2016

The Effectiveness of Quality Protein Maize (QPM) on Chronic Malnutrition in the Southern Coast of Guatemala

REPORT

SEMILLA NUEVA

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Semilla Nueva is a non-profit organization that was founded in 2010 to help rural Guatemalan farmers find a path to better nutrition, lasting food security, and prosperity through more nutritious seeds.

FINANCIAL CONTRIBUTERS AND PARTNERS

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Acknowledgements

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Executive summary

The world-wide prevalence of childhood malnutrition is at an overwhelming high, as chronic undernutrition, or stunting, affects 161 million children under five (Onis, Blossner, & Borghi, 2011). Nutritional deprivation during early childhood development has been shown to cause permanent intellectual and physical stunting, leading to increased mortality rates and susceptibility to disease, reduced intellectual capacity, poorer school performance, and diminished income-earning capacity (Walker, 2007; Hoddinott, 2013). The consequences of malnutrition can be fatal to an affected individual and devastating to a society's economic and social development.

Guatemala has the fourth highest rate of chronic malnutrition in the world (Fiezer, 2013). A recent UNICEF study found that chronic malnutrition costs Guatemala about $8.4 million each day in reduced productivity, hospitalization, student failure, and repetition in the first three years of primary school. Taken together, the impact of malnutrition on the interrelated problems of poverty, health, and social cohesion makes it a key barrier in the development of a post-civil war Guatemala, and one of the highest priorities for the Guatemalan government, civil society, and international development organizations.

Particularly in rural areas, high rates of malnutrition can be partially attributed to diets that are centered on one staple crop. In Guatemala, maize supplies the majority of the caloric intake in a typical rural diet, but lacks the complete protein content and micronutrients to support healthy growth during a child’s first 1000 days (Immink & Alarcon, 1992; Stansbury, 2011). To achieve sufficient quantities of essential amino acids, diets primarily dependent on maize must be supplemented with legumes or animal protein, which are expensive, inaccessible or not prioritized by most families (Pellett & Ghosh, 2004).

Biofortification, defined as the improvement of the nutritional quality of food crops by using conventional plant breeding, agronomic management techniques (i.e. fertilizer application), or genetic engineering (Nestel, Bouis, Meenakshi & Pfeiffer, 2006), can be considered as a strategy to remedy soaring malnutrition rates, especially in parts of the world where access to animal products and other non-staple foods is not economically feasible. In the case of Guatemala, the higher nutritional deficiencies are protein, iron and zinc, especially due to a diet strongly dependent on maize. Therefore, the introduction of biofortified maize with higher protein quality (higher lysine and tryptophan content, two essential amino acids required by monogastric animals), also known as Quality Protein Maize (QPM), has been promoted as a good option to overcome malnutrition in the country, especially in rural areas where maize is the staple food. Semilla Nueva, convinced of the potential of biofortification and specifically of QPM in the improvement of nutritional status of Guatemalans, works to promote production and consumption of QPM varieties among farmers in the southern coast of Guatemala, Semilla Nueva’s main area of intervention.

While the bioavailability of QPM protein is well documented, fewer studies have examined the impact of QPM-based foods on child growth in the context of non-biological elements. Community acceptance, consumption patterns and food preparation practices vary with location, impacting the efficacy of QPM as an agent in alleviating malnutrition. The design and implementation of the study presented in this report is based on a similar QPM efficacy study conducted in the Ethiopian highlands (Akalu et al. 2010). The 2010 study, like the one undertaken by Semilla Nueva, analyzes the impact of QPM on the nutritional status of children, as well as the occurrence of violence and stress among adults, in a community specific setting. The participants of both studies live in rural communities with a high prevalence of child malnutrition and maize as the major staple crop.

The design of the study presented in this report attempted to remedy some of the shortcomings of the Ethiopian study (i.e., small sample sizes, incomplete randomization, wide age ranges and short duration), using a larger sample size with completely randomized QPM and control groups of children ranging 6-29 months. With this enhanced methodological design, Semilla Nueva expected to achieve more precise results, demonstrating the potential of QPM to enhance the growth of young children when consumed in a culturally-appropriate setting. This design included a 14-month study including anthropometric baseline measurements (height and weight) and a thorough baseline survey (including demographic, socio-economic, health and nutritional information, and violence and stress questions) was conducted, followed by four planned follow-up visits to assess QPM effect on linear growth of children and one follow-up survey for the stress and violence study. The QPM variety used was ICTA Maya^{QPM}, a hybrid developed by ICTA (the Guatemalan Institute of Agriculture Science and Technology). The cultural acceptance of this hybrid was the main reason it was used in this study.

Slightly more than 1,000 households were given seed (ICTA Maya^{QPM} for the treatment group and ICTA B7 for the control group), distributed among 39 communities within Suchitepéquez and Retalhuleu. Out of this initial selection, 436 households were included in the study analysis, after a selection process based on inclusion and exclusion criteria. However, after a 9-month study period, no significant differences in anthropometric measurements were found between treatment and control groups. Similar results were obtained in the Stress and Violence study. Understanding the factors that may have caused these inconclusive results is essential to developing new suggestions for further research. The results of baseline surveys provided a comprehensive overview of the demographic and socio-economic conditions of households included in the study; anthropometrics, health and nutritional status showed a study population quite homogeneous, meaning that the sample population was appropriate to analyze the effectiveness of QPM since it was the only external intervention that differed among households.

The primary objective of this study was to measure the impact of QPM on linear growth in children aged 6-29 months and on stress and violence among adults when held up to non-biological factors such as community acceptance, cultural patterns and food preparation. Secondary objectives included evaluating the effect of the intervention on morbidity, stunting, underweight, and wasting rates in children aged 6-29 months. Subgroup data analyses were also expected to be carried out to draw conclusions about the effects of QPM on a population that was chronically malnourished at the start of the study. The results of baseline surveys provided a good overview of the demographic and socio-economic conditions of households included in the study; anthropometrics, health and nutritional status showed a study population quite homogeneous, meaning that the sample population was appropriate to analyze the effectiveness of QPM since it was the only external intervention that differed among households.

Anthropometric measurements were completed to assess the impact of QPM on child growth. Although four follow-up visits for measurements were planned after the baseline, due to a lack of QPM grain among treatment group households after a few months, the follow-up stage of the study was reduced to three visits. After Planting and Storage surveys were essential to confirm that corn yields were very low, affecting availability of maize, especially QPM. The reduced consumption of QPM may have been the reason why no significant differences were found between treatment and control groups and therefore, it was impossible to achieve the original objectives of the investigation. Even though all of the initial favorable conditions were met to conduct this QPM effectiveness study (i.e., cultural acceptance of ICTA Maya^{QPM}, representative sample size, and homogeneity of initial population), the unusually dry growing season was the main confounding factor that hindered the statistical validity of the anthropometric measurements; the results cannot be extrapolated to indicate general trends in child growth during years with more predictable rain cycles. It is therefore suggested that this type of study be conducted a second time, ideally during a year with more typical climatic conditions for the area.

While the initial hypotheses were not confirmed by the results of the study, it is not possible to reject the hypotheses either. All the literature on QPM and its incidence on malnutrition and behavior is still relevant and supports Semilla Nueva's efforts to promote high quality protein varieties of maize among smallholders in the Southern Coast of Guatemala, since all the initial conditions are still met and they justify the idea that QPM is a cost-effective way to improve households' nutritional status. Further analysis of the nutritional status of the target population is necessary to monitor and evaluate the impact of Semilla Nueva's work on promoting biofortified maize. News studies should be designed based on the lessons learned from the present study (i.e., smaller sample population but still representative, taking more precise information on crop yields, samples of tortillas for quality protein analysis, asking quantities of each food group consumed, or even taking blood samples to analyze direct effects of lysine and tryptophan intake from QPM tortilla consumption).

The high vulnerability to extreme environmental conditions that affect crop production, and consequently food availability, observed in this study reaffirms the necessity to develop and promote crops more adapted to extreme climatic conditions while containing superior nutrient levels. Such resources ensure that in times of reduced consumption, minimum nutritional requirements could be covered and prevent population, especially children, from suffering from chronic malnutrition.

Introduction

Malnutrition

The world-wide prevalence of childhood malnutrition is at an overwhelming high, as chronic undernutrition, or stunting, affects 161 million children under five (de Onis et al., 2012). Nutritional deprivation during early childhood development has been shown to cause permanent intellectual and physical stunting, leading to increased mortality rates and susceptibility to disease, reduced intellectual capacity, poorer school performance, and diminished income-earning capacity (Hoddinott et al., 2013; Walker et al., 2007). The consequences of malnutrition can be fatal to an affected individual and devastating to a society's economic and social development.

Guatemala has the fourth highest rate of chronic malnutrition in the world (Friezer, 2013). A recent UNICEF study found that chronic malnutrition costs Guatemala about $8.4 million each day in reduced productivity, hospitalization, student failure, and repetition in the first three years of primary school. Malnutrition has been determined as a cause of anxiety, anti-social behaviors, and oppositional disorder and is also associated with violence and crime (Hoddinott et al., 2013; Walker et al., 2007). Taken together, the impact of malnutrition on the interrelated problems of poverty, health, and social cohesion makes it a key barrier in the development of a post-civil war Guatemala, and one of the highest priorities for the Guatemalan government, civil society, and international development organizations.

Particularly in rural areas, high rates of malnutrition can be partially attributed to diets that are centered on one staple crop. In Guatemala, maize supplies the majority of the caloric intake in a typical rural diet, but lacks the complete protein content and micronutrients to support healthy growth during a child's first 1000 days (Immink and Alarcón, 1992; Stansbury, 2011). To achieve sufficient quantities of essential amino acids, diets primarily dependent on maize must be supplemented with legumes or animal protein, which are expensive, inaccessible or not prioritized by most families (Pellett and Ghosh, 2004).

Biofortification and QPM

In many parts of the world where access to animal products and other non-staple foods is not economically feasible, researchers have been looking towards biofortification of staple crops as a way to remedy soaring malnutrition rates. Biofortification is defined as the improvement of the nutritional quality of food crops by using conventional plant breeding, agronomic management techniques (i.e. fertilizer application), or genetic engineering (Nestel et al., 2006). Since the adoption of biofortified foods relies on existing consumption patterns of traditional staple crops, biofortification can offer culturally and nutritionally appropriate solutions to deficiencies in macro- and micro-nutrients (Bouis, 1999). It must be noted that adoption of biofortified crops is highly dependent on whether the new varieties match or surpass farmer yields and household culinary preferences.

Extensive research has been conducted on the biofortification of maize with different nutrients. The first variety investigated was labeled *opaque-2 (o2)* maize, based on its characteristic single gene mutation (Upadhyay et al., 2009). While conventional maize lacks some essential amino acids (i.e. lysine and tryptophan), *o2* maize has nearly double the crop's essential amino acid concentration. Historically, *o2* maize displayed poor yields and other organoleptic characteristics that limited its applicability and adoption by farmers. Scientists have expanded upon the *o2* maize crop using conventional breeding to develop higher yielding maize varieties with the same improved protein quality (Upadhyay et al., 2009). These crops are collectively referred to as quality protein maize (QPM) (Krivanek et al., 2007).

QPM's effect on malnutrition

The presence of high amino acid concentrations in a food source does not always guarantee that these nutrients are readily metabolized; however, the bioavailability and efficacy of QPM's protein has been repeatedly confirmed by scientific evidence. The nutritional benefit of QPM in both adults and children was reviewed by Dr. Ricardo Bressani in 1991. He found that those who consumed QPM had significantly higher nitrogen retention that those who ate conventional maize, confirming the bioavailability of QPM’s protein (Bressani, 1991). In Peru, a clinical study conducted by Graham et al. (1990) involved children recovering from severe malnutrition in a controlled environment. They found that children consuming an entirely QPM-based diet had similar growth rates to children consuming a modified cow's milk formula, which is known to provide enough protein for healthy growth in children of this age group (13-29 months). Though children studied were initially recovering from severe malnutrition, they reached the 50th percentile of weight-for-height after 90 days of consuming a diet of almost exclusively QPM (Graham et al., 1990).

The aforementioned studies have done a thorough job at addressing how biological factors relate to the success of QPM. However, the effectiveness of QPM, or its success when held up to non-biological factors such as community acceptance, cultural patterns and food preparation, has been investigated to a lesser degree. A study in the western highlands of Ethiopia replaced conventional maize seed with QPM seed and asked communities to maintain typical production and consumption patterns. The study concluded that QPM can "reduce or prevent growth faltering in malnourished children and may support catch-up growth in weight" (Akalu et al., 2010). However, the study design generated weak statistical power in the results. The first portion of the study grouped participating households into only four clusters, which were randomly assigned to either the control or treatment group. The second portion of the study was randomized at the household level, but did not assess seed or grain sharing within communities (Akalu et al., 2010).

A comprehensive meta-analysis of these community-based studies was conducted in 2010 (Gunaratna et al., 2010). This report compiled data of 9 different studies to analyze the effectiveness of QPM. Despite an array of experimental design issues in the studies considered, the report concluded that QPM leads to 9% and 12% increases in the monthly rate of growth in height and in weight, respectively (Gunaratna et al., 2010). The issues in experimental design included small sample sizes, incomplete randomization, wide age ranges, and short duration. In this study, these challenges will be addressed in various ways, which are all outlined in the following methodology. By acknowledging the shortcomings of previous effectiveness studies, Semilla Nueva pretended to make concrete conclusions about the effectiveness of QPM on chronic and acute malnutrition rates, thereby supplementing prior investigations.

Semilla Nueva and ICTA Maya^{QPM}

Semilla Nueva is a non-governmental organization that was founded in 2010 and is registered in both the United States and Guatemala. The organization's efforts focus on the development of new sustainable agriculture technologies, farmer-to-farmer empowerment strategies, and effective engagement with Guatemalan government institutions. Semilla Nueva's work takes place directly on our experimental farm and in 25 communities located in the Suchitepéquez and Retalhuleu departments of Guatemala.

Semilla Nueva has been working in Guatemala with a QPM hybrid called ICTA Maya^{QPM} since 2012. ICTA Maya^{QPM} was developed by the Guatemalan Institute of Agricultural Science and Technology (ICTA) with the intention of improving nutritional status in Guatemala. In 2009, it was liberated, certified, and deemed safe for human consumption (ICTA). It has since been distributed by the Ministry of Agriculture in governmental programs that have the goal of improving food security throughout the country. Samples of ICTA Maya^{QPM} were taken from Semilla Nueva's experimental center and sent for amino acid analysis at the International Maize and Wheat Improvement Center (CIMMYT). The results, which confirm that the grain is considered to be QPM, are shown in the table below.

Table 1 Protein content, and Lysine and Tryptophan levels (as percentage of total protein) in whole grain flour of ICTA Maya and conventional maize and selection criteria and standards for QPM

	ICTA Maya^{QPM}	*Conventional Maize*	*Selection Criteria and Standards**
Protein Content (%)	9.7	<8.0	8.0
Lysine (% of total protein)	4.753	1.6-2.6	-
Tryptophan (% of total protein)	0.747	0.2-0.6	0.75

*Minimum levels for whole grain to be considered QPM. Protein level higher than 8% is desirable as long as the Quality index (Trp in sample/protein in sample) is above minimum (0.8) (Vivek, 2008).

ICTA Maya^{QPM} has been selected for use in Semilla Nueva's programs since it is the only QPM hybrid that has been released nationally in Guatemala. Semilla Nueva's methodology has focused on the implementation of women's food security groups which evaluate new recipes and seeds and share them with their communities. Based on the evaluations that have taken place among farmers and within women's food security groups, Semilla Nueva has seen an overall positive response to ICTA Maya^{QPM}. In a 2014 community survey, 64 households in 11 of Semilla Nueva's involved communities were interviewed about their perception of the hybrid's agronomic and organoleptic characteristics. ICTA Maya was reported to have generally the same taste and texture as conventional maize. 43% of respondents said it tasted the same as other varieties of maize, another 38% said ICTA Maya^{QPM} actually tastes sweeter, and 17% went so far as to use the word "delicious". 57% described the texture of tortillas made with ICTA Maya^{QPM} as softer. When asked if they would continue planting ICTA Maya^{QPM} for home consumption, 94% said they would plant it again, and 52% cited nutritional benefits as their motivation. As a whole, farmers seem willing to accept lower yields when planting ICTA Maya^{QPM} for home consumption, given the nutritional benefits and agreeable organoleptic characteristics.

In addition to the agronomic characteristics provided by the ICTA, Semilla Nueva has concurrently investigated the agronomic characteristics of ICTA Maya^{QPM} in farmers' parcels and in its nearby experimental and training center. In optimal conditions, the ICTA has shown that

ICTA Maya^{QPM} can yield 90 quintals per manzana, or 5.8 metric tons per hectare (ICTA). Data from Semilla Nueva's experiments show that ICTA Maya's average yield in the Suchitepéquez and Retalhuleu departments of Guatemala is 56 quintals per manzana, (3.6 metric tons per hectare). The crop is best suited for altitudes from 0-1500 m about sea level, ideal for Suchitepéquez and Retalhuleu. In the 2014 Semilla Nueva community survey, farmers were also asked about other agronomic traits of ICTA Maya^{QPM} such as frequency of weeds, pests and illness in comparison to the maize variety they normally grow. While respondents reported that farm maintenance of ICTA Maya^{QPM} was largely similar to maintenance of other maize varieties, 10% reported that ICTA Maya^{QPM} cannot be stored as long as conventional maize. ICTA Maya's national support and existing positive response in the region made it the ideal variety to use in the present study.

Justification

The proven effect of QPM on growth rates in other regions of the world suggests that QPM has the potential to offer a culturally appropriate solution to Guatemala's high incidence of malnutrition and the subsequent social and economic issues. Given the proven link between nutrient deficiencies and violence-related crime (Hoddinott et al., 2013; Walker et al., 2007), this study also seeks to observe the effect of quality protein maize (QPM) consumption on intra-familial violence and stress levels in the study communities. In contrast to the wealth of successful efficacy studies on QPM, very few effectiveness trials have taken place globally to date, and none have been carried out in Guatemala. This offers a knowledge gap that the study presented in this document aims to fill.

This study seeks to explore the effectiveness of QPM on linear growth in children aged 6-29 months, as well as explore its potential to impact other indicators of malnutrition (namely stunting, wasting, and underweight) in children, and violence and stress levels in their households. Semilla Nueva's experience with QPM and current involvement in this region of Guatemala present a unique opportunity to quantitatively assess the effectiveness of QPM on chronic malnutrition.

Objectives and hypothesis

Primary objective

The primary objective of this study is to measure the impact of QPM on linear growth in children aged 6-29 months and on decreasing levels of intra-familial violence and stress in rural Guatemalan farming communities when held up to non-biological factors such as community acceptance, cultural patterns and food preparation.

Secondary objectives

Secondary objectives include evaluating the effect of the intervention on morbidity, stunting, underweight, and wasting rates in children aged 6-29 months. Subgroup data analyses will also be carried out to draw conclusions about the effects of QPM on a population that is chronically malnourished at the start of the study.

Hypothesis

It is hypothesized that increasing family production and consumption of QPM can offer a cost effective opportunity to decrease chronic malnutrition in children, particularly in the target age range of 6-29 months and also decrease level of intra-familial violence and stress among young people and adults.

Materials and Methods

Study design

Site selection

The study was set in 39 communities in the Guatemalan departments of Retalhuleu and Suchitepéquez (Table 2 and Figure 1), where Semilla Nueva is active, maize is a staple food, and community leaders had indicated their willingness to support the study. Originally, 40 communities were selected, including El Triunfo in Retalhuleu. However, due to a disagreement between Semilla Nueva and the community leader regarding the conditions for households' participation, this community was not included in the study. Of the 39 communities included, 25 were already part of Semilla Nueva's food security and agricultural extension programs; the 14 remaining communities were selected after contacting community leaders in the surrounding areas to explain the project and see which ones were willing to facilitate participant recruitment.

Table 2 List of communities involved in this study

Department	*Involved in Semilla Nueva programs*	*Not involved in Semilla Nueva programs*
Suchitepéquez	• Línea A-13 • Los Encuentros • Willy Wood • Conrado de la Cruz • Nuevos Bracitos • Tiestos • El Triunfo • La Esperanza • Guajilote • Santa Rita • Línea A-11 • Japón A • Japón B • Nueva Victoria • Nuevo Laredo	• Línea A-11 Sector Icán • Línea B2 Sector Sis • Montecarlo • Manelis • San Marcos Nisa • El Paraíso • Montegloria • Caserío el Martillo • Lupita • Monseñor Romero
Retalhuleu	• Santa Fe el Centro • Santa Fe la Presa • La Montaña • Andrés Jirón • Segunda Calle Norte • San Miguel Las Pilas • Victorias Tres • Nueva Cajolá • Santiago Agrícola • Santa María del Mar y Unión	• Montecristo 3ra Calle • Las Maduras • Cuchuapán • El Refugio

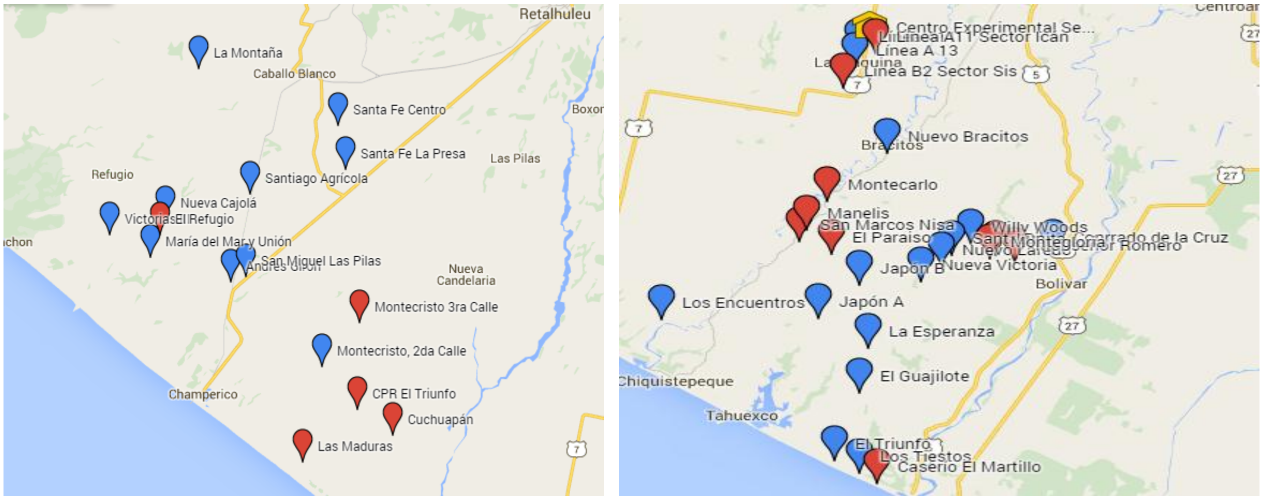

Figure 1 Map of involved communities in the department of Retalhuleu (A) and Suchitepéquez (B); communities marked blue were already involved in Semilla Nueva programs before the beginning of the study. Source: Google Maps

Maize consumption in selected communities

Semilla Nueva conducted a preliminary consumption survey in 2015 to confirm the high maize consumption in the regions selected. One hundred mothers that had a child in the target age range and lived in Semilla Nueva's involved communities were called and asked how many tortillas per day, on average, their child consumed. Three tortillas were then collected from different households in those communities and were measured to estimate the weight of an average tortilla. The unpublished survey results showed that the average child in the target age range and participating communities consumed 3.5 tortillas per day, which equates to 205 grams, 749 kcals, or roughlv 75% of the average daily caloric intake of a child (American Heart Association, 2014). ' (A) data did not account for additional m (B) ntake in the form of traditional foods such as tamales, atol (a sweet maize drink), elote (green maize), etc. However, this overwhelming reliance on maize suggested a risk for inadequate intake of protein and a large potential impact of QPM.

Treatments and randomization

An individually randomized, controlled design was used to assign each participating household to either the treatment group, which received seed of a QPM hybrid (ICTA Maya^{QPM}), or the control group, which received seed of a competitively-yielding conventional maize hybrid (ICTA B-7). All seeds were provided free of charge.

The study was double-blind. There was the possibility that households would increase their daily maize consumption if they were to find out their seed was more nutritious, creating bias within the treatment groups. To avoid such bias, participants were not informed of which seed they received. Instead, they were told that they were receiving one of two types of maize seed of varying nutritional content in order to observe the effect of QPM on malnutrition in their community. Only a small percentage of participants who had worked with ICTA Maya before could have been able to identify ICTA Maya versus ICTA B-7, but that did not occur. Data collectors, other field staff, and study personnel also remained blinded to treatment allocations. The key to the treatment allocations was maintained by a member of Semilla Nueva not involved in data collection or analysis until the conclusion of the study. All of the data storage and analysis were de-identified.

Regardless of seed variety, the amount supplied to each household was enough to fully sow the plot of land the family normally allocates for maize production. Families were asked at the time of seed distribution how much land they normally allocated for maize production for home consumption. The planting guidelines observed for this seed distribution were recommended by ICTA, and yield a conversion factor of 25 pounds of seed per manzana (0.7 ha). Families were instructed to grow the maize according to their traditional practices and to save the grain for family consumption.

Study Population

Target age group

Study subjects included children who were 6 to 29 months of age as of September 1, 2015, residing in households that received seed of either variety. In a 2010 study carried out in 54 countries worldwide, child growth patterns were compared with information from the WHO Global Database on Child Growth and Malnutrition to conclude that growth faltering is especially pronounced in the first 2 years of life (Victora et al., 2010). Additionally, a study that measured the effect of nutritional supplementation throughout different age ranges provided evidence in support of this conclusion. It showed that supplementation only had an impact on height and weight gain during the first three years of life, with benefits declining with age (Schroeder et al., 1995). Therefore, all participants in this study were selected to coincide with this age bracket.

Participant recruitment

Participant recruitment was initiated by Semilla Nueva's field technicians in March 2015. They convened people in the communities for an explanatory meeting, where they informed participants that Semilla Nueva wanted to distribute maize seed in order to conduct a study to measure the effects of two types of seed of varying nutritional values on rates of malnutrition in their communities. Meetings were advertised through loudspeaker announcements by local community leaders and flyers posted at central meeting locations. During these first meetings, households were invited to voluntarily sign up to receive seed and were notified that receiving seed in no way obligated them to participate in the study. This was also reiterated during the informed consent process, when households received the seed. When interested people signed up to receive the seed, they were asked a few questions about the selection criteria (having a child in the age range, living in the community, having land to plant the seed that would be distributed), and also questions about maize consumption and the size of their household. Once the contact lists were ready, households who signed up were contacted by phone or personally to assist in the seed distribution. Treatment assignment was done randomly by giving the treatment seed (ICTA Maya^{QPM}) to the even numbers from the lists and the control seed (ICTA B-7) to the odd numbers from the lists. This process was repeated three times in each community to ensure that all households on the recruitment lists received seed.

Inclusion criteria

Of all the households that signed up to receive seed, only those who met the following inclusion criteria were included in data collection:

- Residence in one of the 39 selected communities

- Child living in the household between 6 and 29 months at the start of the study for whom parents could prove guardianship
- Provided informed consent
- Household had access to enough land to produce maize that would last for the entirety of their annual household consumption. This was determined by a calculation done at the time of inscription, in which the amount of land required to produce enough maize to feed their family for a full 12 months was calculated. This calculation was based off of the quantity of maize families that say that they save each year for personal consumption, as well as the conservative estimate for yield of ICTA Maya of 50 quintals per manzana. Families were then asked how much land they had designated to grow maize for household consumption. If the quantity of land owned was greater than the quantity required, families were eligible to participate.

Exclusion criteria

Households were excluded from data collection if they did not reside in the 39 selected communities, did not have a child in the target age range, or did not provide informed consent. We also excluded participants who did not have access to sufficient land for crop cultivation.

Ethical clearance

The protocol for the study was reviewed by the Institutional Ethics Committee of the INCAP prior to any data collection. As the study participants were infants and young children who had not attained legal age for consent, written permission from a parent or guardian was obtained for all participants. The written consent took place in participants' homes by a study staff member during the baseline survey visit and prior to any data collection. Participants were informed of the risks and benefits of the research and understood that they had the right to withdraw participation at any time. If participants were unable to read and write, a thumbprint was taken and a witness to the consent process was signed. Participants were then provided with a copy of the consent form, which can be found in Annex 1.

Data collection

Study duration and field process

While seed was already distributed (as of late April, 2015 for ICTA Maya^{QPM} and beginning of May, 2015 for ICTA-B7), no data or personal information was collected without approval of the ethical committee. At the time of seed distribution, families were asked their name, whether they had a child between 6 and 29 months of age, how much maize they stored annually for family consumption, and how much land they harvested for their family's maize consumption. Information that required approval of the ethical committee was set to take place in August 2015, which began with a baseline survey in each participating household. Originally, four follow-up visits were foreseen during a total period of 14 months. The rationale for establishing this timespan was the conclusion of the previously mentioned QPM meta-analysis stating that a 9% increase in the growth rate of height can be observed in infants whose diet patterns change within the 1000 day critical period (Gunaratna et al., 2010). This conclusion was based on studies that were all less than 14 months in duration, leading us to believe that such was an appropriate time frame to observe changes in chronic malnutrition. However, unexpected weather conditions (severe droughts) led to a bad production season, and only a few people still had maize stored for self-consumption when the study was halfway completed. At this point, the majority of households were buying conventional maize. Therefore, it was decided to shorten the study period and stop after the third follow-up visit, resulting in a 9-month study with one baseline and three follow-up visits: from August 9 to October 8, 2015, from November 2, 2015 to January 20, 2016, from January 21 to March 4, 2016, and from April 4 to May 23, 2016, respectively. Figure 2 shows the intervention and evaluation process.

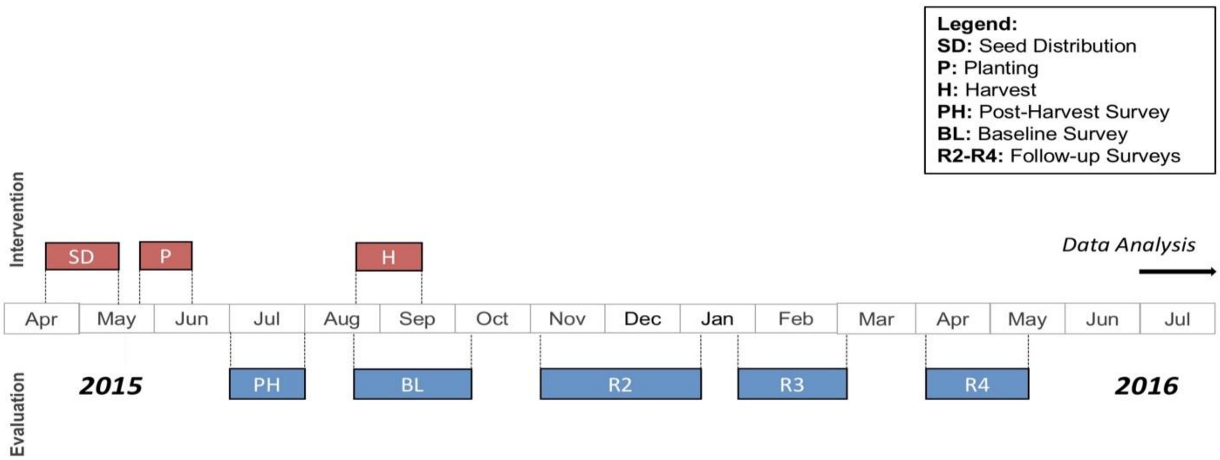

Figure 2 Timeline: Intervention and Evaluation Process of the Study

Baseline survey

The baseline survey took place in August 2015 in the homes of 272 (chosen by simple random sample) across the 39 involved communities, just before rain-fed maize is typically harvested in this region. The survey was administered at each participant's household with both the head of household, the child, and his or her mother present. The survey gathered information on household demographics and socioeconomic indicators, agricultural practices, the medical history of the child, diet patterns of the child and his or her mother, and baseline stress and violence levels. A team of 8 enumerators and 1 survey coordinator was hired to administer the survey to the mother of the index child. In order to facilitate confidence between enumerators and the participant, the team of surveyors was all-female, with experience conducting surveys that contain sensitive questions regarding stress and intra-familial violence. A copy of the baseline survey is available for review in Annex 2.

Baseline anthropometrics

As research conclusions were to be based on chronic and acute malnutrition indicators such as height-for-age, weight-for-age, and weight-for-height z-scores, baseline information on anthropometrics of participating children was essential. In August through October 2015, baseline height and weight measurements were taken in the 39 communities participating in the study. Semilla Nueva Food Security Coordinator, Jennifer Brito, and INCAP Anthropometric Specialist, Maria Lucia Saquin, reconfirmed with children's health records that the children brought to the measurements were eligible within the target age range, and measured their height and weight (Figure 3).

Figure 3 Anthropometric specialist, Maria Lucia Saquin, collects baseline height and weight measurements for children

Follow-up visits

For the three quarterly follow-up visits that were administered in each community, personal invitations were sent out to all participating families to attend a centrally-located meeting. The majority of follow-up surveys were conducted at these meetings and house visits were made to all families who did not attend. The follow-up visit consisted of anthropometric measurements as well as a brief questionnaire that addressed incidence of illness throughout the course of the study, diet patterns of the child (food frequency questionnaire), and whether or not they were still storing and consuming the provided maize. A copy of the follow-up survey can be found in Annex 3.

Follow-up Stress and Violence Survey

In March 2016, families who received the baseline survey were visited again and asked the same questions regarding stress and intra-familial violence. The survey inquired about subjects such as self-reported anxiety of the mother, arguments between spouses, violence among adolescents, etc. Questions were asked with identical wording and to the same female household member as in the baseline survey. The same survey team was hired to administer the follow-up survey to minimize enumerator variation.

Figure 4 A one-on-one interview is conducted to assess change in intra-familial violence and stress levels after 6 months of QPM consumption

Potentially confounding variables

The impact pathway from adoption of a variety to nutritional status of children involves many intervening, potentially confounding factors, and several strategies were considered to measure these factors. One such factor was the potential variation in the nutritional content of the grain produced from the seed given. To monitor this factor, it was stated in the protocol of this study that tortillas would be collected randomly during follow-up visits from both the treatment and control group and frozen. At the end of the study, 3 samples from each treatment group would be sent for laboratory analysis to ensure that amino acid content was in the accepted range for both QPM and conventional maize. Participants would be notified that their grain would be sampled for future analysis. However, due to time constraints, neither tortillas nor grains were sampled and sent for biochemical analysis.

To monitor the extent to which participants were consuming the maize variety that corresponded to their treatment, Semilla Nueva's trained agricultural technicians visited a sample of households 45 to 60 days after planting to assess whether the seed given had been planted, and if not or only part of it, why (After planting survey). The same technician returned during the storage period to determine whether the assigned maize variety was harvested and stored (Storage survey). They verified how much maize grain was stored, how much of the assigned maize variety was stored, how much (if any) of the latter was sold, and once again inquired about annual household maize consumption. During these visits, the specific variety that was distributed to the family was still not revealed in order to maintain the double-blind study design.

Outcome measures of interest

The primary outcome measure were height-for-age z-scores between groups. The child's height was standardized with respect to the child's age and sex using the WHO child growth standards (WHO, 2006). Stunting is defined as a height-for-age z-score that is less than -2. Other secondary outcome measures included:

- Weight-for-height z-scores. There values were also calculated using the WHO Child Growth Standards; acute malnutrition is defined as a weight-for-height z-score less than -2.
- Weight-for-age z-scores. Underweight is defined as a weight-for-age z-score that is less than -2.
- Incidence of morbidity. This was detected through parent recall and is defined as whether a child had fever, diarrhea, or respiratory infections in the preceding two weeks.

These measures were collected by means of a baseline survey as well as three quarterly follow-up visits.

Electronic data capture

Both the baseline survey and the anthropometric measurements, along with their accompanying follow-up questionnaire, were collected using the digital data capture software, KoBoCollect. This software was downloaded by data collectors in their smart phone or a tablet to collect field data. The goal of this electronic data capture was increasing data accuracy by minimizing data copying, identifying data errors on site, and streamlining participants' files.

Data management and confidentiality

Strict confidentiality and privacy was maintained in order to minimize the risk of unintentionally disclosing private information. Data was stored on password-protected computers that were only accessible to study personnel. Data was only shared when it was de-identified, and participants were notified of this during the written consent process. Mobile devices described in Electronic Data Capture section were also password-protected and only accessed by study personnel.

Statistical power and sample size

Among the 1000 households that received seed through Semilla Nueva's program, it was conservatively estimated that 800 would have met the inclusion criteria, including providing informed consent, which resulted in 400 households selected for each treatment group. Based on anthropometric data from children of the target age, collected by Semilla Nueva in 2014 in 11 of the involved communities, the height-for-age z-scores were estimated to have a standard deviation of approximately 1.3. Given the proposed sample size, this study was expected to have 80% statistical power to detect a difference of 0.27 standard deviations in HAZ between groups at the end of the study, assuming a 5% significance level and 10% loss to follow-up. It was conservatively assumed that each participating household would have only one child of the target age. The individually randomized design of the study also eliminated the need to account for intra-community correlation.

Data analysis

Data cleaning and processing

Data was collected using KoBoCollect software, i.e., anthropometric measurements, socio-economic information, nutritional data, as well as health surveys at baseline and follow-up visits were stored in the KoBoToolbox platform (www.kobotoolbox.org) in an account previously created to design the surveys. From this platform, data was downloaded in Excel spreadsheet format. Since data was introduced at different times, depending on when the surveys and measurements were carried out, each time data was downloaded, a new spreadsheet was created. Therefore, at the end of the field work, data for each survey and round of measurements were in different Excel files. All files had to be cleaned first, i.e., all data from a same variable had to be in a same column, and missing, incomplete or inconsistent information had to be verified. After cleaning each file, it was necessary to introduce all data collected into a unique database (one single Excel file). For that, an ID number for each child was used to introduce all measurements (baseline and three follow-up rounds) and answers from the surveys (baseline and two follow-up rounds) for each child included in the study. The *After Planting* survey and *Storage* survey were conducted using paper-format questionnaires. In these cases, data collected had to be digitized in Excel to be included in the database.

Once the database was completed, it was possible to start treating data for analysis. For anthropometric measurements, WHO Anthro, a software created by the World Health Organization for assessing growth of the world's children, was used to calculate anthropometric z-scores: height-for-age (HAZ), weight-for-age (WAZ), and weight-for-height (WHZ). These calculations were completed by the software, taking into account information such as date of birth, date of measurement, gender, mean weight in kg, mean height in cm, and whether height was measured standing or recumbent. The software provides three options to introduce data: anthropometric calculator (to assess an individual's nutritional status), individual assessment (follow a child's growth from birth), and nutritional survey (conduct nutritional surveys covering the same age group) (World Health Organization, 2011). In this study, since the objective was to assess nutritional status of children within a same age group, the nutritional survey module was used to introduce directly all data compiled in one Excel file using the .csv format. Once the z-scores were calculated by the program, they were exported to a new Excel file, also with the .csv format, and then included in the main database. Other anthropometric variables were calculated using weight and height:

- Growth rate related to height (mm/month): $GR_H = (H_F - H_B)/t$ where, H_F is height at final round (mm); H_B is height at baseline (mm); t is time between final and baseline (month).
- Growth rate related to weight (g/month): $GR_W = (W_F - W_B)/t$ where, W_F is weight at final round (g); W_B is weight at baseline (g); t is time between final and baseline (month).

Statistical analysis

The purpose of the data collected was to identify significant differences between treatment and control groups for all outcome measures indicated in *Outcome measures of interest* section. In order to see any differences that could be only attributed to the treatment (i.e., type of seed given), it was necessary to assess homogeneity of the population between groups and within each group. For that, socio-economic data, nutritional assessment, and producing and storage of seed had to be analyzed as well to see the degree of similarity between treatment and control groups. Therefore, frequency, descriptive statistics and statistical tests were used to analyze data of this study (anthropometric and follow-up surveys including *After Planting* and *Storage* surveys). In secondary analysis, factors such as education levels and consumption patterns were included in regression models to see if they accounted for variation in the outcomes or modified the overall effect of QPM. In addition to Excel, GNU PSPP was used to treat data for statistical analysis. GNU PSPP is an open-source program for statistical analysis of sampled data.

Difference between the treatment groups were assessed with $\chi 2$ tests or Fisher's exact tests for categorical outcomes and t-tests, ANOVA or Wilcoxon rank-sum tests for continuous outcomes. All subjects that were given seed and initially met the inclusion criteria were included in the data analysis. Subgroup data analyses were also conducted to assess differences in the outcome measures between treatments. Age at baseline was the variable to classify children in subgroups. Three groups were formed: group 1 (6-11 months), group 2 (12-23 months), and group 3 (>23 months).

Results

Population included in the study

The selection process of children included in the study for anthropometric measurements followed these steps: 1) Randomizing and distributing seeds to families that self-reported as willing to participate in the study (completely randomized design at household level), had a child less than 24 months of age as of May 2015, and lived in one of 39 selected communities; 2) In the first round of anthropometrics (baseline), measuring all families that received seed, were living in one of the selected communities, and had children less than 48 months of age as of September 1, 2015; 3) Measuring and recording anthropometrics for children that were measured at the baseline and continued to attend follow-up surveys, with the intention of only including children in the analysis that fell within the original age range, i.e., birth date between March 1, 2013 and Feb 28, 2015 corresponding to 6-29 months (Figure 5).

From 1,016 households that received seed from Semilla Nueva, after the selection process and taking into account only children within the age range at baseline that were measured in all rounds, data analysis was conducted with a sample of 436 children. Around 800 children were expected to be included in the study analysis, almost twice the final sample size. Since the baseline survey was completed after the baseline for anthropometrics, data from 175 households within the full sample of 436 children selected for the study analysis are included in the baseline survey. For the follow-up surveys, although they were conducted after children were measured, it was not always possible to collect data related to child's health and nutritional patterns because the person accompanying the child was not always the mother or someone that knew the answers. Therefore, for the second follow-up survey, data was obtained from 394 respondents, and for the last follow-up survey, data was collected from 419 respondents. The last two surveys that were included in the study were the *After Planting* and *Storage* surveys. For the former, 201 households were visited, whereas the second survey was carried out in 145 households. A summary of the number of participants per survey is presented in Table 3.

As each survey yielded a different number of respondents, only the children that were measured in the baseline and in all the follow-up surveys were included in the final sample of 436 children. To confirm that this selection did not affect the results of the anthropometric data or the statistical significance between treatment groups, significance tests were conducted between the anthropometric results including children that did not attend every follow-up survey and the results of children that were present for every measurement. Since no statistical difference was observed between the two groups, children that did not attend all of the surveys were excluded from the final analysis.

Table 3 Number of participants included in the study according to the survey. Table includes children/households that were measured/surveyed and that were included in the analysis

Data Collection	*Number of Participants (Total)*	*Number of Participants (QPM group)*	*Number of Participants (CM group)*
Anthropometrics – Baseline	436	213	223
Baseline Survey	175	92	83
Anthropometrics – Round 2	436	213	223
Follow-up Survey – Round 2	394	192	202
Anthropometrics – Round 3	436	213	223
Anthropometrics – Round 4	436	213	223
Follow-up Survey – Round 4	408	195	213
After-Planting Survey	201	88	13
Storage Survey	145	142	3
Stress and Violence Baseline	163	82	81
Stress and Violence Follow-up Survey	163	82	81

Area of Focus

- Study set in **39** communities in Retalhuleu and Suchitepéquez.
- Reasons: Semilla Nueva is active, maize is a staple food, and community leaders willing to support the study.
- **25/39** communities already part of Semilla Nueva's food security and agricultural extension programs; **14/39** communities selected based on participant recruitment facility.

↓

Recruitment of Participants

- **1,016** households received seed - total population (**404** from Retalhuleu and **612** from Suchitepéquez)

↓

Seed Distribution – Completely Randomized Design at Household Level

- **ICTA Maya^{QPM}** seed was given to the **even** numbers of the recruitment lists and **ICTA B7** was given to the **odd** numbers.

- **516** households received ICTA^{Maya} (QPM seed) – **51%** of the total population
- **500** households received ICTA B7 (conventional seed) – **49%** of the total population

↓

Exclusion Criteria

- **466** households were excluded from the study because they did not meet the selection criteria - **46%** of the total population.

- **229** households were excluded from the QPM group. From them:
  - 5% woman still pregnant
  - 40% child out of age range
  - 14% child did not live in the community
  - 6% participant was unreachable
  - 2% baby died
  - 22% did not want to participate
  - 1% woman had an abortion
  - 4% child was at the hospital or at the recovery centre
  - 5% child moved to another community, region or country.

- **237** households were excluded from the conventional group. From them:
  - 7% woman still pregnant
  - 42% child out of age range
  - 13% child did not live in the community
  - 3% participant was unreachable
  - 1% baby died
  - 20% did not want to participate
  - 1% woman had an abortion
  - 4% child was at the hospital or at the recovery centre
  - 10% child moved to another community, region or country.

↓

Inclusion Criteria

- **550** households were included in the study since they met all the inclusion criteria, but only **436** participated in all rounds of anthropometric measurements - **43%** of the total population.

Figure 5 Summary of the recruitment and selection process of participants for the Effectiveness of QPM Study

Baseline data

Socio-economic attributes of participating households

Socioeconomic and demographic attributes were similar between treatment and control groups. Table 4 presents the main characteristics of households. Mothers of index children were generally young women under 30 (75%), on average 26 years old. The youngest mothers were 16 years old. Overall, the mothers were generally married or living with a partner (90%) and economically dependent on their husbands (88%). Around 40% of them were indigenous, belonging mostly to the Mam and Quiché groups. However, the main language spoken was Spanish. Education levels were low: almost half of the mothers of index children completed at least primary school (6 years). Households were large, with 6 people on average and at least 2 children under 5 years of age in 41% of the cases.

Living conditions were poor: although the majority of households had access to basic services such as water (tap or well), electricity and latrines, they were still largely dependent on wood as a cooking fuel and many lacked sanitation systems (sewage or wastewater disposal). The majority of households did not participate in any social aid programs (Table 5). The exception is the Vitacereal program, in which more than half of households participated.

More than half of the female respondents (53%) were engaged in farming at least one day per week to support household income or for self-consumption. In the case of their husbands or partners, the rate is higher (83%); the males usually worked more than 4 days per week, mostly on their own or rented land. Farms were small (1.1 ha on average), and maize/sesame was the most common crop rotation each year, with only one harvest of each plant. One third of households had home gardens, mostly for self-consumption. The majority of households owned chickens (72%), half owned pigs (48%), and very few owned cattle (3%). Livestock products obtained were mostly for self-consumption or for both self-consumption and selling.

Table 4: Sociodemographic characteristics of participating households and children in the southern coast of Guatemala

Category	***Characteristic***	***QPM***[a]	***Conventional maize***[a]
Mother of Index Child	Indigenous --%	42	43
	Native language is Spanish --%	80	80
	Completed primary school -- %	29	29
Household	Size of household	6.59 ± 2.75	5.83 ± 2.29
	Access to water tap or well --%	92	93
	Access to electricity in house --%	82	88
	Access to flush toilet --%	1	11
	Access to latrine --%	85	80
	Wood used as cooking fuel --%	99	99
Land Area	Arable land (ha)	1.49 ± 1.85	1.49 ± 1.09
Livestock	Household has poultry --%	77	66
	Household has pigs --%	47	49
	Household has cattle --%	0	0

[a.] Values are means ± SD or percentages.

Table 5 Percentage of households participating in a social program at baseline

Group	1*	2*	3*	4*	5*	6*
Conv. Maize (n =83)	2.4	59.0	0	2.4	9.6	6.0
QPM (n = 92)	7.6	53.3	0	5.4	8.7	2.2

1 = Bolsa segura del gobierno; 2 = Vitacereal; 3 = Programa de apadrinamientos por ONG; 4 = Hambre Cero; 5 = Fertilizantes; 6 = Remesas de familiares en el extranjero

Attributes of children

The results of the first round of children's measurements did not yield significant differences between conventional maize and QPM groups after running a Chi-square test, Fisher's exact test, and ANOVA. Participating children ranged from 6 to 29 months at the baseline (18 months on average) and more than half were between 12 and 23 months old. From all participating children, 63% of were still breastfeeding at the baseline, as complementary feeding started at almost 7 months on average. Vaccine coverage rate at baseline was 77%. The prevalence of undernutrition at the baseline was mostly related to stunting and incidences of being underweight, especially among children older than 12 months. A significant difference was found only between stunted children of QPM and conventional maize groups within the group 2 age range, meaning that at baseline there were more children stunted in the treatment group than in the control group (Table 6).

Children's health was assessed through questions related to their birth, whether they had any chronic disease, and whether they were sick or recovering from a disease at the moment of the survey. Here again no differences between treatment and among age range groups were found, except for the percentage of children with diarrhea which was much higher in 6-11 month-old children of the QPM group (60%) than in the conventional maize group (30%). The majority of children were not born prematurely and very few cases of chronic disease were reported at birth. However, at the moment of the baseline survey, around half of children were sick or were recovering from a disease. Cough was the predominant symptom reported (60-80% of children), followed by fiver (around 50% of children), and diarrhea (30-60% of children), all groups included.

Regarding nutrition, respondents were asked food frequency questions related to different types of food grouped according to their nutritional characteristics. Only tortilla consumption was assessed by asking the number eaten by the child the day before the survey Figure 6. Although it seems there are differences in tortilla consumption patterns between treatment groups (QPM group eating slightly less than the conventional maize group), no statistical difference was found after running a t-test. The average number of tortillas consumed by children in the conventional maize and the QPM groups for the age groups 1, 2 and 3 is 1.0 ± 0.7 and 1.0 ± 1.3, 2.3 ± 2.3 and 1.9 ± 1.2, and 2.4 ± 1.6 and 2.5 ± 1.3, respectively.

Table 6 Children's profile at baseline according to treatment group and age range

Category	*Characteristic*		*QPM*[a]	*Conventional maize*[a]
Index Child	Male Sex --%		48	48
	Age at baseline (months)		18 ± 7	19 ± 7
	Age group 6-11 months --%		22	20
	Age group 12-23 months --%		53	50
	Age group > 23 --%		26	30
	Breastfeeding at baseline --%		62	64
	Age when complementary feeding started (months)		6.45 ± 2.87	6.69 ± 2.87
	Weight at baseline (kg)*			
		Age group 1	7.41 ± 0.98	7.51 ± 0.86
		Age group 2	8.96 ± 1.16	9.12 ± 1.30
		Age group 3	10.36 ± 1.32	10.55 ± 1.08
	Height at baseline (cm)*			
		Age group 1	66.87 ± 2.91	67.39 ± 1.76
		Age group 2	75.09 ± 4.33	75.81 ± 4.16
		Age group 3	81.45 ± 3.46	82.30 ± 2.99
	All vaccinations at baseline --%		74	82
Prevalence of undernutrition	Stunted (HAZ < -2)* --%			
		Age group 1	37	31
		Age group 2	54	41[b]
		Age group 3	46	50
	Underweight (WAZ < -2)* --%			
		Age group 1	17	20
		Age group 2	27	21
		Age group 3	26	23
	Wasted (WHZ < -2)* --%			
		Age group 1	4	4
		Age group 2	7	6
		Age group 3	0	0

[a.] Values are means ± SD or percentages. [b] Statistically different ($p < 0.05$) after running Fischer's exact test.
*Age groups are: 1 = 6-11 months; 2 = 12-23 months; 3 = >23 months

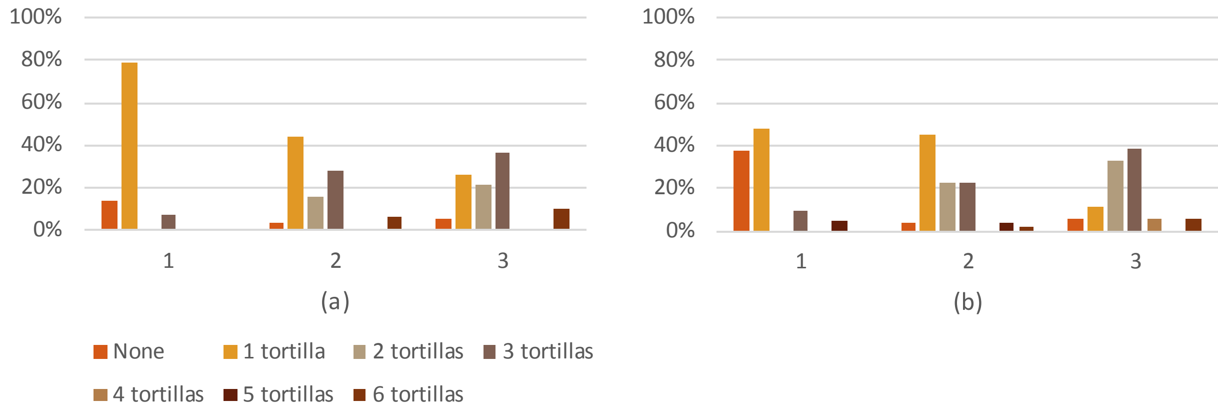

Figure 6 Tortilla consumption at baseline according to treatment group, conventional maize (a) and QPM (b), and age range 6-11 months (1), 12-23 months (2), and >23 months (3).

Concerning food consumption frequency, the data was stratified by age group, indicating trends in diet and the overall nutritional profile of the study group. There were no significant differences found between treatment groups. According to the frequency data, consumption of certain food groups seemed dependent on age group. For example, in the first age group (children 6-11 months at baseline), 40% did not regularly consume green leafy vegetables, while only 16% of the third age group (>23 months at baseline) fall into this category. Similar trends are observed in the consumption of beta-carotene vegetables, starch, legumes, chicken, eggs, and oils/fats. For example, 23% of the first age group never regularly consumed legumes, while 40% of the third age group consumed legumes 1-2 times a week at *minimum*. These data trends indicate increases in the consumption of certain food groups with age; however, other food categories were consumed infrequently by all age groups. Milk, dairy, beta-carotene fruits, sweets, fish and red meat were never regularly consumed by over 50% of study participants in each age group. In the case of milk, for example, the percentages of non-regular consumption are 85%, 79% and 81% for age groups 1, 2 and 3 respectively. In the case of fish, non-regular consumption ranged between 50-65% for all age groups, but 1-2 times a week consumption increased by 32 percentage points between first and third age groups. These types of trends indicate that while a majority of children did not consume fish on a regular basis, those that did consume fish saw a general pattern of increased consumption with age. Overall, the baseline food-consumption frequency data shows important trends in both diet development and diet profile by indicating what types of consumption changed with age and what was generally lacking from the diets of all study participants.

Respondents were also asked whether children were given any nutritional supplement, such as minerals or vitamins (Table 7). There was no significant difference in the usage of nutritional supplements between treatment groups. In both of the treatment groups, children primarily took “chispitas” supplements, a mix of micronutrients (iron, zinc, folic acid, and vitamins). Other prominent supplements were calcium and zinc.

Table 7 Rate of children that were given any nutritional supplements according to the treatment group: conventional maize (CM) and QPM

Group	*Age range*	*1**	*2**	*3**	*4**	*5**
CM	1 (n = 14)	21%	29%	21%	29%	0%
	2 (n = 50)	16%	30%	16%	56%	2%
	3 (n = 19)	16%	26%	21%	47%	0%
QPM	1 (n = 21)	5%	19%	5%	33%	0%
	2 (n = 53)	21%	32%	15%	42%	0%
	3 (n = 18)	17%	28%	17%	50%	0%

*1 = Ferrous sulphate; 2 = Vitamin A; 3 = Folic acid; 4 = Chispitas (mix of different vitamins and minerals); 5 = ATLC (therapeutic food ready for consumption)

Follow-up data

After the baseline survey, two follow-up surveys were conducted; the first was conducted with round 2 of measurements (Dec. 2015 – Jan. 2016) and with round 4, the final round, of measurements (Apr. – May 2016). These follow-up surveys paralleled the original anthropometric measurements, and their purpose was to gather information on children's food consumption and health status to assess child morbidity during the study intervention period. A total of 394 mothers or primary guardians of the participating children were surveyed during the second round while 408 respondents participated in the fourth round survey.

Incidence of morbidity

In the second round survey, more than half of children surveyed seemed to be recovering from an acute illness contracted over the previous 2 weeks, while about 14% of children were reported to be sick at the time of the survey. In 38% of the cases, respondents stated their child was recovering from a fever, 27% from a cough, and 16% from diarrhea. These values are averages from all children surveyed, as there was no significant difference between age groups. Of the children reported to be currently sick at the time of the survey, 10% were afflicted with a cough, 10% with a fever, and 4% with diarrhea. There were also reports of respiratory illness, vomiting and skin infection, but incidence for each respective illness remained under 3% of children surveyed.

In the fourth round survey, 26% of children within the first age group (6-11 months at baseline) were reported having a chronic illness, while an average of 36% of children in the older age groups (both 11-23 and >23) reported having a chronic illness. At the time of the survey, 25% of children in the first age group were sick, 19% in the second age group, and only 10% in the third age group. Meanwhile, an average of 54% of all children surveyed were reported to be recovering from an illness. Of those recovering, incidence of illness is fairly similar among all age groups; 31% were recovering from a cough, 46% from a fever, and 16% from diarrhea (the rest of the reported illnesses, such as respiratory infection, had incidences below 3%). Of those children that were reported being sick at the time of the survey, incidence remained fairly constant across all age groups. On average, 10% of children were reported having a cough, 15% reported having a fever, and 11% reported having diarrhea. Incidence for each other illness reported remained below 3%.

Food consumption

Results of the second round and fourth round surveys regarding percentage of children breastfed are shown in Figure 7.

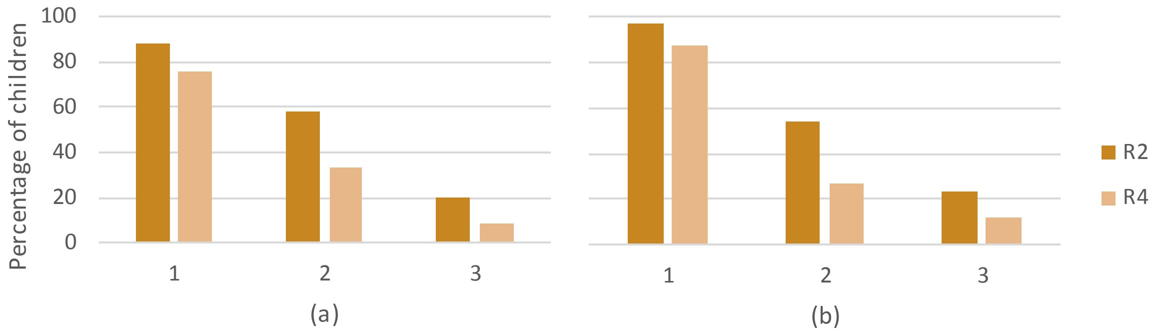

Figure 7 Percentage of children breastfed in round 2 and round 4 according to age groups and treatment groups: Conventional maize (a) and QPM (b).

The follow-up surveys were conducted using a consumption frequency questionnaire. Only one question related to the amount of tortillas consumed the day before the survey was asked. The other questions were about the frequency of consumption per week of different types of food, which were grouped according to their nutritional characteristics. No significant differences were found between treatment groups (Conventional maize and QPM) after running a t-test for the number of tortillas consumed and a Chi-square test for the food frequency data. However, statistical differences between rounds were found in all food groups except for tamales, eggs, legumes, and nuts/seeds after running a Wilcoxon test. Tamale consumption remained low in all age groups and in both rounds of follow-up surveys (more than 50% of children had never consumed tamales), whereas eggs are the food more often consumed.

Although the frequency data did not reveal significant differences in consumption patterns between treatment groups, there is a discernable decrease in overall food consumption frequency between the second and fourth follow-up survey. The following example (

Figure 8) provides a consumption profile of study participants in the third age bracket (>23 months) in the QPM treatment group. In areas such as legumes/nuts/seeds, vitamin-A rich tubers and vegetables, green leafy vegetables, and white roots/tubers, consumption frequency declined in the fourth follow-up survey. At the most, these groups were consumed 3-4 times a week, with the majority of study participants eating such groups only 1-2 times a week. Such results suggest a general food shortage in the later months of the study, a phenomenon not exclusive to a particular food group.

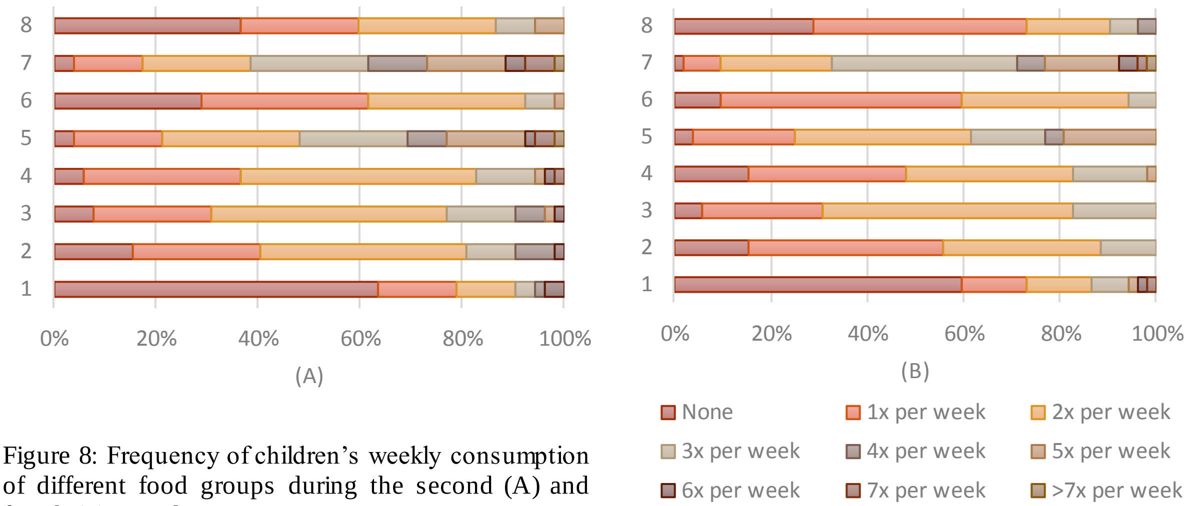

Figure 8: Frequency of children's weekly consumption of different food groups during the second (A) and fourth (B) round surveys. QPM group.
Age Group: >23 years, at baseline.
Food groups: 1 = Tamal; 2 = Vitamin A-rich tubers and vegetables; 3 = White roots and tubers; 4 = Dark green leafy vegetables; 5 = Legumes, nuts and seeds; 6 = Meat and viscera; 7 = Eggs; 8 = Milk and dairy

The frequency data also reveal general diet patterns within each age group, suggesting variance in consumption with age. For example, the frequency graphs in (Figure 9) show consumption frequency for the conventional treatment group in Round 4. Trends in the consumption data among different age groups indicate a shift in dietary patterns as a child matures. For example, milk and dairy consumption seems to be higher in the older age group, as does meat and viscera. Consumption frequency of eggs also increases in the older age groups; in the 6-11 month group, eggs are consumed at most 3-4 times a week, by only about 25% of the study participants. However, in both the 12-23 and the >23 age groups, eggs are consumed more than 4 times a week by at least 25% of the study group, if not more (as seen in the >23 age group).

Animal product consumption was also analyzed to see if there was a correlation between the frequency of high quality protein consumption (animal protein) and anthropometric data (z-scores). All data on consumption frequency of animal products (eggs, milk and dairy, and meat) were summed up to obtain the new variable "consumption frequency of animal products". This variable was divided in tertiles (centiles at 1/3 and 2/3) in both rounds (2 and 4). This division resulted in four categories of consumption: none, low, medium, and high consumption. An ANOVA test was run to see if there is any significant differences between levels of consumption related to the z-scores (weight-for-height, height-for-age, and weight-for-age). A statistical difference was found within the second age group in the second round ($p<0.05$), with a positive correlation between frequency of animal product consumption and z-scores ($R^2>0.95$). Considering that a potential synergy could occur between consumption of animal products and maize, maize consumption was also divided into categories of consumption and then an ANOVA two way was run to see if there are any interactions between variables. No interaction was found.

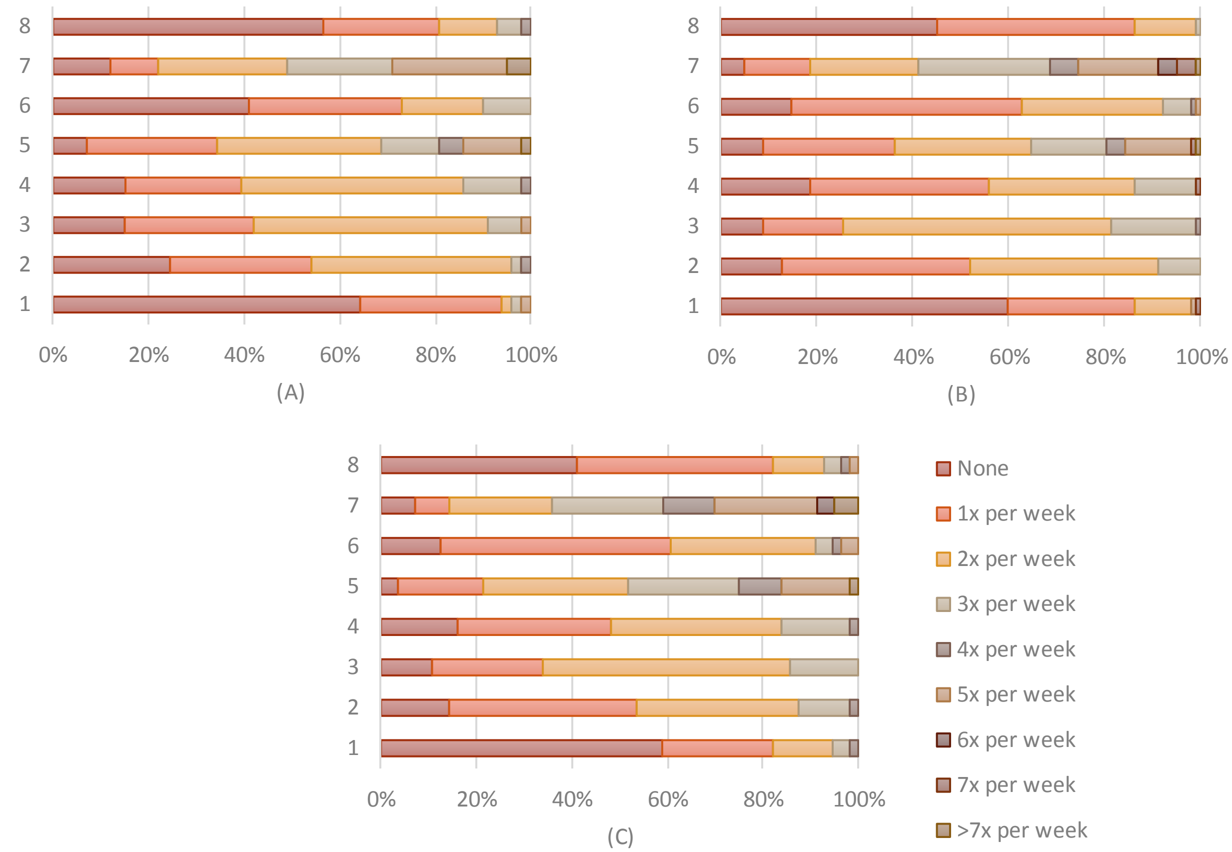

Figure 9 Children's weekly consumption frequency of different food groups during the fourth round survey. Conventional Maize Group. Age groups: 6-11 months (A), 11-23 months (B), >23 months (C), all at baseline.
Food groups: 1 = Tamal; 2 = Vitamin A-rich tubers and vegetables; 3 = White roots and tubers; 4 = Dark green leafy vegetables; 5 = Legumes, nuts and seeds; 6 = Meat and viscera; 7 = Eggs; 8 = Milk and dairy.

Since tamales were not consumed in most of the cases, and the consumption frequency was very low, it was concluded that tortillas were the primary means of maize consumption for the children studied. Therefore, data on tortilla consumption was collected by measuring the amount of tortillas eaten the day before each survey. The results are shown in Table 8.

Table 8: Number of tortillas consumed by children the day before the survey (baseline, second round, and final) according to age range (mean ± SD)

Round	*Age group**	*Conventional maize*	*QPM*	*p*
2	1	1.4 ± 1.9 (n = 41)	0.9 ± 0.9 (n = 38)	0.113
	2	2.1 ± 1.7 (n = 102)	1.9 ± 1.4 (n = 90)	0.319
	3	2.5 ± 1.5 (n = 56)	2.4 ± 1.8 (n = 52)	0.768
4	1	1.1 ± 0.9 (n = 41)	0.7 ± 0.8 (n = 38)	0.095
	2	2.1 ± 2.0 (n = 102)	2.0 ± 1.7 (n = 90)	0.699
	3	2.8 ± 1.7 (n = 56)	2.8 ± 2.4 (n = 52)	0.931

*Age groups are: 1 = 6-11 months; 2 = 12-23 months; 3 = >23 months, all at baseline.

A preliminary consumption survey, conducted in 2015 by Semilla Nueva, showed that a typical tortilla weighs an average of 58.5g (unpublished). Therefore, the children's consumption of tortillas in this study was calculated by multiplying the average number of tortillas consumed by the average weight of one tortilla. To assess the consumption of maize from tortilla, a conversion factor (1.17) was used to determine the equivalent quantity of maize grain (Table 9). This factor was derived from measuring the weight of tortillas resulting from one pound of dry maize grain (454 g). It was calculated that from 100g of dry maize grain, 117g of tortillas can be obtained. The conversion factor differs from one study to another - e.g., in another study, the conversion factor obtained was 1.46 (Dr. Mazariegos, personal communication, October 2016) - and thus this factor can only be applied to the tortilla consumption in this study. It is important to convert the tortilla consumption data because, according to a study on the chemical composition of tortillas made from conventional maize and QPM conducted in Guatemala, the nutritional quality of tortillas differs from that of raw maize (Bressani et al., 1990).

This preliminary data and the amount of tortillas consumed by children the day before the survey were the means to calculate the quantity of protein, lysine and tryptophan intake at rounds 2 and 4 of the follow-up surveys (Table 10). As it is explained in the next section, a lot of households that received QPM seed did not harvest QPM grain and those who harvested could not store grain for a long time due to bad yields. Furthermore, tortilla samples were not taken for nutritional analysis during the follow-up surveys. Therefore, the results shown in Table 10 represent the theoretical protein, lysine, and tryptophan intake the day before the survey per treatment group, assuming that tortillas eaten by children came from grain harvested from the seed provided. Taking into account the daily protein, lysine and tryptophan requirements of children[1], the percentage of daily requirements covered by maize consumption was calculated (Table 11).

Table 9 Equivalent quantity (g) of dry maize grain consumption based on the number of tortillas consumed by children the day before the survey

Round	*Age group**	*Conventional maize*	*QPM*
2	1	70 ± 95	45 ± 45
	2	105 ± 85	95 ± 70
	3	125 ± 75	120 ± 90
4	1	55 ± 45	35 ± 40
	2	105 ± 100	100 ± 85
	3	140 ± 85	140 ± 120

*Age groups are: 1 = 6-11 months; 2 = 12-23 months; 3 = >23 months, all at baseline.

[1] The daily protein requirements (g/kg of BW) of children differ according to age: 2.5 for 4-6 months; 2.2 for 7-9 months; 2.0 for 10-12 months; 1.6 for 1-2 years, and 1.55 for 2-3 years (FAO/WHO/UNU, 1985). The daily lysine and tryptophan requirements for children are 64 and 14 mg/kg of BW, respectively (Swendseid, 1981).

Table 10 Theoretical quantity (g) of maize protein, lysine, and tryptophan consumed by children the day before the follow-up surveys (based on tortilla-to-maize conversion)

Round	*Group*	*Age group**	*Protein*	*Lysine*	*Tryptophan*
2	CM**	1	5.6 ± 7.6	0.112 ± 0,152	0.022 ± 0.030
		2	8.4 ± 6.8	0.168 ± 0.136	0.034 ± 0.027
		3	10 ± 6	0.200 ± 0,120	0.040 ± 0.024
	QPM***	1	4.4 ± 4.4	0.209 ± 0.162	0.033 ± 0.033
		2	9.2 ± 6.8	0.437 ± 0.323	0.069 ± 0.051
		3	11.6 ± 8.7	0.551 ± 0.414	0.087 ± 0.065
4	CM**	1	4.4 ± 3.6	0.088 ± 0.072	0.018 ± 0.014
		2	8.4 ± 8.0	0.168 ± 0.160	0.034 ± 0.032
		3	11.2 ± 6.8	0.224 ± 0.136	0.045 ± 0.027
	QPM***	1	3.4 ± 3.9	0.162 ± 0.185	0.025 ± 0.029
		2	9.7 ± 8.2	0.461 ± 0.390	0.072 ± 0.061
		3	13.6 ± 11.6	0.646 ± 0.551	0.102 ± 0.087

*Age groups are: 1 = 6-11 months; 2 = 12-23 months; 3 = >23 months, all at baseline.
**The rate of protein considered for the conventional maize was 8%. The rate of lysine and tryptophan was 2 and 0.4 (as % of the protein content).
***The rate of protein considered for the QPM was 9.7%. The rate of lysine and tryptophan was 4.753 and 0.747 (as % of the protein content).

Table 11 Theoretical percentage of protein, lysine and tryptophan supplied from tortilla consumption in second and fourth rounds according to treatment groups and age range.

		Protein supplied by maize (%)		*Lysine supplied by maize (%)*		*Tryptophan supplied by maize (%)*	
	Age group*	**R2**	**R4**	**R2**	**R4**	**R2**	**R4**
CM	1	37	32	22	16	20	15
	2	55	52	27	25	25	23
	3	57	60	28	29	25	27
QPM	1	30	23	41	27	29	19
	2	61	60	73	70	52	51
	3	68	75	79	86	57	62

*Age groups are: 1 = 6-11 months; 2 = 12-23 months; 3 = >23 months, all at baseline.

QPM availability in households during the study period

Since the purpose of the present study was to see the effectiveness of QPM consumption on chronic malnutrition in young children of Guatemala, it was necessary to assess the availability of QPM during the study period. This assessment was possible with the two surveys (After Planting Survey and Storage Survey) conducted in July 2015 and November-December 2015, respectively. The results of these surveys are shown in Table 12 and Figure 10.

QPM and conventional maize seeds were distributed to households randomly selected from the list of participants in April and May 2015, respectively. The results of these two surveys show that within the QPM group, planting all the seed provided was done in 2/3 of households, using on average 1/3 of the arable land. In 32% of the cases, respondents stated that they did not plant or they planted but did not harvest. The main reason for not planting or harvesting was the severe drought that prevented the seed from germinating or the crop from growing properly after germination. Other reasons provided included pest attacks, no land availability, no seed received, and an increase in the nearby river level (flooding the crop).

From respondents that stated that they harvested QPM (28%), half of them produced 5 qq or less (230 kg). By the time the Storage Survey was conducted (Nov-Dec 2016), less than half of the respondents reported still having QPM stored for self-consumption. Taking into account the annual maize consumption and the amount of QPM stored, an estimation of the storage time was calculated (Figure 10).

Table 12: Characteristics of maize consumption and QPM production in the target group

Category		*Value*[a]
Annual maize consumption per household (kg)		1,175 ± 545
QPM seed given (kg)		7.7 ± 3.5
QPM Planted area (ha)		0.3 ± 0.2
Households that planted all QPM seed provided (%)		65
Households that harvested QPM (%)	< 5 qq[b]	14
	6-10 qq	7
	> 10 qq	7
	Total	28

[a] Values are means ± SD or percentages.
[b] 1 qq = 46.008 kg

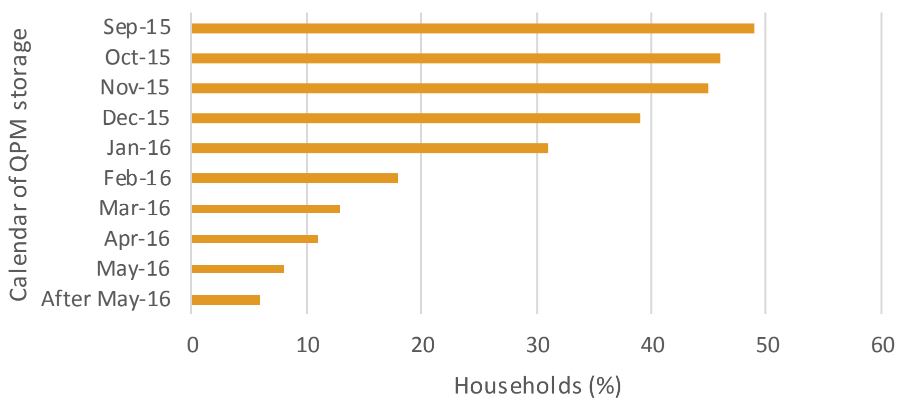

Figure 10 Evolution of QPM availability in households of the treatment group over time

Anthropometric changes in children in QPM and conventional maize households

At baseline, children in the QPM and conventional maize groups did not differ significantly in any variable examined. Undernutrition was prevalent in the study sample, as demonstrated in Table 4. Over the 9-month study, the Z-scores did not differ significantly between treatment groups. Only growth rate (mm per month^{-1}) for the first age group (6-11 months at baseline) was significantly different between conventional maize and QPM groups (Table 13). WHZ (weight-for-height Z-score) varied significantly during the study period (Figure 11), including an improvement in both groups in the third round of measurements and then a decrease in the WHZ mean during the last round of measurements. Data was also analyzed according to gender; even though there are some differences between genders (e.g. growth rate within the >23 months group), these differences were found in both maize groups (Conventional maize and QPM).

Table 13: Anthropometric changes and growth rates of children in the conventional maize (CM) and QPM groups during the study period (mean ± SD)

Outcome	*Gp.*	*Age group**	*Baseline*	*R2*	*R3*	*R4*
HAZ	CM	1	-1.53 ± 0.72	-1,83 ± 0,89	-1,97 ± 0,92	-1.95 ± 0.98
		2	-1.86 ± 1.05	-1,99 ± 1,04	-2,02 ± 1,07	-1.94 ± 1.05
		3	-1.97 ± 0.94	-1,88 ± 0,90	-1,80 ± 0,91	-1.70 ± 0.89
	QPM	1	-1.60 ± 1.04	-2,08 ± 1,09	-2,25 ± 0,96	-2.28 ± 0.93
		2	-2.04 ± 1.04	-2,20 ± 1,01	-2,16 ± 0,99	-1.99 ± 0.97
		3	-2.07 ± 0.94	-2,01 ± 0,89	-1,96 ± 0,91	-1.85 ± 0.8
WAZ	CM	1	-1.15 ± 1.04	-1,18 ± 0,95	-1,25 ± 0,96	-1.50 ± 0.94
		2	-1.28 ± 1.06	-1,27 ± 1,05	-1,21 ± 0,96	-1.30 ± 0.92
		3	-1.32 ± 0.85	-1,14 ± 0,88	-1,05 ± 0,86	-1.09 ± 0.9
	QPM	1	-1.15 ± 0.98	-1,25 ± 1,03	-1,35 ± 0,95	-1.66 ± 0.97
		2	-1.42 ± 0.97	-1,42 ± 0,91	-1,30 ± 0,82	-1.39 ± 0.83
		3	-1.32 ± 0.85	-1,25 ± 0,87	-1,11 ± 1,08	-1.23 ± 0.85
WHZ	CM	1	-0.39 ± 1.14	-0,33 ± 0,91	-0,41 ± 0,91	-0.78 ± 0.82
		2	-0.51 ± 0.97	-0,36 ± 0,94	-0,25 ± 0,84	-0.39 ± 0.79
		3	-0.16 ± 0.76	-0,16 ± 0,76	-0,07 ± 0,76	-0.20 ± 0.78
	QPM	1	-0.29 ± 0.86	-0,21 ± 0,88	-0,33 ± 0,85	-0.76 ± 0.91
		2	-0.58 ± 1.01	-0,45 ± 0,88	-0,28 ± 0,83	-0.49 ± 0.86
		3	-0.36 ± 0.75	-0,20 ± 0,82	-0,11 ± 0,77	-0.27 ± 0.87
Growth rate (g month^{-1})	CM	1	-	-	-	151.15 ± 86.37
		2	-	-	-	167.32 ± 66.24
		3	-	-	-	198.57 ± 85.49
	QPM	1	-	-	-	132.85 ± 69.47
		2	-	-	-	168.68 ± 76.68
		3	-	-	-	182.98 ± 53.22
Growth rate (mm month^{-1})	CM	1	-	-	-	**9.5 ± 2.4[a]**
		2	-	-	-	7.5 ± 1.6
		3	-	-	-	7.4 ± 1.3
	QPM	1	-	-	-	**8.5 ± 1.7[a]**
		2	-	-	-	7.9 ± 1.9
		3	-	-	-	7.4 ± 1.6

*Age groups are: 1 = 6-11 months; 2 = 12-23 months; 3 = >23 months, all at baseline.
[a] Growth rate (mm month^{-1}) differed significantly between treatment groups ($p = 0.039$) after running an ANOVA test.

Since no differences were found between treatment groups during the study period, the QPM group was divided in two sub-groups: one group in which children came from households that still had QPM grains stored in January, and the second one that did not. The means of Z-scores were calculated for each round and presented in Figure 12. Again, no significant differences were found among groups.

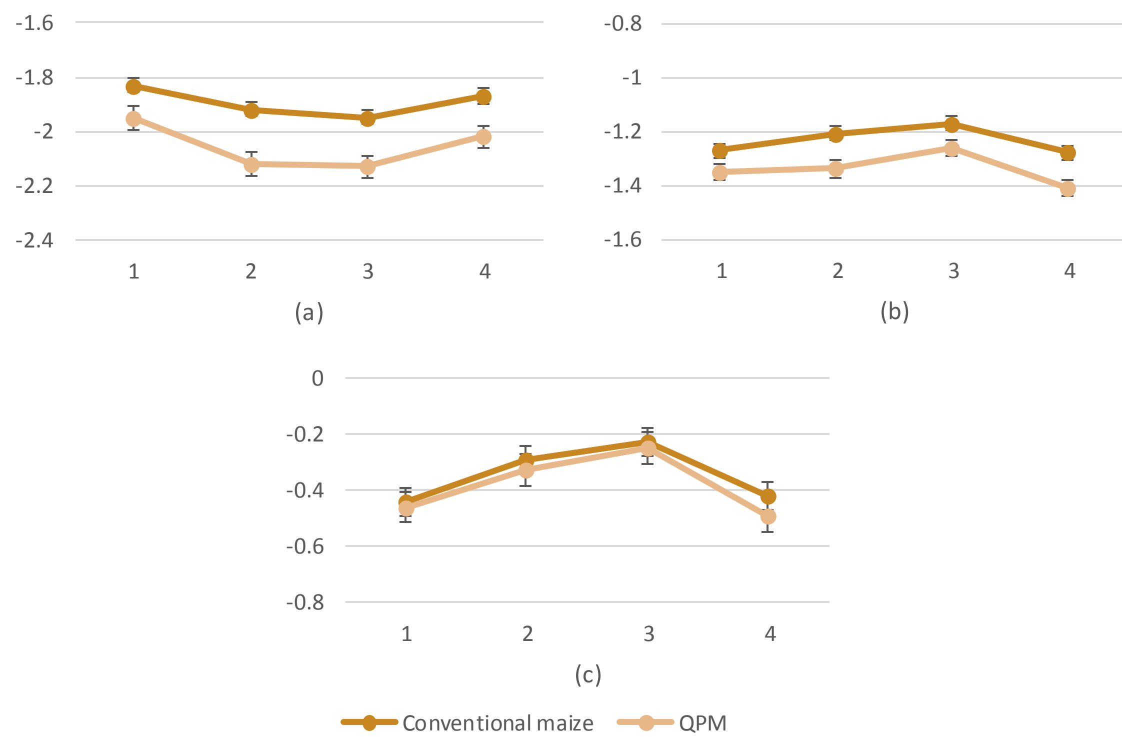

Figure 11 Mean height-for-age z-scores (a), weight-for-age z-scores (b), and weight-for-height z-scrores (c) over time in the QPM and conventional maize groups (error bars are SEs)

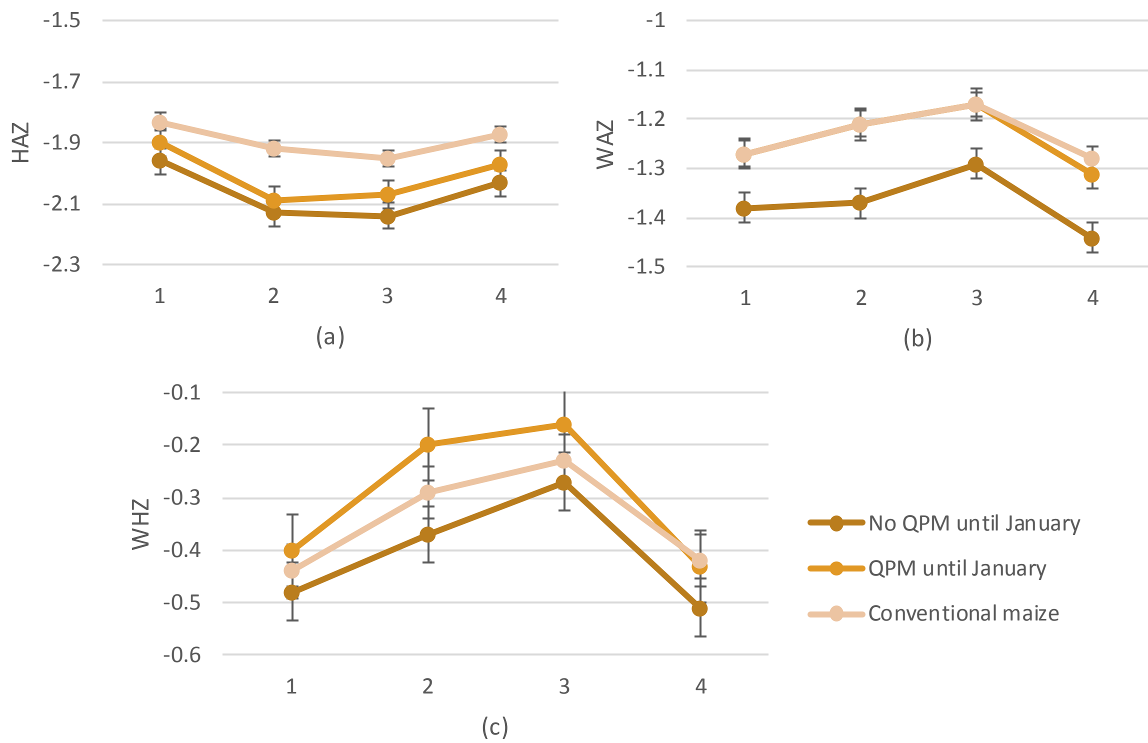

Figure 12 Mean height-for-age z-scores (a), weight-for-age z-scores (b), and weight-for-height z-scores (c) over time in the QPM (grain stored until January and no grain stored until January) and conventional maize groups (error bars are SEs)

Stress and Violence Study

This part of the study aimed to analyse the incidence of QPM consumption, more precisely of tryptophan, on individuals' aggressiveness and thus on social interactions within households and within the communities. Questions asked at baseline and at the follow-up surveys to the mothers of children included in the study included the following themes: worrying or stressful situations, emotional states, power relations, intra and inter familial violence, and sexual abuse. Overall, no significant differences were found between treatment and control groups after running a Chi-square test for each variable analysed; statistical differences were found between baseline and follow-up results for variables such as "worrying or stressful situations" and "frequency of insults during quarrels", after running a Wilcoxon test.

At baseline, around half of the respondents stated they were not living in any types of worrying situations, whereas the other half considered themselves as living a somewhat worrisome situation (32%) and some, a very worrisome situation (23%). Results differed in the follow-up visits because more than half of the respondents declared not living any worrisome situations and none of the rest reported living a very worrying situation. Among respondents living in stressful situations, issues in the household were identified as the major cause of concern and, more specifically, household finances were the principal issue (30% at baseline and follow-up visits).

Concerning emotional states, in general respondents stated not being nervous (more than 60% at both baseline and follow-up visits), but the number of women that responded being a little bit and very nervous, increased in the follow-up visits (from 22% and 15% to 30% and 17%, respectively), although not significantly. The majority of women indicated they were not angry (more than 60% in both periods) but during the follow-up visits, the treatment group (QPM) presented less women not angry than the control group (conventional maize). Concerning self-confidence on dealing with household issues, more than half of women did not feel self-confident to deal with those issues at both baseline and follow-up visits; however, there was an increase in women regarding self-confidence from one survey to the other, especially in the treatment group, although not significantly.

Power relations were assessed through the question, "Who makes decisions at home?" In 70% of the cases, respondents stated that they decided for both their spouses and themselves. Less than 15% responded only that their husbands make decisions. Similar results were obtained at the follow-up visits. Concerning intra-familial violence, queries were made regarding quarrels between spouses, between children, and physical violence of fathers towards their children. Most women indicated arguing sometimes or never with their spouse. Similar results were obtained in the follow-up survey. Insults during quarrels never happened in the majority of the cases or sporadically and more than 90% of respondents stated their husband never used physical violence against them (around 4% reported having been threatened with a weapon) and against children it never happened in around 88% of the cases. Fights between siblings was also reported to be inexistent in around 90% of the cases in both baseline and follow-up visits. Violence outside the household was also reported to be almost inexistent (around 95% of respondents stated their children did not use to fight with other children or young people and in very few cases mothers reported that other people had used physical violence against their children a few times during the last month).

Finally, sexual abuse was also assessed through two questions: 1) whether respondents had sexual relations with their partner without consent in the last month, and 2) whether their partner used violence to force them to have sexual relations in the last month. For both questions, less than 5% of respondents responded affirmatively at baseline as well as at follow-up visits. However, only 56% of respondents reported knowing where to call in case of suffering a situation of violence.

Discussion

While the bioavailability of QPM protein is well-documented, fewer studies have examined the impact of QPM-based foods on child growth in the context of non-biological elements. Community acceptance, consumption patterns and food preparation practices vary with location, impacting the efficacy of QPM as an agent in alleviating malnutrition.

The design and implementation of the study presented in this report is based on a similar QPM effectiveness study conducted in the Ethiopian highlands (Akalu et al., 2010). The 2010 study, like the one undertaken by Semilla Nueva, analyzes the impact of QPM on the nutritional status of children in a community specific setting. The participants of both studies live in rural communities with a high prevalence of child malnutrition and maize as the major staple crop. As previously mentioned, the study conducted by Akalu et al. (2010) had several issues with experimental design, including small sample sizes, incomplete randomization, wide age ranges and short duration. The design of the study presented in this report attempted to remedy some of these shortcomings, using a larger sample size with completely randomized QPM and CM treatment groups of children ranging 6-29 months. With this enhanced methodological design, Semilla Nueva expected to achieve more precise results, demonstrating the potential of QPM to enhance the growth of young children when consumed in a culturally-appropriate setting. However, after a 9-month study period, no significant differences in anthropometric measurements were found between treatment groups - except for growth rate (mm per month) in children between 6-11 months at baseline, although it resulted in a lower growth rate for the treatment group than the control group. Similar results were found in the Stress and Violence study, in which only changes occurred between baseline and follow-up survey, but without any differences between treatment groups. Thus, it was necessary to find out the factors that might have influenced these unexpected results.

Baseline surveys, including anthropometrics, child nutritional and health status, and demographic and socio-economic conditions of the sample households show that the population included in the study is relatively homogeneous. Both groups were similar regarding poor livelihood conditions, and food consumption followed similar patterns in all households (i.e. diets low in diversity and strongly based on maize consumption). Only stunting prevalence rate was statistically higher in the QPM group (6-12 months at baseline) than in the CM group at baseline, and tortilla consumption was marginally lower in the former group than in the latter, although not significantly. Concerning health and chronic malnutrition, the results indicate that child morbidity was predominant in both groups (>50%) and acute malnutrition affected around half of children measured, especially in the two older age groups (>12 months). Food supplements such as incaparina did not seem to improve child nutritional status, since no correlation was found between frequencies of consumption and less incidence of acute malnutrition (R^2 = 0.001). Education level of the mother is also a factor mentioned in the literature as influencing healthcare and nutritional status of children (Thakur et al., 2014). In this case, no correlation was found between education level of the mother and child acute malnutrition (R^2 = 0.0551). The baseline analysis confirms that the situation of households in the southern coast of Guatemala is critical regarding well-being of children. The vicious cycle of poverty, malnutrition and disease prevents populations from achieving better livelihoods (Black et al., 2008; Thakur et al., 2014). Thus, taking into account the homogeneity of the study population at baseline was essential to ensure that both groups were under the same conditions and that the treatment of QPM consumption could be observed.

Once the treatment started, the follow-up visits were important to assess the effect of QPM on children. Measurements of height and weight were the means to monitor the evolution of children and follow-up surveys on health and nutritional status provide interesting information on child growth and development in the study region. This information is very important, as the anthropometric results alone did not show statistical differences between the treatment and control groups. The supplementary data collected through the execution of this study provides crucial insight into the scope and severity of malnutrition in Guatemala, as well as the practicality of QPM in developing countries.

Regarding breastfeeding, the FAO recommends breastfeeding babies until they have reached 6 months: "Provided that the mother has adequate breastmilk, breastfeeding alone with no added food or medicinal supplementation is all that is needed for the normal infant during the first six months of life" (Latham, 1997). After six months, breastfeeding should be supplemented with non-solid and then solid food "to provide extra energy, protein, iron, vitamin C and other nutrients for growth" (Latham, 1997). In this study, the average age to start food complementation was 6-7 months, following FAO's recommendation. Moreover, more than 70% of children of the first age group (6-11 months at baseline) were still breastfed in the fourth round, when they were 15-20 months. These results could be considered appropriate, as long as the mother has adequate breastmilk.

The food consumption frequency data obtained from the second and fourth follow-up surveys, which estimates the nutrient intake of study participants (measuring consumption of food groups apart from maize), shows distinct trends in the consumption of particular food groups; overall eggs were the most frequently consumed food group (consumed at least 3x per week by >40% of all participants for each age group), followed by legumes and white roots/tubers. The food groups least consumed are meat/viscera, milk/dairy and green leafy vegetables (consumed at most 2x per week by <80% of all participants for each age group). As was mentioned, there was no statistically significant difference between treatment groups in diet trends. According to Latham (1997), animal products are not necessary as protein source in infant diet. Instead, legumes are a good source of protein and iron, to some extent. However, a positive correlation between frequency of animal products consumption and anthropometric z-scores was found in the second round, within the second age group (12-23 months at baseline). Children that consumed animal products more often had better z-scores, although no difference was found between treatment groups. It is unclear why this correlation was not found in the two other age groups and in the fourth round. It might be related to the quantity consumed (probably not enough for age requirements) and, especially in the last round, seasonal food insecurity may have occurred, as the food frequency data suggest.

Regarding maize consumption, cross-sectional analysis indicates that older children consumed more tortillas than younger children; in longitudinal analysis, tortilla consumption increased overall during the study period, except for the first age group, which was lower. These results were expected considering that children's energy requirements are related to body weight. However, even though maize consumption increased according to age, and except eggs, it was the main protein-source food, children in this study did not reach the necessary amount of maize to cover their respective daily protein, lysine and tryptophan requirements. The low consumption is observed especially in the first age range group. However, consumption of *atol* (a beverage made from boiled corn and highly consumed by young children) was not asked and therefore the real maize consumption may not have been fully assessed. As it was explained before, the amount of protein consumed by the study participants is purely theoretical, as the 2nd and 4th follow-up surveys only asked respondents how many tortillas were consumed the previous day before the survey. Furthermore, the nutritional composition of the tortillas consumed were extrapolated from a 2015 preliminary consumption survey by Semilla Nueva. The nutrition profiles of study participants are also estimations, as food consumption data was collected on the basis of frequency, rather than quantity. Therefore, no definitive data exists on the exact nutrient intake of the study participants. Nevertheless, these data suggest that the majority of study participants supplemented a maize-based diet with some high-quality protein (eggs and beans). However, there was minimal consumption of calcium and vitamin-rich food groups (dairy and green leafy vegetables) and the main source of protein (i.e., maize) was not eaten enough to cover the protein requirements for appropriate growth.

As the data was collected on the basis of frequency rather than quantity, it is not known how much of a typical diet is supplemented (or missing) these food groups. Rather, the frequency data better illustrates the general lack of diversity within the maize-based Guatemalan diets of young children. Bio-fortified QPM can help fill the gaps in such limited diets by providing “a more balanced protein source relative to common maize without sacrificing energy, yield, and micronutrients” (Nuss and Tanumihardjo, 2011). In other words, even though in this study it was not possible to observe the effectiveness of QPM to overcome child malnutrition, other studies have proven its benefits on improving child nutritional status, especially on stunting children (Akalu et al., 2010). Considering the theoretical results obtained in this study, it can be observed that with similar maize consumption, QPM can supply up to 75% of the daily protein requirements, whereas CM only covers up to 60%. To evaluate the nutritional impact of QPM, Dr. Bressani estimated maize intakes required to meet protein needs using regression analysis of nitrogen retention values from human feeding trials. Nitrogen balance within the body is a traditional method for estimating protein metabolism, with a positive value indicating the occurrence of protein deposition (Nuss and Tanumihardjo, 2011). According to his research, Dr. Bressani found that with consumption of traditional maize, 23.6g/kg BW (body weight) is required to achieve nitrogen equilibrium, while only 8.2g/kg BW is required with QPM consumption (Nuss and Tanumihardjo, 2011).

Due to limited resources, laboratory analysis of QPM tortillas could not be conducted; the overall protein, lysine and tryptophan contents were theoretical or taken from analysis done the previous year. Obtaining exact nutrient profiles of tortillas is incredibly important, as tortillas account for the majority of maize ingestion for young children and are therefore the largest indicators of protein intake through maize consumption. Several published reports indicate changes in selected nutrient and protein contents of QPM and conventional maize during the preparation of tortillas in rural settings (Bressani et al., 1990; Serna-Saldivar et al., 2008). One study conducted in Guatemala analyzed conventional and ICTA quality-protein maize both raw and prepared as tortillas, using a lime-cooking process common in rural communities. The comparative chemical data presented in the report indicates that the process of converting raw maize and QPM into tortillas affects the nutritional profile of each food. The results indicate that for both conventional and QPM, the protein quality was higher in tortillas than in raw maize. Conversion from raw maize to tortillas also revealed increases in calcium and magnesium and small decreases in potassium and sodium (Bressani et al. 1990). Since this report analyzed tortilla presentation comparable to what was most likely conducted by this study’s participants, it is important to note the altered nutritional profile of maize subjected to such a cooking process. Therefore, any future investigations of QPM in Guatemala should include laboratory analysis of tortillas to account for any potential nutritional alterations.

No correlation was found between maize consumption and anthropometric results, as there was no significant difference between treatment groups; the most plausible reason for this occurrence is that households that were given QPM seed were not able to produce and store enough grain to feed their families during the long study period. As shown in the charts depicting growth indicators over the study period between the conventional and quality-protein maize treatment (see Figure 11), there were general decreases for both treatment groups between months 3 and 4 of the study in weight-for-height z-scores (WHZ) and weight-for-age z-scores (WAZ). The hypothesized reason for this decrease in anthropometric z-scores is the limited availability of stored maize during the last months of the study, as evidenced by the results of the

Storage Survey conducted in November-December 2016 (see Figure 10), where by December 2015 less than 40% of QPM households still had grain in storage. These results principally stem from the severe drought during the 2015 growing season, which hindered agricultural production and thus the economic status of many Guatemalan farmers. The storage statistics indicate a general food shortage in the months before the planting season, which subsequently affected the anthropometric growth of many of the study participants. However, according to a study assessing the consumption of QPM in Africa, a serving of the bio-fortified corn can cover a greater part of daily protein requirements than a serving of conventional maize (Nuss and Tanumihardjo, 2011).

From the results of theoretical protein intake and the storage grain, it can be concluded that in times of food shortage, it requires less consumption of QPM to fulfill a child's daily protein requirement than conventional maize. As this study observed an atypical growing season with reduced yields, these results show that consumption of QPM tortillas is nutritionally advantageous in times of restricted food access.

Regarding the Stress and Violence study, inconclusive results were also obtained. A similar explanation can be provided: insufficient QPM consumption due to a lack of grain availability during the whole study period. In general, intra-familial violence does not seem a major problem, according to responses given by female participants. Only in a few cases quarrels between spouses include insults, physical violence, and/or a weapon threat. Overall, respondents considered themselves not to be living in a stressful situation or at least not in an overwhelming situation. Most of them felt that they were able to deal with the worrying situation, which was in most of the cases related the household economy. Interestingly, in the follow-up survey, respondents were less stressed than at baseline, although in March 2016, the time when the follow-up survey took place, food shortage due to the bad growing season was already latent. More control over the treatment group consumption (e.g., blood analysis to assess levels of serotonin, from which tryptophan is a precursor, and which is involved in behavioral processes) would have provided a deeper analysis of these phenomena.

Overall, the main factor that explicates the inconclusive results is the reduced amount of QPM that children ate during the intervention period. As previously mentioned while reporting the results of the After Planting and Storage Surveys (conducted in July 2015 and November/December 2015, respectively), QPM cultivation and subsequent storage were affected by unusually severe drought conditions during the growing season (April – November 2015). As a result, 32% of respondents to these follow-up surveys stated that they did not plant QPM or they planted QPM but did not harvest. Data collection during the study period was hindered by climatic factors, particularly El Niño conditions that impacted crop production (including both QPM and conventional maize varieties) throughout the Guatemala and the rest of Central America.

According to the Guatemala's National Institute for Seismology, Volcanology, Meteorology and Hydrology (INSIVUMEH) the months of April, May and June of 2015 were characterized by strong heatwaves and severe local storms (INSIVUMEH, 2015). In July, it was reported that El Niño atmospheric conditions were "moderate to strong," which led to high temperatures and irregular rainfall. According to the report, the average national precipitation in July was 72% of what is normally recorded for that month; in August, average national rainfall decreased to 62% of normal amounts (INSIVUMEH, 2015).

According to the World Food Program, 2015 marked "the worst 'El Niño' phenomenon of the last decades," affecting 1.5 million people in Guatemala, primarily day laborers and subsistence farmers (OCHA, 2015). In an analysis of areas affected by El Niño, the WFP cited Retalhuleu, an area containing many households in the QPM Effectiveness study, as one of the municipalities with the highest frequency of drought (WFP, 2015). Retalhuleu was also included in a list, published by INSIVUMEH, of areas that experienced no rain for 45 days during the months of July and August (OCHA, 2015).

Overall, the below-average rainfall in the *primera* crop cycle (March-July) severely impacted early crop development, especially as the majority of annual maize crop production occurs during the *primera* season (WFP, 2015). Rainfall deficits and irregularities can greatly hinder seed germination and often result in delayed planting or replanting of seeds. According to the Guatemalan Ministry of Agriculture, Livestock and Food (MAGA), Retalhuleu was the department most affected; in the month of June, corn and bean crops experienced heavy stress due to fierce rains in the first weeks followed by a harsh drought (MAGA, 2015). The Ministry also cited the department of Suchitepequez (which includes the rest of the households participating in the study) as having also experienced severe rainfall fluctuations, with precipitation has high as 600 mm in Mazatenango in early June, followed by weeks of no rain in July (MAGA, 2015). Such extreme conditions stunt early plant development, leading to damaged crops and reduced yields. As the households involved in this study were in areas severely impacted by heavy rains followed by severe drought, normal maize cultivation practices and production were not realized during the study period. The unusual weather patterns caused by El Niño are therefore a likely reason why some respondents were unable to plant or harvest QPM, thereby shrinking the sample of households that successfully planted, harvested and stored the biofortified seed. In addition, ICTA Maya^{QPM} is not reported to be a drought tolerant variety, whereas ICTA B7 has been promoted in dry areas of Guatemala. However, the ICTA B7 (conventional maize) seed distributed in the beginning of the study experienced some germination problems, possibly due to inappropriate storage before distribution. Therefore, the lack of drought tolerance of the former and the bad germination of the latter might have stressed the critical situation caused by El Niño.

Conclusions and recommendations

The primary objective of this study was to measure the impact of QPM on linear growth in children aged 6-29 months and on stress and violence among adults when held up to non-biological factors such as community acceptance, cultural patterns and food preparation. Secondary objectives included evaluating the effect of the intervention on morbidity, stunting, underweight, and wasting rates in children aged 6-29 months. Subgroup data analyses were also expected to be carried out to draw conclusions about the effects of QPM on a population that was chronically malnourished at the start of the study. The results of baseline surveys provided a good overview of the demographic and socio-economic conditions of households included in the study; anthropometrics, health and nutritional status showed a study population quite homogeneous, meaning that the sample population was appropriate to analyze the effectiveness of QPM since it was the only external intervention that differed among households.

Anthropometric measurements were completed to assess the impact of QPM on child growth. Although four follow-up visits for measurements were planned after the baseline, due to a lack of QPM among treatment group households after a few months, the follow-up stage of the study was reduced to three visits. After Planting and Storage surveys were essential to confirm that corn yields were very low, affecting availability of maize, especially QPM. The reduced consumption of QPM may have been the reason why no significant differences were found between treatment and control groups and therefore, it was impossible to achieve the original objectives of the investigation. However, it is important to note that there was a significant difference in stunting between treatment groups: more children were stunted at baseline in the treatment group than the control group within the age range 12-23 months, the largest group of the sample population. These less favorable conditions for the QPM group may have prevented the treatment population from experiencing a positive response to the biofortified maize, especially taking into account that the period of QPM consumption was probably not sufficient to have an effect on child anthropometrics. Although all of the initial favorable conditions were met to conduct this QPM effectiveness study (i.e., cultural acceptance of ICTA Maya^{QPM}, representative sample size, and homogeneity of initial population), the unusually dry growing season was the main confounding factor that hindered the statistical validity of the anthropometric measurements; the results cannot be extrapolated to indicate general trends in child growth and stress and aggressiveness in adults during years with more predictable rain cycles.

While the initial hypotheses were not confirmed by the results of the study, it is not possible to reject the hypotheses either. All the literature on QPM and its incidence on malnutrition and behavior is still relevant and supports Semilla Nueva's efforts to promote high quality protein varieties of maize among smallholders in the Southern Coast of Guatemala, since all the initial conditions are still met and they justify the idea that QPM is a cost-effective way to improve households' nutritional status. Semilla Nueva, with its purpose of helping rural Guatemalan farmers find a path to better nutrition, lasting food security, and prosperity through biofortified crops, must include in its annual plans the monitoring and evaluation of the projects implemented. Taking into account that Semilla Nueva will keep working on promoting production and consumption of QPM varieties, there is a need to assess the impact of this work in the mid and long term. Therefore, new studies on chronic malnutrition and the effects of QPM consumption need to be conducted, this time including methodological modifications based on the lessons learned from the present study.

For instance, since this study revealed that the population of interest is relatively homogeneous in terms of socio-economic and demographic conditions, it could be possible to study smaller sample populations that are still representative of the focus area. This could help improve the monitoring and evaluation process of QPM promotion. The evaluation of an open-pollinated QPM variety might also be an important focus of study, since it is possible for farmers to save seeds for the following season. Thus the study could be conducted for a longer period, where it would be possible to assess child growth over a longer time period, and changes in adults' behavior at different periods of the year. In addition, including a more controlled setting (i.e., taking more precise information on crop yields, samples of tortillas for quality protein analysis, asking quantities of each food group consumed, or even taking blood samples to analyze direct effects of lysine and tryptophan intake from QPM tortilla consumption) might improve the accuracy of the results and provide relevant data that explains more precisely the households' conditions.

Semilla Nueva is aware that ideally, humans need to have a balanced diet in order to experience appropriate growth and development as well as a good mental and physical health. However, the present study has shown that this ideal situation is right now far from being a reality in the Guatemalan communities where the organization works. Socio-economic and even political factors make livelihoods in these communities difficult and thus households are often not able to access better diets. In this study, it was observed that the studied populations were highly exposed to seasonal food insecurity due to adverse climatic conditions. This high vulnerability to extreme environmental conditions, factors that affect crop production and consequently food availability, reaffirms the necessity of developing and promoting crops more adapted to extreme conditions that also contain superior nutrient levels. Such resources ensure that, even with reduced consumption, minimum nutritional requirements could be covered and prevent populations, especially children, from suffering from chronic malnutrition.

References

Akalu, G., Taffesse, S., Gunaratna, N.S., De Groote, H., 2010. The effectiveness of quality protein maize in improving the nutritional status of young children in the Ethiopian highlands. Food Nutr. Bull. 31, 418–430.

Black, R.E., Allen, L.H., Bhutta, Z.A., Caulfield, L.E., De Onis, M., Ezzati, M., Mathers, C., Rivera, J., Maternal, Group, C.U.S., others, 2008. Maternal and child undernutrition: global and regional exposures and health consequences. The lancet 371, 243–260.

Bouis, H.E., 1999. Economics of enhanced micronutrient density in food staples. Field Crops Res. 60, 165–173. doi:10.1016/S0378-4290(98)00138-5

Bressani, R., 1991. Protein quality of high lysine maize for humans. Cereal Foods World 36, 806–811.

Bressani, R., Benavides, V., Acevedo, E., Ortiz, M.A., others, 1990. Changes in selected nutrient contents and in protein quality of common and quality protein maize during rural tortilla preparation. Cereal Chem 67, 515–518.

De Onis, M., Blössner, M., Borghi, E., 2012. Prevalence and trends of stunting among pre-school children, 1990–2020. Public Health Nutr. 15, 142–148. doi:10.1017/S1368980011001315

FAO/WHO/UNU, 1985. Energy and protein requirements. Report of a joint FAO/WHO/UNU Expert Consultation. World Health Organ. Tech. Rep. Ser. 724, 1–206.

Friezer, E., 2013. Guatemala fights chronic malnutrition. Info Sur Hoy.

Graham, G.G., Lembcke, J., Morales, E., 1990. Quality-Protein Maize as the Sole Source of Dietary Protein and Fat for Rapidly Growing Young Children. Pediatrics 85, 85–91.

Gunaratna, N.S., Groote, H.D., Nestel, P., Pixley, K.V., McCabe, G.P., 2010. A meta-analysis of community-based studies on quality protein maize. Food Policy 35, 202–210. doi:10.1016/j.foodpol.2009.11.003

Hoddinott, J., Alderman, H., Behrman, J.R., Haddad, L., Horton, S., 2013. The economic rationale for investing in stunting reduction: Economic rationale for stunting reduction. Matern. Child. Nutr. 9, 69–82. doi:10.1111/mcn.12080

Immink, M.D.C., Alarcón, J.A., 1992. Household food security and crop diversification among smallholder farmers in Guatemala [WWW Document]. FAO. URL http://www.fao.org/docrep/U8050t/u8050t06.htm (accessed 11.14.16).

INSIVUMEH, 2015. Informes Climáticos Mensuales. Instituto Nacional de Sismología, Vulcanología, Meteorología e Hidrología.

Krivanek, A.F., De Groote, H., Gunaratna, N.S., Diallo, A.O., Friesen, D.K., 2007. Breeding and disseminating quality protein maize (QPM) for Africa.

Latham, M., 1997. Human nutrition in the developing world - Food and Nutrition Series, No. 29 [WWW Document]. URL http://www.fao.org/docrep/W0073E/W0073E00.htm (accessed 9.27.16).

MAGA, 2015. Sistema de Monitoreo de Cultivos: Boletín N°7 (No. 7). Ministerio de Agricultura, Ganadería y Alimentación - Gobierno de Guatemala.

Nestel, P., Bouis, H.E., Meenakshi, J.V., Pfeiffer, W., 2006. Biofortification of staple food crops. J. Nutr. 136, 1064–1067.

Nuss, E.T., Tanumihardjo, S.A., 2011. Quality Protein Maize for Africa: Closing the Protein Inadequacy Gap in Vulnerable Populations. Adv. Nutr. Int. Rev. J. 2, 217–224. doi:10.3945/an.110.000182

OCHA, 2015. Drought in Central America in 2015 - Situation Report (as of October 6, 2015) (Situation Report). United Nations Office for the Coordination of Humanitarian Affairs (OCHA).

Pellett, P.L., Ghosh, S., 2004. Lysine fortification: past, present, and future. Food Nutr. Bull. 25, 107–113.

Schroeder, D.G., Martorell, R., Rivera, J.A., Ruel, M.T., Habicht, J.P., 1995. Age differences in the impact of nutritional supplementation on growth. J. Nutr. 125, 1051S–1059S.

Serna-Saldivar, S.O., Guerra, C.A., Macias, P.H., Cuellar, J.L., Ortiz, R.E., Ibarra, A.D., Carrillo, G.V., 2008. Evaluation of the lime-cooking and tortilla making properties of Quality Protein Maize hybrids grown in Mexico. Plant Foods Hum. Nutr. 63, 119–125. doi:10.1007/s11130-008-0080-1
Stansbury, G., 2011. Maize, Rice, Beans…& Sprinkles? [WWW Document]. IFPRI Insights Mag. URL http://insights.ifpri.info/2011/10/maize-rice-beans%E2%80%A6-sprinkles/ (accessed 11.14.16).
Swendseid, M.E., 1981. Essential amino acid requirements: a review [WWW Document]. FAO/WHO/UNU. URL http://www.fao.org/3/contents/3905b6bb-1bc8-581c-b07b-bfab249f81e6/M2772E00.HTM (accessed 11.15.16).
Thakur, M.S., Naik, J.D., Sheetu, M.K., Langre, S., Pandey, V.O., 2014. Anthropometric assessment and morbidity profile of under five children attending immunization clinic at Urban health centre. Sch J App Med Sci 2, 352–356.
Upadhyay, S.R., Gurung, D.B., Paudel, D.C., Koirala, K.B., Sah, S.N., Prasad, R.C., Pokhrel, B.B., Dhakal, R., 2009. Evaluation of quality protein maize (QPM) genotypes under rainfed mid hill environments of Nepal. Nepal J. Sci. Technol. 10, 9–14.
Victora, C.G., Onis, M. de, Hallal, P.C., Blössner, M., Shrimpton, R., 2010. Worldwide Timing of Growth Faltering: Revisiting Implications for Interventions. Pediatrics 125, e473–e480. doi:10.1542/peds.2009-1519
Vivek, B.S. (Ed.), 2008. Breeding quality protein maize (QPM): protocols for developing QPM cultivars. CIMMYT, Mexico, D.F.
Walker, S.P., Wachs, T.D., Gardner, J.M., Lozoff, B., Wasserman, G.A., Pollitt, E., Carter, J.A., International Child Development Steering Group, 2007. Child development: risk factors for adverse outcomes in developing countries. Lancet Lond. Engl. 369, 145–157. doi:10.1016/S0140-6736(07)60076-2
WFP, 2015. Initial analysis of the impact of the drought on food securty in Guatemala, El Salvador, and Honduras (Situation Report). World Food Programme - Latin America and the Caribeean.
World Health Organization, 2011. WHO Anthro. WHO.

Annex 1: Informed Consent Form

Study of Effectiveness of the QPM maize on Chronic Malnutrition in Guatemala

Information for individual participants and Informed Consent Form -- Mothers of child of 6 to 29 months old

Project IRB #: 052/2015

Sponsored by: Semilla Nueva, Texas A&M Center for Conflict and Development

Researchers: Lisa Eash (Semilla Nueva); Dr. Shahriar Kibriya (Texas A&M University)

Introduction

This research will take into account the cultural and social aspects of the participant communities and the proper application of the principles of protection of all study participants. To ensure that you are informed about all aspects of this investigation, you are asked to read (or have someone else read aloud) this consent form. Also, you will be asked to sign (or record your finger print in front of a witness), indicating your consent. A copy of this form will be provided to you for your reference. This form may have some words that are unfamiliar to you, so please ask for an explanation of anything that you don't understand.

Justification of the project

We invite you to participate in this research in order to prove the effect of quality protein maize (QPM) on the health of children in your community. QPM is a type of maize that has been shown improve the nutrition of children by providing nutrients that support physical and mental development. To better understand how QPM can affect your community, we want to investigate the benefits in your children and family.

We are asking you to participate voluntarily, to help us to understand whether QPM should be promoted throughout Guatemala.

Research Information

We are asking you to participate to this investigation as you meet the following characteristics:

- You live in one of the involved communities from Suchitepéquez and Retalhuleu
- You have a child between 6 to 29 months old
- You produce corn for family consumption each year

Do I have to participate?

You can decide if you want participate or not. Even after given you have given your consent, you can decide to stop participation at any moment, without explanation needed. Your decision to stop participating will not affect access to any health services associated with the study.

What happen if I decide to participate?

If you decide participate, you will answer questions for a baseline survey, which will be carried out in your household. Surveyors will ask you questions about the health and diet of you and your child. The survey will also include questions about your household and agricultural practices. There will also be a component that asks you about your mental and emotional well-being, and any incidences of violence. These personal questions will take place in the privacy of your own home, and only you and the interviewer will be present. You have the right to decline to answer any questions asked. This baseline survey will take about an hour and half.

Additionally, you would have to plant the seed that is given to you and save the grain for family consumption. There is a chance that this maize will be sampled once during the duration of the study. Every three months, you will need to bring your child to a centrally-located meeting spot, where a shorter survey will be administered that will include questions about your child's diet and health. At those meetings, your child's weight and height will also be measured.

In total, you will be asked to complete the baseline survey, and four follow-up visits every three months. The study will be about a year in duration, lasting from August 2015 to August 2016.

Possible Disadvantages or Risks

We don´t have knowledge of any risk or inconvenience to the participants of this project. The interviews and measurements that will be conducted do not cause the child any pain or harm.

The main inconveniencies of the study have to do with the time that will be spent with the baseline survey and the four follow-up surveys. If these surveys take up too much time, they can be paused or completed at a later time.

The interview personnel will treat to all the participants and their families with respect and participants' schedules will be accommodated as needed.

Possible Benefits

By participating in the study, you will gain the knowledge of the height and weight of your child and how their measurements compare with the average measurements for a child their age. Also, you have already received maize seed to plant for this growing season (2015).

You will not receive any payment for your participation. However, the purpose of the study is to obtain information to improve the nutrition of the women and children in your community and throughout your country.

If you decide not to participate

You are free to decide be part of the study or not. If you decide not to participate, this will not affect any other health or nutritional service that you normally receive. Any health personnel in your community know that you don't need to be a part of this study if you don't want.

Confidentiality

We will protect to the best of our ability all information and comments that you provide. The information will be strictly confidential and will be kept anonymous. All the information will be safely maintained in locked cabinets or into a secure computer with password access.

If data is shared with personnel not directly associated with the study, any names of communities and participants will not be included. Community and participant names will also not be used in project reports and publications.

Withdrawal from the Study

You can stop your participation of the study at any moment. If you do, this will not affect and community or health services that you normally receive.

Your Right as a Participant

The study has been reviewed and approved by the Ethical Committee of the INCAP. If you have any questions regarding the study or your rights as a participant, contact Lisa Eash from Semilla Nueva by telephone at 3162 6334 or the president of the Ethical Committee of the INCAP, Licda. Valentina Santa Cruz, by telephone at 2472 3762, extension 1142, between the hours of 8:00 am and 5:00 pm, from Monday to Friday. Any costs associated with your phone call will be refunded.

This agreement certifies that:

- ☐ I was invited to participate into the study, and agree with all information mentioned above in this form.
- ☐ I read this form, or this form was read to me aloud in Spanish, and I understand it in its entirety.
- ☐ I have spoken with the personnel of the project who explained to me the benefits and the risks of participating in this study.

I Understand

- ☐ I am free to accept or decline the invitation to participate.
- ☐ if I decide participate, I am free to change my decision later or to stop my participation. If I later decide to stop my participation, I will continue to receive the same health and community services.

I give my consent to participate in this study. I agree that the information provided about my family and myself will be revised and analyzed by members of the evaluation team, who will maintain confidentiality to the best of their ability.

I agree to participate in this study.

Name: ____

Date: ____

Witness

Name: ____

Date:____

Annex 2: Baseline Survey

Semilla Nueva

Instituto de Nutrición de Centro América y Panamá —INCAP —

NAME OF PROTOCOL: Study of the Effectiveness of Quality Protein Maize on Chronic Malnutrition in Guatemala

Baseline, 2015

Instructions: This form will be completed by project personnel by means of an interview with mothers that have given their informed consent to participate. If the mother has not given written informed consent, please **do not proceed with the interview.**

SECTION I: GENERAL INFORMATION

No.	Question	Answer
1	ID of the mother (assigned code) ID of the child (assigned code)	**# M______________________; Initials:** **# C______________________; Initials:**
2	Number of Health Card	#______________________; N/A:
3	Community Name:	
4	Place of Survey Administration:	1|__] Home 2|__] Health Center or Community Center 3|__] Project Headquarters 4|__] Other, Specify:
5	Date of Survey Administration	dd_________; mm:___________; year: 2015

SECTION II: DEMOGRAPHIC DATA (Survey Administered with the Mother)

No.	Question	Answer
6	What is your birth date?	a[__|__] day b[__|__] month c[__|__][__|__]year d|__]Doesn't know
7	What age are you?	1[__|__] years 2|__]Doesn't know

8	What is your marital status?	1|__]Married 2|__]Living with spouse 3|__]Single 4|__]Other, Specify:
9	ETHNIC GROUP	1[__| Indigenous 2[__| Ladina 3[__| Other, Specify:
10	Do you speak Spanish?	1|__]Yes; 2|__]No
11	What is your native language?	1[__| Spanish 2[__| Quiché 3[__| Ixil 4[__| Mam 5[__| Other; Specify:
12	What language was the interview conducted in?	1[__| Spanish 2[__| Quiché 3[__| Ixil 4[__| Mam 5[__| Other; Specify:
13	How many kids under five do you have? 13.1 Number of Children: _______	13.2 What ages are they? (LISTED YOUNGEST TO OLDEST) 1|__] _______ months 2|__] years_______; months:______ 3|__] years_______; months:______ 4|__]_ years_______; months:______
14	Do you have a job for which you receive a salary?	1|__]Yes; 2|__]No
15	Do you work in the field tending to crops, either to sell or for your own family's consumption?	1[__|Yes, I work in the field once per week. 2[__|Yes, I work in the field 1-3 days per week. 3[__|Yes, I work in the feld 4-7 days per week. 4[__|I don't work in the field
16	The house in which you live is...	1[__|your own house 2[__|a rented house 3[__|An apartment or rented room 4[__|Other, specify:
17	Main material of floor ANSWER BY OBSERVATION	1|__] Natural floor (dirt or sand) 2|__] Rustic floor (wooden) 3|__] Mud or clay bricks 4|__] Polished wood floor

		5[__] Mosaic or granite 6[__] Ceramic tiles 7[__] Cement 8[__] Other; Specify;
18	Main material of roof ANSWER BY OBSERVATION	1[__] straw/palm leaves 2[__] tile 3[__] sheet metal 4[__] asbestos metal 5[__] concrete/ceramic 6[__] other; specify:
19	Main material of wall ANSWER BY OBSERVATION (recycled material is considered: cartons, plastics, nylon, aluminum)	1[__] mud 2[__] adobe 3[__] block 4[__] sheet metal 5[__] wood 6[__] clay bricks 7[__] recycled material 8[__] other; specify:
20	Do they have electricity in the house?	1[__] Yes 2[__] No
21	What appliances do they have in their home? (MARK ALL THAT APPLY)	1[__]Corn mill 2[__]Radio 3[__]Television 4[__]Cable 5[__]House phone 6[__]Cell phone 7[__] Refrigerator 8[__]Blender 9[__]Washing machine 10[__]Microwave 11[__] Computer
22	Which of the following vehicles do they have in their home? (MARK ALL THAT APPLY)	1[__] Bicycle 2[__]Motorcycle 3[__] Car 4[__] Pickup Truck
23	The majority of the year, how is water supplied to the house? (MARK ALL THAT APPLY)	1[__] Piping that flows into the house 2[__] By truck 3[__] Outdoor public spigot that supplies water to various families 4[__] River, lake, gorge, or natural spring

		5|__] Well 6|__] Other; Specify:
24	What do you usually do to purify or clean water for drinking? (MARK ALL THAT APPLY)	1|__] Boil 2|__] Add bleach 3|__] Solar cleaning 4|__] Nothing 5|__] Other: (specify)
25	¿What type of sanitary service do you have in the house?	1|__] Private toilet connected to a sewage system 2|__] Shared toilet connected to a sewage system 3|__] Toilet connected to a septic tank 4|__] Improved latrine (provided by NGOs) 5|__] Latrine, open pit 6|__] Does not have sanitary service 7|__] Other: (Specify)
26	What type of fuel or what do they usually use in their house to cook?	1|__] Propane gas 2|__] Kerosene 3|__] Electricity 4|__] Firewood 5|__] Charcoal 6|__] Agricultural residue 7|__] Other: (Specify)
27	Where is their kitchen located?	1|__] Inside the house, in the same room as where they sleep 2|__] Inside the house, in a different room from where they sleep 3|__] Separate from the house 4|__] There's no specific place for cooking, they make a fire outside the house.
28	How many people live in their home?	#___________
29	How many rooms for sleeping are in their home?	#___________

SECTION III: AGRICULTURAL PRACTICES

No.	Question	Answer
30	Do you or your husband work in agriculture?	1|__]Yes; 2|__]No
31	In the agricultural work you do, are you employed by yourself or by someone else?	1I__I ____________Self-employed 2I__I _____________Employed by someone else

32	Do you primarily work on your own land, on your family's land, on rented land, or on someone else's land without paying rent?	1[__] Own land 2[__] Family's land 3[__] Rented land 4[__] Someone else's land without paying rent 5[__] Other 6[__] Doesn't know
33	What size is the parcel or parcels in which you grow crops? USE THE UNIT EXPRESSED BY THE SURVEYEE Measurement unit:______________________ Size of the measurement unit in meters squared: ______________________	WRITE THE SIZE OF THE PARCELS IN CUERDAS, AS IT IS DESCRIBED BY EACH PERSON. ___ ___ . ___ ___ ___ . ___ ___ ___ . ___
34	Does your family have a vegetable garden for income or for family consumption?	1[__|Yes, mainly for income 2[__|Yes, mainly for home consumption 3[__|Yes, it produces enough for both sale and home consumption 4[__|No, we do not have a garden If they answered 1, 2, or 3, go on to the next question.
35	What type of vegetables grow in the family garden? MARK ALL THAT APPLY.	1[__| Tuber or root vegetables (carrots, beets, turnips, etc.) 2[__| Green leafed vegetables (lettuce, spinach, etc). 3[__| Medicinal plants ______________________ 4[__| Hierba mora / quilete / macuy________________________ 5[__| Amaranth ____________ 6[__| Chipilin ________________________ 7[__| Other native plants___________________
36	Does your husband work in the field tending to crops, either to sell or for your own family's consumption?	1[__|Yes, he works in the field once per week. 2[__|Yes, he works in the field 2-3 days per week. 3[__|Yes, he works in the field 4-7 days per week. 4[__|He does not work in agriculture

37	The land which you and your husband farms is owned by you or is rented?	1[__] Owned by them 2[__] It's their parents' land, they don't pay to use it 3[__]It's someone else's land but they don't pay rent 4[__]It's someone else's land and they pay rent
38	Do you raise animals in your house?	1[__]Yes 2[__]No
39	What animals? ¿Some other animal?	1[__]Chickens, hens or other birds kept in pens or barns. 2[__]Rabbits 3[__]Pigs 4[__] Goats or sheep 5[__] Cows or calves 6[__] Others; Specify:
40	¿What do you do with the animals you raise or the products they make? I.E. MILK, CHEESE, CREAM, BUTTER, MEAT, EGGS, ETC.	1[__]mainly for household consumption 2[__] mainly for sale 3[__] there's enough for sale and home consumption 4[__] Don't know
41	How often do you eat meat from the animals that you raise?	1[__]Everyday 2[__] More than 3 times per week 3[__] 2 to 3 times per week 4[__] Once per week 5[__] Once every 15 days 6[__] Once per month
42	Do your children eat the meat from the animals that you raise?	1[__]Yes 2[__] No
43	How often do you eat the products (milk, cheese, eggs, etc) from the animals you raise? ONLY NOTE THE PRODUCTS THAT WERE PRODUCED IN THE HOME	1[__]Every day 2[__] More than 3 times per week 3[__] 1-3 times per week 4[__] Once every 15 days 5[__] Once per month
44	Do your children eat the products from the animals you raise?	1[__]Yes 2[__] No

SECTION IV: HEALTH AND DIET OF THE PARTICIPATING CHILD

No.	Questions	Answers
48	1. Sex of the child 2. Birth date: 3. Age of the child: 4. Documentation of the child's age ("X" NEXT TO THE CORRESPONDING ANSWER)	1|__] Male; 2|__] Female dd:____; mm:_____; year_____ _________ months 1|__] Mother's report; 2|__] Health id card 3|__] Birth certificate
49	¿Has any medical personnel ever told you that your baby was born premature or was small for his or her age at birth?	1|__] a) Premature __________number of months born before due date; b) birth weight ______.____kg 2|__] a) Small, but was born around the due date); b) birth weight _____.____kg 3|__]Not premature or underweight at birth 4|__] Doesn't know
50	Has any medical personnel ever told you that your baby has a chronic illness?	1|__] Yes, specify: 2|__] No
51	In the past two weeks, how your child's health seemed?	1|__] Apparently healthy (without symptoms or signs of illness) 2|__] Right now he or she is recovering from an acute illness that took place in the past two weeks (diarrhea, fever, cold, etc.); 3|__] He or she has had an illness for more than the past 3 weeks (diarrhea, vomiting, cough, etc.)
52	Which of the following options best describes how you feed your baby?	1|__] Breast feeding 2|__] Liquids 3|__] Formula 4|__] Solid foods
53	Do you currently breastfeed your child? REFERS TO MOTHER'S MILK IN THE LAST 24 HOURS	1|__] Yes, 2|__] No →
54	Do you remember how many times you breastfed your child yesterday?	# _____times in the day →

		#______times in the night →
55	At what age did you stop breastfeeding your child?	months
56	At what age did you start giving your child liquid or solid foods? REFERS TO THE FIRST TIME YOU GAVE YOUR CHILD LIQUID OR SOLID FOODS	1|__]First liquid: meses 2|__]First solid food: meses 3|__] Still has not given the child liquid or solid food
57	How many meals did your child receive yesterday? TAKE NOTE OF MEALS ONLY … Does not apply, due to illness 15A. SURVEYOR: COUNT THE NUMBER OF MEALS	1|__] breakfast 2|__] snack 3|__] lunch 4|__] snack 5|__] dinner 6|__] snack 7|__] does not apply No.:
58	If the child was sick yesterday, mark if he or she ate as he/she normally does	1|__] WAS SICK, DID NOT EAT NORMALLY 2|__] WAS SICK, BUT STILL ATE NORMALLY 3|__] WAS NOT SICK
60	Has your child's height been measured in the last 12 months?	1|__] Yes 2|__] No →
61	Where did they measure the child?	1|__] House 2|__] Community Center 3|__] Health Center 4|__] Hospital 5|__] Other
65	The last time they measured your child, did they explain the best way to feed or care for your child?	1|__] Yes 2|__] No 3|__] Doesn't remember
66	Has your child received vaccines from the health center?	1|__] Has received all the vaccines appropriate for his or her age 2|__] Has received vaccines, but not all those appropriate for his or her age 3|__] Has not received any vaccines
67	In the last week, has your child taken vitamins such as...	1|__] Iron sulfate

		2|__] Vitamin A 3|__] Folic Acid 4|__] Chispitas 5|__] ATLC (alimento terapéutico listo para consumo) 6|__] Other; Specify:
68	Does your family receive some sort of help such as food, income or money? MARK ALL THAT APPLY IN THE PAST 3 MONTHS	1|__] Financial assistance from the government 2|__] Vitacereal 3|__] Sponsorship programs from NGO 4|__] Hambre cero 5|__] Fertilizers 6|__] Remittances from family members in the USA 7|__] Other; Specify: 8|__] None of the above 9|__] Has not accepted any 10|__] Does not apply
69	Was there a celebration in your community yesterday?	1|__] Yes 2|__] No
70	Was there a celebration in your family yesterday?	1|__] Yes 2|__] No
71	71A Has your child had a fever in the past 2 weeks?	1|__] Yes 2|__] No 3|__] Doesn't know
	71B Has your child had a cough in the past 2 weeks?	1|__] Yes 2|__] No 3|__] Doesn't know
72	72A Has your child had diarrhea in the past two weeks?	1|__] Yes 2|__] No → 3|__] Doesn't know →
	72B Was there blood in your child's diarrhea in the past two weeks?	1|__] Yes 2|__] No 3|__]Doesn't know
	72C When your child is sick do you give him or her more liquids, less liquids, or the same amount of liquids than when he or she is healthy?	1|__] The same 2|__] More liquids 3|__] Less liquids 4|__] Doesn't know

SECTION V: DIET DIVERSITY OF THE MOTHERS

No.	Questions	Answers
73	Yesterday did you eat inside your home or outside?	1[__] Just inside the home 2[__] Ate some food outside the home
74	Yesterday did you eat tortillas, tamalitos, corn products, oatmeal, bread, rice, pastas, or other grain-based foods?	1[__] Yes 2[__] No 3[__] Doesn't know
75	Yesterday did you eat squash, pumpkin, carrot or sweet potato (yellow or orange on the inside)?	1[__] Yes 2[__] No 3[__] Doesn't know
76	Yesterday did you eat potatoes, yuca, taro, or other root vegetables?	1[__] Yes 2[__] No 3[__] Doesn't know
77	Did you eat herbs or green leafy vegetables yesterday?	1[__] Yes 2[__] No 3[__] Doesn't know
78	Did you eat mango, papayo, or mamey yesterday?	1[__] Yes 2[__] No 3[__]Doesn't know
79	Did you eat any other fruit or vegetable yesterday?	1[__] Yes 2[__] No 3[__] Doesn't know
80	Did you eat liver, kidney, heart or other organs yesterday?	1[__] Yes 2[__] No 3[__] Doesn't know
81	Did you eat any meat such as beef, pork, lamb, goat, chicken, or duck yesterday?	1[__] Yes 2[__] No 3[__] Doesn't know
82	Did you eat eggs yesterday?	1[__] Yes 2[__] No 3[__] Doesn't know
83	Did you eat fresh or dried fish or shellfish yesterday?	1[__] Yes 2[__] No 3[__] Doesn't know
84	Did you eat any foods made with beans, peas, lentils, habas, peanuts, other nuts, or seeds yesterday?	1[__] Yes 2[__] No 3[__] Doesn't know

85	Did you eat cheese, cream, yogurt or other lactose products yesterday?	1|__] Yes 2|__] No 3__] Doesn't know
86	Did you eat foods prepared with oils, fats, mayonnaise, margarine, or butter yesterday?	1|__] Yes 2|__] No 3| __] Doesn't know
87	Did you eat sweets such as chocolate, candy, cake or cookies yesterday?	1|__] Yes 2|__] No 3__] Doesn't know
88	Did you use condiments such as chilis, spices, herbs, chicken broth, ketchup, mustard or tomato paste yesterday?	1|__]Yes 2|__] No 3| __] Doesn't know

SECTION VI: DIET DIVERSITY OF THE CHILD

No.	Questions	Answers
89	Yesterday, during the day and the night, did you give your child any food that was not liquid such as... READ OPTIONS	1 |__] cereals, bread, tortillas, rice, pasta, or other grain-based food 2 |__] Güicoy, carrot, sweet potato or other yellow or orange vegetable 3 |__] Potatoes, yuca, ichintal, or other root vegetable 4 |__] Herbs such as macuy, bledo, or other that is dark green 5 |__] Mango, papaya or other fruit that contains vitamin A 6 |__] Any other fruit or vegetable 7 |__] Liver, kidney, heart or other organ 8 |__] Any meat such as chicken, beef, pork, etc 9 |__] Eggs 10|__] Dried or fresh fish or shellfish 11|__] Beans, habas, lentils, peanuts, other nuts or seeds 12|__] Cheese, yogurt, other milk products 13|__] Foods made with oils, fats, or butter 14|__] Sweets such as chocolate, candy, or baked goods 15|__] Condiments such as chili, spices or herbs 16|__] Does not apply

90	During yesterday and last night, did your child drink any liquid from a bottle?	1|__] Yes 2|__] No 3| __] Does not know

SECTION IX: ANTHROPOMETRICS OF CHILD AND MOTHER

No.		**Child**	
	Measurements:	#1	#2
101	Weight (0.1 kilograms)		
102	Height (0.1 cm)		
103	Observation: Weight taken with 1) MINIMAL CLOTHING 2) USUAL CLOTHING		
104	WEIGHT OF THE CLOTHING (KG)		
105	Equipment used for anthropometrics 105.1 Balance 105.2 Height board	1|__]Balance: assigned code:__________ 2|__]Balance different than one assigned for the project (Specify in the observations why it is different) 1|__] Height board: Assigned code _________ 2|__] Height board different than the one assigned for the project (Specify in the observations why it is different)	
106	Relevant observations: 1|__] Yes;	2 ___ If not, skip to question 107	
107	Date of interview: Surveyor:	dd________ mm_________ year 2015 ID: Name:	

Consumption Frequency Questionnaire for Mother and Child

DATE:		**Participant ID**	

Interview will be carried out by study personnel.
INSTRUCTIONS FOR THE FAMILY: We want to ask questions about what you and your child have eaten in the past week. For every food mentioned, please tell us how many times you and your child have eaten it in the past week.

Food or Drink		**Mother**	**Child**
1. Tortilla			
2. Tamalito			
3. Incaparina			
4. Meat (beef, lamb, pork, organs)			
5. Rabbit meat			
6. Chicken			
7. Fish			
8. Eggs			
9. Cow's milk			
10. Milk (goat or other)			
11. Cheese			
12. Pigeon pea			

Weight of an average tortilla in the house (g):	

Annex 3: Follow-Up Survey

Semilla Nueva

Instituto de Nutrición de Centro América y Panamá —INCAP —
NAME OF PROTOCOL: Study of the Effectiveness of Quality Protein Maize on Chronic Malnutrition in Guatemala

Follow-up questionnaire, 2015

SECTION I: GENERAL INFORMATION

Question	Question	Answer
1	ID of the mother (assigned code) ID of the child (assigned code)	**# M______________________; Initials:** **# C______________________; Initials:**
2	Number of Health Card	**#______________________;** N/A:
3	Community Name:	
4:	Place of Survey Administration:	1|__] Home 2|__] Health Center or Community Center 3|__] Project Headquarters 4|__] Other, Specify:
5	Date of Survey Administration	dd________; mm:__________; year: 2015

SECTION II: HEALTH AND DIET OF THE PARTICIPATING CHILD

No.	Question	Answer
6	1. Sex of the child 2. Birth date: 3. Age of the child: 4. Documentation of the child's age ("X" NEXT TO THE CORRESPONDING ANSWER)	1|__] Male; 2|__] Female dd:____; mm:_____; year_____ _________ months 1|__] Mother's report; 2|__] Health id card 3|__] Birth certificate

7	In the past two weeks, how your child's health seemed?	1|__] Apparently healthy (without symptoms or signs of illness) 2|__] Right now he or she is recovering from an acute illness that took place in the past two weeks (diarrhea, fever, cold, etc.); 3|__] He or she has had an illness for more than the past 3 weeks (diarrhea, vomiting, cough, etc.)
8	Which of the following options best describes how you feed your baby?	1|__] Breast feeding 2|__] Liquids 3|__] Formula 4|__] Solid foods
9	Do you currently breastfeed your child? REFERS TO MOTHER'S MILK IN THE LAST 24 HOURS	1|__] YES, 2|__] NO →
10	Do you remember how many times you breastfed your child yesterday?	# ______times in the day → #______times in the night →
11	At what age did you start giving your child liquid or solid foods? REFERS TO THE FIRST TIME YOU GAVE YOUR CHILD LIQUID OR SOLID FOODS	1|__]First liquid: meses 2|__]First solid food: meses 3|__] Still has not given the child liquid or solid food
12	How many meals did your child receive yesterday? TAKE NOTE OF MEALS ONLY … Does not apply, due to illness 12A. SURVEYOR: COUNT THE NUMBER OF MEALS	1|__] breakfast 2|__] snack 3|__] lunch 4|__] snack 5|__] dinner 6|__] snack 7|__] does not apply No.:
13	If your child was sick yesterday, mark if he or she ate as he/she normally does	1|__] WAS SICK, DID NOT EAT NORMALLY 2|__] WAS SICK, BUT STILL ATE NORMALLY 3|__] WAS NOT SICK
14	In the last week, has your child taken vitamins such as...	1|__] Iron sulfate 2|__] Vitamin A 3|__] Folic Acid 4|__] Chispitas

		5|__] ATLC (alimento terapéutico listo para consumo) 6|__] Other; Specify:
15	Does your family receive some sort of help such as food, income or money? MARK ALL THAT APPLY IN THE PAST 3 MONTHS	1|__] Financial assistance from the government 2|__] Vitacereal 3|__] Sponsorship programs from NGO 4|__] Hambre cero 5|__] Fertilizers 6|__] Remittances from family members in the USA 7|__] Other; Specify: 8|__] None of the above 9|__] Has not accepted any 10|__] Does not apply
16	Was there a celebration in your community yesterday?	1|__] Yes 2|__] No
17	Was there a celebration in your family yesterday?	1|__] Yes 2|__] No
18	18A Has your child had a fever in the past 2 weeks? 18B Has your child had a cough in the past 2 weeks?	1|__] Yes 2|__] No 3|__] Doesn't know 1|__] Yes 2|__] No 3|__] Doesn't know
19	19A Has your child had diarrhea in the past two weeks?	1|__] Yes 2|__] No → 3|__] Doesn't know →
	19B Was there blood in your child's diarrhea in the past two weeks?	1|__] Yes 2|__] No 3|__]Doesn't know
	19C When your child is sick do you give him or her more liquids, less liquids, or the same amount of liquids than when he or she is healthy?	1|__] The same 2|__] More liquids 3|__] Less liquids 4|__] Doesn't know
20		1 |__] cereals, bread, tortillas, rice, pasta, or other grain-based food 2 |__] Güicoy, carrot, sweet potato or other yellow or orange vegetable

	Yesterday, during the day and the night, did you give your child any food that was not liquid such as… READ OPTIONS	3 [__] Potatoes, yuca, ichintal, or other root vegetable 4 [__] Herbs such as macuy, bledo, or other that is dark green 5 [__] Mango, papaya or other fruit that contains vitamin A 6 [__] Any other fruit or vegetable 7 [__] Liver, kidney, heart or other organ 8 [__] Any meat such as chicken, beef, pork, etc 9 [__] Eggs 10[__] Dried or fresh fish or shellfish 11[__] Beans, habas, lentils, peanuts, other nuts or seeds 12[__] Cheese, yogurt, other milk products 13[__] Foods made with oils, fats, or butter 14[__] Sweets such as chocolate, candy, or baked goods 15[__] Condiments such as chili, spices or herbs 16[__] Does not apply
26	During yesterday and last night, did your child drink any liquid from a bottle?	1[__] Yes 2[__] No 3[__] Does not know

SECTION IX: ANTHROPOMETRICS OF CHILD AND MOTHER

No.		Child	
	Measurements:	#1	#2
101	Weight (0.1 kilograms)		
102	Height (0.1 cm)		
103	Observation: Weight taken with 1) MINIMAL CLOTHING 2) USUAL CLOTHING		
104	WEIGHT OF THE CLOTHING (KG)		
105	Equipment used for anthropometrics 105.1 Balance 105.2 Height board	1[__]Balance: assigned code:__________ 2[__]Balance different than one assigned for the project (Specify in the observations why it is different) 1[__] Height board: Assigned code _________ 2[__] Height board different than the one assigned for the	

		project (Specify in the observations why it is different)
106	Relevant observations: 1|__] YES;	2 ___ NO Skip to question 107
107	Date of interview: Surveyor:	dd_______ mm________ year 2015 ID: Name:

Consumption Frequency Questionnaire for Mother and Child

DATE:		**Participant ID**	

Interview will be carried out by study personnel.

INSTRUCTIONS FOR THE FAMILY: We want to ask questions about what you and your child have eaten in the past week. For every food mentioned, please tell us how many times you and your child have eaten it in the past week.

Food or Drink		**Mother**	**Child**
1. Tortilla			
2. Tamalito			
3. Incaparina			
4. Meat (beef, lamb, pork, organs)			
5. Rabbit meat			
6. Chicken			
7. Fish			
8. Eggs			
9. Cow's milk			
10. Milk (goat or other)			
11. Cheese			
12. Pigeon pea			