, WAZ and HAZ in children participating in program compared to the healthy reference group.

This aim was testing the hypothesis that there was a significant difference in outcomes (wasting, WHZ, WAZ and HAZ) between the nutrition intervention group and the healthy reference group; we hypothesized that the nutrition intervention group would have more improvement in these anthropometric measurements over the follow up period compared to the healthy reference group. The first logistic regression model analyzed the change in wasting (Yes or No) for those in the intervention compared to those in the healthy reference group, to observe the differences in mean change over time between the two groups using grouping as the independent variable, adjusting for BW and age. Second, three multivariate linear regression analyses were developed using change in WHZ, WAZ, and HAZ adjusting for BW and age and the bootstrapping method was utilized for variables that were not normally distributed.

d. Tertiary Aim

The tertiary aim was to determine if there are differences in outcomes of wasting and WAZ only in the Nutrition intervention group in relation to household size.

This aim tested the hypothesis that there was a significant difference in outcomes of interest in the nutrition intervention group only, measured by change in wasting and WAZ by household size, we hypothesized that those children in smaller household sizes had improved outcomes compared to those in larger household sizes. For the dichotomous measure of household size, five people per household were utilized due to the mean household size of 5.94. To answer this aim a logistic regression analysis and a multivariate analysis using only the nutrition intervention group was performed. The analysis looked at change in categories of wasting and change in WAZ from pre intervention to post intervention by category of household size, measured continuously and dichotomously (less than or equal to five people in household versus greater than 5 people in household) to examine if household size effected the outcomes of interest. These models adjusted for birth weight, age, gender, barrio and LOT.

CHAPTER 4
STUDY RESULTS

I. Propensity Score Matching

Figure one shows the results of the difference in predicted probability propensity scores between intervention group (Nutrition Program =1) and the healthy reference group (Nutrition Program = 0) prior to matching. Table 4 shows the descriptive statistics of the probability propensity scores for the two groups prior to matching

Figure 1: Frequency of Probability propensity scores by Group before matching

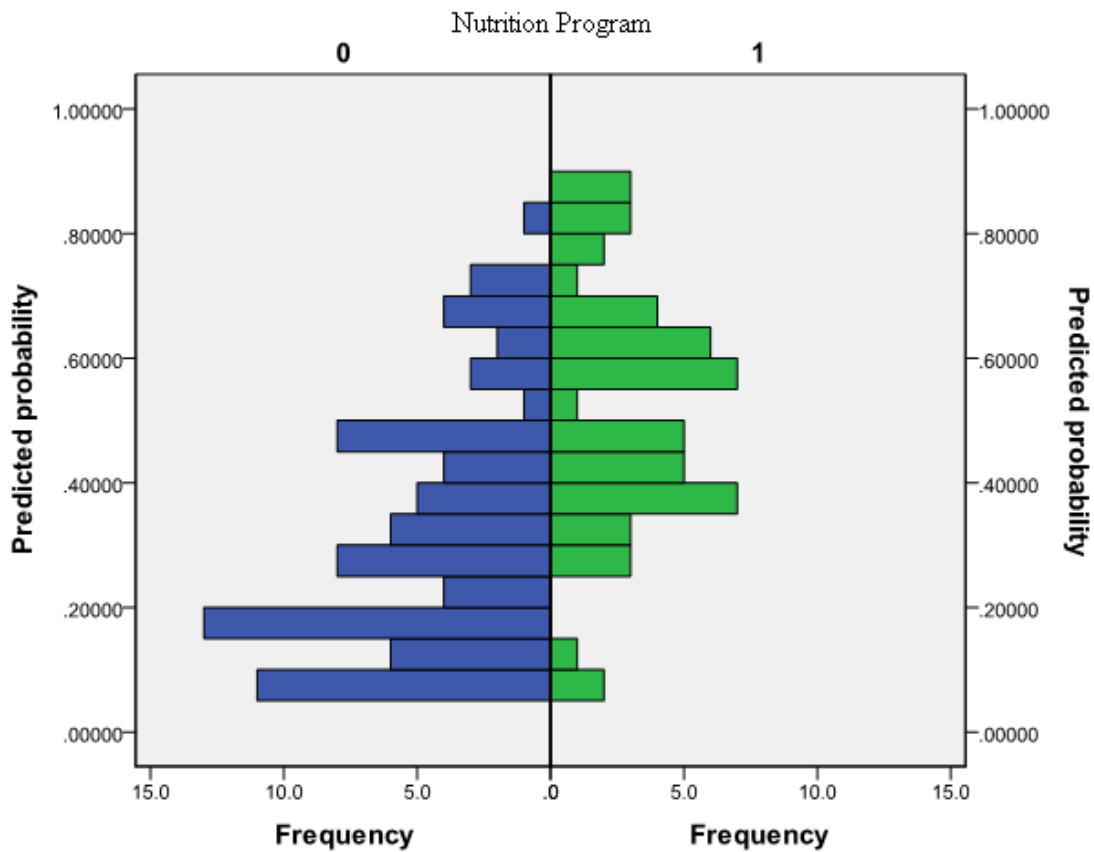


Table 4: Descriptive Statistics of Probability propensity scores by Group before matching

| Group | N | Median | Range | Min | Max | Mean | Std. Dev | Variance |
|-------------------|----|--------|-------|-------|-------|-------|----------|----------|
| Nutrition Program | 53 | 0.532 | 0.795 | 0.082 | 0.877 | 0.521 | 0.197 | 0.039 |
| Healthy Reference | 79 | 0.287 | 0.765 | 0.053 | 0.818 | 0.321 | 0.199 | 0.039 |

Figure two shows the results of the difference in predicted probability propensity scores between intervention group (Nutrition Program =1) and the healthy reference group (Nutrition Program = 0) after matching. Table 5 shows the descriptive statistics of the probability propensity scores for the two groups after matching.

Figure 2: Frequency of Probability propensity scores by Group after matching

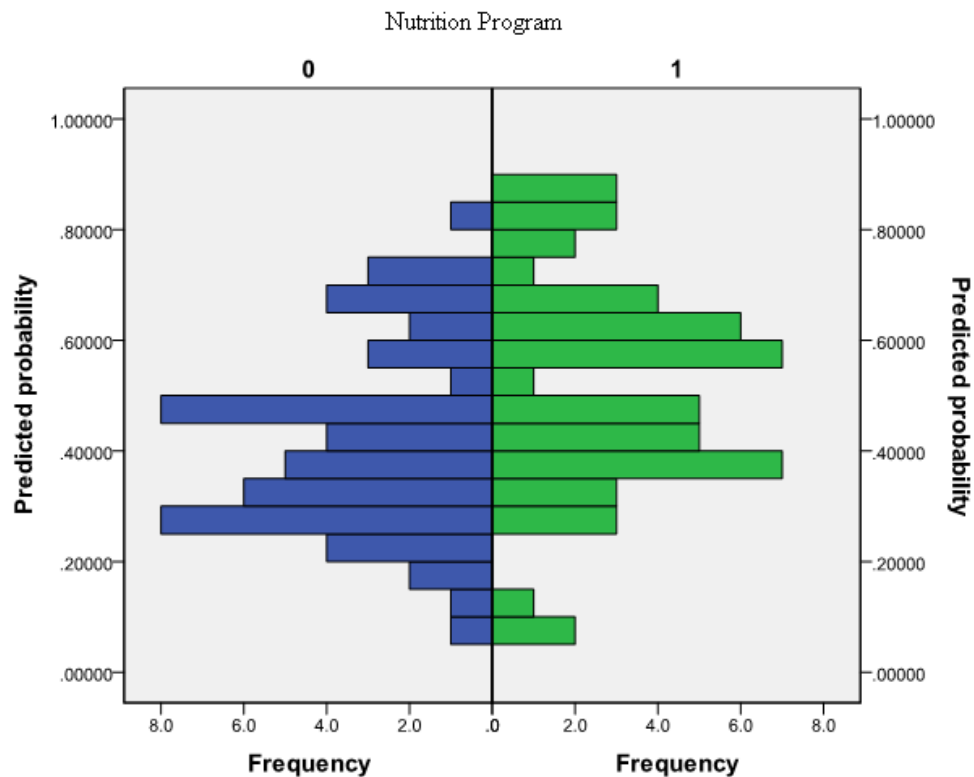


Table 5: Descriptive Statistics of Probability propensity scores by Group after matching

| Group | N | Median | Range | Min | Max | Mean | Std. Dev | Variance |
|-------------------|----|--------|-------|-------|-------|-------|----------|----------|
| Nutrition Program | 53 | 0.532 | 0.795 | 0.082 | 0.877 | 0.521 | 0.197 | 0.039 |
| Healthy Reference | 53 | 0.391 | 0.736 | 0.082 | 0.818 | 0.417 | 0.174 | 0.030 |

II. Test for Normality

Table 6 shows the results of the Shapiro-Wilk test for normality. These results showed that three of the outcome variables, change in WAZ, HAZ and WHZ were not normally distributed ($p < 0.001$).

Table 6: Shapiro-Wilk Normality Test Results for change in Weight for Age Z-score, Height for Age Z-score and Weight for Height Z-score

Shapiro-Wilk Normality Test Results for change in Weight for Age Z-score, Height for Age Z-score and Weight for Height Z-score

| | Shapiro-Wilk | | |
|----------------------------------|--------------|----|------|
| | Statistic | df | Sig. |
| Change Weight for Age Z Score | .895 | 84 | .001 |
| Change Height for Age Z Score | .858 | 84 | .001 |
| Change Weight for Height Z Score | .926 | 84 | .001 |

Table 7 shows the results of the Shapiro-Wilk test for normality for the residuals of the above variables. All variables tested were not normally distributed ($p < 0.001$).

Table 7: Shapiro-Wilk Normality Test Results for Unstandardized Residuals of change in Weight for Age Z-score, Height for Age Z-score and Weight for Height Z-score

Shapiro-Wilk Normality Test Results for Unstandardized Residuals of change in Weight for Age Z-score, Height for Age Z-score and Weight for Height Z-score

| | Shapiro-Wilk | | |
|--|--------------|----|------|
| | Statistic | df | Sig. |
| Unstandardized Residual change Weight for Age Z-score | .913 | 84 | .001 |
| Unstandardized Residual change Height for Age Z-score | .858 | 84 | .001 |
| Unstandardized Residual change Weight for Height Z-score | .937 | 84 | .001 |

III. Primary Aim: Demographic Characteristics

The baseline (pre intervention) measures were calculated using mean, median, mode and standard deviation for the continuous variables of age and household size while percents for categorical data of gender and barrio were calculated. Table 8 shows the baseline demographic variables for both the intervention and the reference group. The intervention group was primarily female (67.9%), from Barrio 1 (60.7%), with a mean age of 2.25 years and a mean household size of 5.94 people per household. The reference group was also primarily female (56.6%), from Barrio 1 (50.9%), with a slightly younger mean age of 1.63 years and no household size data available. The length of time (in months) for the intervention group showed that the average amount of time participants were receiving intervention was 6.12 months. The length of time in the reference group (i.e. the time that elapsed between their first measurement visits to the second measurement visits) was an average of 5.62 months. The length of times were not

significantly different between the two groups ($p = 0.432$). The Intervention group has a mean birth weight of 2.85 kg, which was significantly lower than the mean birth weight of the healthy reference group of 3.2 kg ($p < 0.012$). The only demographic characteristics that remained significantly different between the two groups after propensity score matching was the age ($p = 0.039$) and birth weight ($p = 0.012$).

Table 8: Baseline Demographic Data for Intervention and Reference Group

| Baseline Demographic Data for Intervention and Reference Group | | | | | |
|--|------------------------|-------|---------------------|-------|---------|
| | Intervention (n=53) | | Reference (n=53) | | P Value |
| Age (yrs) | | | | | |
| Mean | | 2.25 | | 1.63 | |
| Median | | 1.9 | | 1.24 | 0.039 |
| Range | | 5.44 | | 4.6 | |
| SD | | 1.62 | | 1.34 | |
| Gender | n | % | n | % | |
| Female | 38 | 67.9 | 30 | 56.6 | |
| Male | 18 | 32.1 | 23 | 43.4 | 0.225 |
| Barrio | n | % | n | % | |
| 1 | 34 | 60.7 | 27 | 50.9 | |
| 2 | 16 | 28.6 | 18 | 34 | |
| 3 | 5 | 8.9 | 6 | 11.3 | |
| 4 | 1 | 1.8 | 2 | 3.8 | 0.738 |
| Household | n= 54 | | | | |
| Mean | | 5.94 | | NA | |
| Median | | 5.5 | | NA | |
| Range | | 10 | | NA | |
| SD | | 2.19 | | NA | |
| ≤5 | 27 | 50% | | NA | |
| >5 | 27 | 50% | | NA | |
| Length of Time (months) | n=51 | | n=45 | | |
| Mean | | 6.12 | | 5.62 | |
| Median | | 6.9 | | 5.16 | 0.432 |
| Range | | 10.48 | | 12.58 | |
| SD | | 2.89 | | 3.16 | |

Table 8, continued

| | | | |
|--------------|------|------|-------|
| Birth Weight | n=43 | n=43 | |
| Mean | 2.85 | 3.2 | |
| Median | 3 | 3.2 | 0.012 |
| Range | 2.9 | 2.9 | |
| SD | 0.63 | 0.59 | |

(Note: Mann Whitney test was utilized for all data that was not normally distributed)

In the nutrition intervention group, pre and post intervention measurements for the children are displayed in Table 9. There was a decrease in children with wasting from 83% at pre intervention to 32% after the nutrition intervention; this was significant ($p < 0.001$). There were similar increases in means of WHZ and WAZ, showing children getting closer to a healthy weight standard deviation during the intervention, both of which were significant ($p < 0.001$). The height growth and chronic wasting (stunting), however, showed the opposite effects. There was an increase in children with stunting from 26.8% at pre intervention to 50% at post intervention, which was significant ($p < 0.001$). This is also shown by the HAZ median decrease from -1.1 to -1.75, which was significant ($p < 0.001$).

Table 9: Intervention Group Pre-Post Anthropometric Measures

| Intervention Group Pre-Post Anthropometric Measures | | | | | |
|---|----------------------------|------|-----------------------------|----|---------|
| | Pre Intervention (n=53) | | Post Intervention (n=50) | | P value |
| | n | % | n | % | |
| Wasting | | | | | |
| No | 9 | 17 | 34 | 68 | |
| Yes | 44 | 83 | 16 | 32 | < 0.001 |
| Stunting | | | | | |
| No | 38 | 67.9 | 25 | 50 | |
| Yes | 15 | 26.8 | 25 | 50 | < 0.001 |

Table 9, continued

| | | | |
|---------------------------|-------|-------|---------|
| Weight for Height Z-score | | | |
| Mean | -1.6 | -0.11 | |
| Median | -1.5 | -0.4 | < 0.001 |
| Range | 7.4 | 5.3 | |
| SD | 1.25 | 1.31 | |
| Weight for Age Z-Score | | | |
| Mean | -1.68 | -1.33 | |
| Median | -1.6 | -1.3 | < 0.001 |
| Range | 4.9 | 5 | |
| SD | 0.97 | 1.14 | |
| Height for Age Z-Score | | | |
| Mean | -1.02 | -1.98 | |
| Median | -1.1 | -1.75 | < 0.001 |
| Range | 5.6 | 8.8 | |
| SD | 1.37 | 1.88 | |

(Note: Mann Whitney test was utilized for all data that was not normally distributed)

In the Reference group, pre and post intervention measurements for the children are displayed in Table 10. There was a decrease in children with acute wasting from 13.2% at baseline to 2.2% at the second measurement; this was significant ($p < 0.024$). There was a similar increase in the WHZ median which was significant ($p < 0.005$). There was a slight increase in WAZ median from 0.11 to 0.21, which was not significant ($p = 0.858$). There was not a significant change in the percent of children stunted (18.9% vs. 22.2%) between baseline and second measurement. However there was a significant decrease in HAZ median from -0.6 to -0.9 ($p < 0.011$).

Table 10: Reference Group Pre-Post Anthropometric Measures

| Reference Group Pre-Post Anthropometric Measures | | | | | |
|--|----------------------------|------|-----------------------------|------|---------|
| | Pre Intervention (n=53) | | Post Intervention (n=45) | | P Value |
| | n | % | n | % | |
| Wasting (n, %) | | | | | |
| No | 46 | 86.8 | 44 | 97.8 | |
| Yes | 7 | 13.2 | 1 | 2.2 | 0.024 |

Table 10, continued

| Stunting (n, %) | n | % | n | % | |
|----------------------------------|----|-------|----|-------|-------|
| No | 43 | 81.1 | 35 | 77.8 | |
| Yes | 10 | 18.9 | 10 | 22.2 | 0.533 |
| Weight for Height Z-score | | | | | |
| Mean | | 0.57 | | 1.25 | |
| Median | | 0.5 | | 1.2 | 0.005 |
| Range | | 5.7 | | 7.4 | |
| SD | | 1.3 | | 1.51 | |
| Weight for Age Z-score | | | | | |
| Mean | | 0.11 | | 0.21 | |
| Median | | 0 | | 0.1 | 0.858 |
| Range | | 4.2 | | 6.5 | |
| SD | | 0.96 | | 1.22 | |
| Height for Age Z-score | | | | | |
| Mean | | -0.59 | | -1.23 | |
| Median | | -0.6 | | -0.9 | 0.011 |
| Range | | 7.6 | | 7.8 | |
| SD | | 1.53 | | 1.54 | |

(Note: Mann Whitney test was utilized for all data that was not normally distributed)

IV. Secondary Aim: Evaluation of Nutrition Program

Table 11 describes the unadjusted change variables in the two groups. There was a significant difference between the intervention group and the reference group in wasting, stunting, WHZ and WAZ ($p < 0.001$, $p < 0.031$, $p < 0.028$ and $p < 0.034$). However, the change in stunting was significantly worse in the nutrition intervention group compared to the healthy reference group, where all other measures (wasting, WAZ, WHZ) were significantly improved in the nutrition intervention group compared to healthy reference group. The only measurement that was not significantly different in the two groups was the change in HAZ, where both of the groups had a similar decrease or worsening over the follow up periods ($p = 0.445$).

Table 11: Change in Anthropometric Measures from pre to post intervention in Intervention and Reference group

| Change in Anthropometric Measures from pre to post intervention in Intervention and Reference group | | | | | |
|---|---------------------------|------|------------------------|-------|---------|
| | Intervention Group (n=50) | | Reference Group (n=45) | | P Value |
| | n | % | n | % | |
| Change in Wasting | | | | | |
| Improved | 28 | 56 | 5 | 11.1 | |
| No change/worse | 22 | 44 | 40 | 88.9 | <0.001 |
| Change in Stunting | | | | | |
| Improved | 0 | 0 | 4 | 8.9 | |
| No change/worse | 50 | 100 | 41 | 91.1 | 0.031 |
| Change in Weight for Height Z-score | | | | | |
| Mean | | 1.48 | | 0.69 | |
| Median | | 1.05 | | 0.4 | 0.028 |
| Range | | 8 | | 6.7 | |
| SD | | 1.9 | | 1.58 | |
| Change in Weight for Age Z-score | | | | | |
| Mean | | 0.35 | | 0.02 | |
| Median | | 0.4 | | 0.1 | 0.034 |
| Range | | 3.5 | | 5.3 | |
| SD | | 0.62 | | 0.83 | |
| Change in Height for Age Z-score | | | | | |
| Mean | | -1 | | -0.76 | |
| Median | | -0.4 | | -0.2 | 0.445 |
| Range | | 8.3 | | 9.2 | |
| SD | | 1.9 | | 1.94 | |

(Note: Mann Whitney test was utilized for all data that was not normally distributed)

a. Change in Wasting – Logistic Regression

A logistic regression was performed for change in Wasting for those in the intervention compared to those in the healthy reference group; these results are shown in Table 12. This analysis showed there was a log-odds increase of 2.36 in change for wasting among those in the Nutrition program compared to the healthy reference group, this was statistically significant ($p < 0.001$, 95% CI 3.15 to 35.25). The second logistic

regression model adjusted for age and birth weight. This analysis showed there was a log-odds increase of 2.64 in change in wasting for those in the Nutrition program compared to the healthy reference group, this was also statistically significant ($p < 0.001$, 95% CI 3.78 to 51.48).

Table 12: Logistic Regression Output for change in Wasting by Intervention

Category

Logistic Regression Output for change in Wasting by Intervention Category

| | B | S.E. | Wald | df | Sig. | Exp(B) | 95% Confidence Interval | |
|---------------------------------------|--------|-------|--------|----|------|--------|-------------------------|--------|
| | | | | | | | Lower | Upper |
| Step 1 ^a Nutrition Program | 2.636 | .666 | 15.661 | 1 | .001 | 13.954 | 3.782 | 51.481 |
| Age | -.334 | .201 | 2.763 | 1 | .096 | .716 | .483 | 1.062 |
| Birth Weight | .104 | .449 | .053 | 1 | .818 | 1.109 | .460 | 2.675 |
| Constant | -2.017 | 1.510 | 1.785 | 1 | .182 | .133 | | |

(Adjusted for birth weight and age)

b. Change in WAZ

A regression analysis was performed to examine the change in WAZ for those in the intervention compared to those in the healthy reference group; results shown in Table 103. This analysis showed there was a 0.4 increase in change in WAZ for those in the Nutrition program compared to the healthy reference group, adjusting for age and birth weight; this was statistically significant ($p < 0.045$, 95% CI 0.009 to 0.796). This large of a difference between groups is clinically meaningful.

Table 13: Regression analysis output of change in Weight for Age Z-score by Intervention Category using Bootstrap

| Regression analysis output of cWAZ-score by Intervention Category using Bootstrap | | | | | | |
|---|----------------------|----------------------|-------|-------|-------------------------|-------|
| | Observed Coefficient | Bootstrap Std. Error | Z | P> z | 95% Confidence Interval | |
| Nutrition Program | 0.403 | 0.201 | 2.01 | 0.045 | 0.009 | 0.796 |
| Birth Weight | 0.176 | 0.102 | 1.73 | 0.084 | -0.023 | 0.376 |
| Age | 0.018 | 0.065 | 0.28 | 0.780 | -0.109 | 0.145 |
| Constant | -0.637 | 0.355 | -1.80 | 0.073 | -1.331 | 0.058 |

cWAZ = change in weight for age z score
(Adjusted for age and birth weight)

c. Change in HAZ

A regression analysis was performed for change in HAZ for those in the intervention compared to those in the healthy reference group; results shown in Table 14. This analysis showed there was a 0.881 decrease in change in HAZ for those in the Nutrition program compared to the healthy reference group, adjusting for age and birth weight; this was statistically significant ($p < 0.041$, 95% CI -1.73 to -0.36).

Table 14: Regression analysis output of change in Height for Age Z-score by Intervention Category using Bootstrap

| Regression analysis output of cHAZ-score by Intervention Category using Bootstrap | | | | | | |
|---|----------------------|----------------------|-------|-------|-------------------------|--------|
| | Observed Coefficient | Bootstrap Std. Error | Z | P> z | 95% Confidence Interval | |
| Nutrition Program | -0.881 | 0.431 | -2.04 | 0.041 | -1.726 | -0.036 |
| Birth Weight | 0.270 | 0.323 | 0.84 | 0.403 | -0.363 | 0.904 |
| Age | 0.659 | 0.153 | 4.31 | 0.001 | 0.359 | 0.1959 |
| Constant | -2.37 | 1.07 | -2.21 | 0.027 | -4.476 | -0.272 |

cHAZ = change in height for age z score
(Adjusted for age and birth weight)

d. Change in WHZ

A regression analysis was performed for change in WHZ among those in the intervention compared to those in the healthy reference group; results are shown in Table 15. This analysis showed there was a 1.4 increase in change in WHZ for those in the Nutrition program compared to the healthy reference group, adjusting for age and birth weight; this was statistically significant ($p < 0.001$, 95% CI 0.614 to 2.16).

Table 15: Regression analysis output of change in Weight for Height Z-score by Intervention Category using Bootstrap

| Regression analysis output of cWHZ-score by Intervention Category using Bootstrap | | | | | | |
|---|----------------------|----------------------|-------|-------|-------------------------|--------|
| | Observed Coefficient | Bootstrap Std. Error | Z | P> z | 95% Confidence Interval | |
| Nutrition Program | 1.389 | 0.395 | 3.51 | 0.001 | 0.614 | 2.163 |
| Birth Weight | -0.79 | 0.279 | -0.28 | 0.778 | -0.626 | 0.469 |
| Age | -0.616 | 0.139 | -4.43 | 0.001 | -0.889 | -0.343 |
| Constant | 1.632 | 0.902 | 1.81 | 0.070 | -0.135 | 3.400 |

cWHZ = change in weight for height z score
(Adjusted for age and birth weight)

V. Tertiary Aim: Evaluation of Household Size in Intervention Group

Household size was measured in two ways, first as a continuous variable and second as a categorical variable of less than or equal to 5 people living in the household. This variable was only available in the Nutrition intervention group so all analysis was conducted using only the intervention group.

a. Change in Wasting by Household size

Household size, as a continuous variable, was used in logistic regression with change in wasting (1 = improved, 0 = did not improve) as the outcome variable. The results showed that unadjusted change in wasting by household size was not statistically significant ($p = 0.926$) and when adjusting for age, birth weight, gender, location and length of time in the nutrition program the results continued to be not statistically significant ($p = 0.796$). Results from analysis are shown in Table 16.

**Table 16: Logistic Regression Output Change in Wasting by Household Size
(continuous)**

Logistic Regression Output for Change in Wasting for Household Size (continuous)

| Model | B | Significance | Exp(B) | 95% Confidence Interval | |
|-------|----------------------|--------------|--------|-------------------------|-------|
| | | | | Lower | Upper |
| 1 | | | | | |
| | Household | .926 | .986 | .725 | 1.341 |
| | Constant | .653 | 1.569 | | |
| 2 | | | | | |
| | Household | .796 | 1.051 | .720 | 1.535 |
| | Age | .166 | .717 | .448 | 1.148 |
| | Birth Weight | .800 | 1.182 | .324 | 4.315 |
| | Female | .342 | .425 | .073 | 2.480 |
| | Barrio (location) | .300 | .475 | .117 | 1.938 |
| | Length Of Time | .256 | .851 | .645 | 1.124 |
| | Constant | .278 | 20.174 | | |

Household size, as a dichotomous variable, was utilized to run a logistic regression with change in wasting (1 = improved, 0 = did not improve). The results showed that change in wasting category by household size in both unadjusted and

adjusting for age, birth weight, gender, location and length of time in program were not statistically significant ($p = 0.246$ and $p = 0.711$), see Table 17.

**Table 17: Logistic Regression Output Change in Wasting by Household Size
(category)**

Logistic Regression Output for Change in Wasting for Household size (category)

| | B | S.E. | Significance | Exp(B) | 95% Confidence Interval | |
|----------------------|-------|-------|--------------|--------|-------------------------|-------|
| | | | | | Lower | Upper |
| 1 Household category | -.773 | .666 | .246 | .462 | .125 | 1.703 |
| Constant | .773 | .494 | .117 | 2.167 | | |
| 2 Household | -.311 | .838 | .711 | .733 | .142 | 3.789 |
| Age | -.310 | .245 | .207 | .734 | .454 | 1.187 |
| Birth Weight | .336 | .672 | .618 | 1.399 | .375 | 5.223 |
| Female | -.738 | .908 | .417 | .478 | .081 | 2.835 |
| Barrio (location) | -.594 | .720 | .410 | .552 | .135 | 2.265 |
| Length Of Time | -.146 | .144 | .311 | .864 | .652 | 1.146 |
| Constant | 2.545 | 3.008 | .398 | 12.738 | | |

b. Change in WAZ by Household size

Household size, as a continuous variable, was included in the linear regression model predicting change in WAZ. The unadjusted results showed that change in WAZ by household size was not statistically significant ($p = 0.683$). The model adjusting for age, birth weight, gender, location and length of time in program the results continued to be not statistically significant ($p = 0.381$), see Table 18.

Table 18: Linear Regression Output Change in Weight for Age Z score by Household Size (continuous)

Linear Regression Output for Change in Weight for Age Z score for Household Size (cont.)

| Model | | Unstandardized Coefficients | Standardized Coefficients | | 95.0% Confidence Interval for B | |
|-------|--------------|-----------------------------|---------------------------|------|---------------------------------|-------------|
| | | B | Beta | Sig. | Lower Bound | Upper Bound |
| 1 | (Constant) | .466 | | .119 | -.126 | 1.058 |
| | Household | -.019 | -.067 | .683 | -.113 | .075 |
| 2 | (Constant) | -.154 | | .825 | -1.560 | 1.252 |
| | Household | -.043 | -.152 | .381 | -.142 | .056 |
| | Age | .050 | .130 | .415 | -.073 | .173 |
| | Birth Weight | .355 | .381 | .043 | .012 | .699 |
| | Female | -.065 | -.050 | .764 | -.502 | .372 |
| | Barrio | .016 | .018 | .927 | -.348 | .381 |
| | Total Months | -.054 | -.269 | .141 | -.127 | .019 |

a. Dependent Variable: Change in Weight for Age Z-score

Household size, as a dichotomous variable, was included in the linear regression model predicting change in WAZ. The unadjusted results showed that change in WAZ by household size was not statistically different, so that those children in the intervention group and living in households of 6 or more people had a similar in change of WAZ ($p = 0.659$). When adjusting for age, birth weight, gender, location and length of time in the nutrition program in the model, it continued to be not statistically significant ($p = 0.446$).

Table 19: Logistic Regression Output change in Weight for Age Z score by Household Size (category)

Linear Regression Output for Change in Weight for Age Z score for Household Category

| Model | | Unstandardized Coefficients | Standardized Coefficients | Sig. | 95.0% Confidence Interval for B | |
|-------|--------------|-----------------------------|---------------------------|------|---------------------------------|-------------|
| | | B | Beta | | Lower Bound | Upper Bound |
| 1 | (Constant) | .395 | | .006 | .122 | .668 |
| | Household | -.085 | -.072 | .659 | -.472 | .302 |
| 2 | (Constant) | -.336 | | .658 | -1.868 | 1.196 |
| | Household | -.164 | -.139 | .446 | -.597 | .269 |
| | Age | .059 | .155 | .345 | -.067 | .185 |
| | Birth Weight | .349 | .375 | .048 | .003 | .695 |
| | Female | -.052 | -.041 | .812 | -.499 | .394 |
| | Barrio | .005 | .005 | .978 | -.357 | .367 |
| | Total Months | -.052 | -.259 | .166 | -.126 | .023 |

a. Dependent Variable: Change in Weight of Age Z-score

CHAPTER 5

CONCLUSION

The results show several important outcomes of the Nutrition Program at the NPS clinic.

I. Propensity Score matching

Prior to the propensity score matching, the groups were significantly different in all demographic variables. However after matching, only age and birth weight remained significantly different (Table 8), with the nutrition intervention group being significantly older. Also, the groups' distribution of predicted probability propensity score was more similar after matching, as visually demonstrated in Figure 1 and Figure 2 as well as shown by the mean and median in Table 4 and 5. While it would have been helpful to have had addressed variables be matched to reduce the differences the matching was useful, specifically since the two groups differed so drastically prior to matching. However, this matching does not eliminate the bias seen by having groups differ at baseline by anthropometric factors and this limitation will be discussed in further in the limitation section.

II. Primary Aim

In the intervention group, measurements of weight (wasting, WAZ and WHZ) were all significantly improved from baseline to post intervention measures (Table 9). This shows that the nutrition intervention was successful in increasing the weight of malnourished children. However, what are most concerning are the pre and post intervention measurements in the two height measurements, stunting and HAZ. Both of these measurements showed significant worsening over the intervention period, where

the percent of children with stunting doubled from 25% to 50% and the HAZ also became almost two times worse over the 9 month time period. What these preliminary results indicate is that the nutrition intervention was clinically significantly successful in adding weight to children but was unsuccessful in increasing or maintaining age appropriate linear growth. One explanation for these results is that the children were getting adequate calories but not nutrient dense calories, specifically high quality protein and fat. When low protein quality, high carbohydrate diets are eaten often weight will increase but height growth will not (Golden, 2009; Briend & Prinzo, 2009). The nutritional supplements given to the patients were high in carbohydrates (rice, oatmeal and cornmeal) and extremely low in animal protein sources (sardines or tuna), which is not uncommon in such packets due to the cost of animal protein.

In the healthy reference group, the only two factors that significantly differed from baseline to second measurement were WHZ and HAZ (Table 10). As expected, the measures of malnutrition of stunting and WAZ were not significantly different overtime, showing that the reference group children did not gain weight beyond their age appropriate standards or the expected weight gain standards for healthy children. However, this group showed a worsening in height parameters, HAZ, so that in the approximately 5-6 months between measurements, HAZ decreased by two times from -0.6 to -1.2, which is very similar to the decrease in HAZ seen in the intervention group. This indicates that even children with no intervention were showing a decrease in linear growth. This decrease was most likely not seen in the stunting variable because the group was healthier, and taller, at baseline and would have had to demonstrate a more extreme decrease in height to move into the category of stunted. The significant increase seen in

WHZ and wasting can be contributed to the HAZ decrease. When their age standard height decreased this showed a superficial increase in weight for height and the wasting but not because weight was increasing more because HAZ linear growth was failed to progress. For example, if a child is gaining standard age appropriate weight but is not gaining standard, age appropriate height this will cause their WHZ and their category of wasting to show improvement, but this improvement will be because of a failure to maintain or gain standard, age appropriate height, not due to catch up weight gain.

III. Secondary Aim

The unadjusted change in anthropometric measurements seen in Table 11 further shows the improvement in weight measurements for the intervention group and the worsening of height measurements in both groups. All three of the measurements for weight (Wasting, WAZ and WHZ) indicated that the intervention group had a significant improvement over time compared to the healthy reference group. The change in stunting is important to examine because it showed that in the intervention group not one of the children showed improvement in stunting, and this was significantly worse when compared to the healthy reference group. Also, because in the intervention group there were no children that improved in stunting, that variable could not be examined in any logistic regression analyses. The lack of improvement in stunting likely suggests the children did not receive adequate high biological value protein and fat. The only change in anthropometric measurement that was not significantly different between the two groups was HAZ, as discussed before; this further demonstrates that both groups experienced similarly worsening in HAZ over time.

In the adjusted regression analysis, similar results were demonstrated, measures of wasting, weight for age and weight for height, among children enrolled in the nutrition program showed significant improvement overtime and showed significant improvement when compared to healthy reference group living in the same location. The unadjusted and adjusted models yielded very similar results, showing that age and birth weight were did not significantly confound the results. The results for the change in measure of height (HAZ) showed a significant difference between the two groups and indicated that those in the intervention group experienced a significant decrease in change in HAZ over the follow up period compared to the referent group. These results point to two important conclusions concerning the efficacy of the nutrition intervention. First, the nutrition intervention did help to increase malnourished children's weight so that these children became closer to the age appropriate weight and healthy weight for height parameters. Also, children in the reference group did not show the same amount of weight gain as those in the intervention group, further strengthening the hypothesis that the weight gain was due to the intervention. Second, while weight gain was improved, linear growth significantly worsened for both groups, and worsened more in the intervention group over time. This indicates that while the intervention helped children gain weight, the nutrition program did not improve linear growth; these children just increased their weight for height but not closer to age appropriate parameters for growth.

IV. Tertiary Aim

The linear regressions examining the effect of household size on weight and height parameters among the children participating in the intervention showed that household size was not related to the outcomes of weight or height measurements among children in

the nutrition program. One hypothesis was that the food distributed as part of the nutrition intervention was not consumed by the malnourished child but the provided food was consumed by the entire household; thus leading to malnourished children living in larger households taking longer to show improvements in weight since they were not getting as much of the intervention, or food, as children living in smaller households. However, there was no evidence that household size effected the change in wasting or change in WAZ observed among the intervention group. It could be that in order to see this effect a larger cut off of household size (greater than 5 people per household) would need to be chosen and that the effect of larger households is not seen among 5 person households but may exist for much larger household sizes. Another theory is that only the number of children in the household effect the distribution of goods, so that if there were a larger number of children, no necessarily just a large number of people, in the house hold that results would be significant. Future studies should consider looking only at number of children living in household or use a larger cut off point.

V. Limitations

The study has several limitations, most related to the group assignments and the bias that was introduced with non-randomized control studies. There was significant selection bias due to study design. For example, children in the intervention group presented malnourished to clinic visits and the healthy reference groups were not malnourished at any point during the intervention period. This led to the two groups differing drastically at baseline by age, gender, location and this selection bias can lead to distorted results. However, it is neither feasible nor ethical to conduct a randomized

clinical trial in this population of malnourished children and so an observational study was the most plausible design available.

In an attempt to reduce the selection bias, propensity score matching was utilized. However, propensity scores do not eliminate selection bias and work best in large samples. Also, propensity score matching cannot measure or reduce unmeasured confounders or hidden bias, which can be numerous in a study of this design. The propensity score matching did reduce the population, so that twenty six of the cases with lower propensity scores (or those participants who differed the most in age, gender and location from the intervention group) were not included in analysis. This reduced the generalizability of the study findings to the larger population but increased internal validity

In this study, the intervention group was below the average standard deviation for all measures of malnutrition at baseline. Due to these pre-intervention levels, regression towards the mean is a major concern. This affects the internal validity of the study and can lead to the conclusion that the weight increase seen in the intervention group is due to the treatment when in fact it is due to chance. Whenever a group starts out statistically lower than the average, with the goal of getting closer to the average, the statistical results can show a larger than actual improvement simply due to regression towards the mean and not as a result of the actual intervention. This effect could have contributed to the large improvement in weight (WAZ, WHZ and wasting) seen in the intervention group.

Lastly, there is concern of measurement bias due to measurement error. All of the measurements to assess outcomes and categorize baseline and post intervention status

were collected in the clinic setting. Measures of weight and height can be especially difficult in young children and infants since lack of movement during measurement and cooperation from not only the children and nurse measuring but also the parent is needed. Height measurement can be of particular concern and are one of the more difficult measures to obtain reliably. Obtaining measurements of malnutrition are dependent on the anthropometric skills of person(s) obtaining them. Specifically when these measurements are obtained in clinical settings where employees are over worked and expected to multitask frequently, the accuracy of the measurements can be compromised. Therefore, it is imperative that all measurements be obtained by highly qualified and trained individuals that understand the importance of accurate and reliable measures. The intervention group was measured every two weeks, while the healthy reference group was only measured at baseline and final time point. This increase in measurement error could occur in the intervention group relative to the healthy reference group, which could explain the differences seen and exaggerate the effects of the intervention. Specifically it would be advisable to show reliability of measurements at time of measuring to ensure accuracy. This could be accomplished by conducting a retraining of all healthcare workers who will be taking heights of young children. After the training, the healthcare workers could demonstrate their ability to obtain reliable measures by measuring children and then having another trained staff member measure the same child. The measurements should be equivalent, if they were not, further training should be given.

While this is an observation study and cause and effect cannot be determined, comparing the nutrition intervention group to the healthy reference groups, with propensity score matching, strengthens the power of the study findings. However,

observational studies provide weaker evidence than experimental study designs and should be used only as preliminary evidence, not as proof of a causal relationship between anthropometric measurement changes due to the nutrition intervention program.

CHAPTER 6

DISCUSSION

Obesity has become a concern around the world; however obesity is not usually a health topic studied in developing nations. However, as shown in this study, if a nutrition intervention increases weight but does not increase linear growth the intervention is at risk of causing an increase in obesity. As discussed earlier, if food is not nutrient dense, children will be at an increase their risk for obesity due to lack of catch up height with corresponding excess weight gain (Golden, 2009). Linear growth is known to be slightly more complex and slower to improve and increase than weight measurements, because linear growth needs a specific set of macronutrients and micronutrients while weight often just needs calories, of any composition to increase (Michaelson et al, 2009). For this reason, it is important to carefully examine not only the amount of food distributed in nutrition packets but also the quality of that food to prevent further health consequences in the form of obesity.

This nutrition intervention program showed that in this particular population, nutrition supplementation and education as part of a primary care center is successful in increasing weight in malnourished infants and children under the age of five years. However, further research is needed to determine if these results can be repeated and generalized to other populations. Also further research regarding the interventions impact on linear growth needs to be conducted. Recommendations for improving height outcomes include increasing the amount of high quality protein and high quality fatty acid, ensuring there is adequate amounts of micronutrients and minerals and decreasing low nutrient dense, high fiber foods (Golden, 2009).

Lastly, the largest public health value is to not only assess child growth but to follow up with policy action to improve the health and nutritional status of children. Policy actions are likely to have the greatest impact on child malnutrition if they are directed at the early stages of child development, a time of rapid growth, as discussed in chapter two. Some examples of policies are to increase access and affordability of adequate and high quality food by food fortification or improved access to land for agriculture; preventative programs that address parental education aimed at healthy feeding habits during the complimentary feeding (0-2 years) and breastfeeding and provide accessible primary care to all children (ECLAC, 2006). Nutrition interventions that improve growth of children will help to decrease the prevalence of malnutrition, while also preventing the negative functional consequences of malnutrition throughout life. Therefore, enacting programs that reduce malnutrition not only benefit the child's health and development in the short term, they can also promote future, long-term growth and improve health for the lifetime.

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APPENDIX A
IRB PROTOCOL



Office for Human Subjects Protections
Institutional Review Board
Medical Intervention Committees A1 & A2
Social and Behavioral Committee B

3400 North Broad Street
Philadelphia, Pennsylvania 19140
Phone: 215.707.3390 Fax: 215.707.8387
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MEMORANDUM

To: **NELSON, DEBORAH B**
CHP-PUBLIC HEALTH (0910)

From: Richard C. Throm
Director, Office for Human Subjects Protection
Institutional Review Board Coordinator

Date: 17-Feb-2011
Re: Exempt Request Status for IRB Protocol:

13724: Evaluating a Nutrition Assistance and Education Program in the Dominican Republic

It has been determined by Expedited Review that this study qualifies for exemption status as follows:

45 CFR 46 Protection of Human Subjects

Section 101 (b): Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

Exemption 4: Collection or Study of Existing Data. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.

Nothing further is required from you at this time; however, if anything in your research design should change, you must notify the Institutional Review Board immediately.

If you should have any questions, please feel free to contact me at 215-707-8757.

Thank you for keeping the IRB informed of your clinical research.