Micronutrient Powder Delivery Systems: Operations Research in Namutumba District, Uganda

Research Protocol

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SUMMARY

Introduction
In order to combat high rates of childhood anemia, the Uganda Ministry of Health is leading a process to research effective delivery mechanisms for micronutrient powders (MNPs). To support this goal, SPRING will conduct an implementation research study to assess the effectiveness and cost-effectiveness of two MNP delivery mechanisms implemented by the Ministry of Health (MOH) — facility distribution and community distribution—in Namutumba District. This work will be conducted in partnership with other implementers and evaluators in the country under the leadership of the MOH. Depending on final procurement, distribution is planned to begin in January 2016 and research will conclude with the 2016 endline survey around October.

Objectives
This research activity will use qualitative and quantitative methods to identify which of two MNP distribution methods in use in Namutumba is the most effective and cost effective in order to inform the development of a national MNP program. To achieve this objective, SPRING will develop country-specific evidence on the performance of two delivery mechanisms for MNPs, based on coverage of the district, adherence of target populations to use guidelines, and cost of delivering MNP to the target populations.

Methods
A cluster randomized design will be used to assess differences between the two delivery channels. SPRING will collect quantitative and qualitative data over nine months to inform implementation of the national pilot study. After three months of implementation, SPRING will conduct a round of qualitative interviews and focus groups to document challenges and successes of distribution. The study will conclude with a household endline survey that collects data on outputs of interest, including MNP coverage and adherence to MNP use by caretakers.

Data analysis and dissemination
Monitoring data will be analyzed monthly and shared with stakeholders to inform roll-out of the MNP distribution activities. Qualitative data will be analyzed for identification of key barriers and successes to inform program implementation, as well as to inform finalization of the endline survey. Upon completion of the household survey, research findings will be shared with key stakeholders in order to inform the development of a national MNP program in Uganda, as well as to add to the global evidence base regarding use of MNP.
INTRODUCTION

Background

Anemia is an important public health problem that affects almost half of all children worldwide (Stevens et al. 2013). Children with anemia experience long-term and irrevocable cognitive and developmental delays and exhibit decreased worker productivity as adults (Walker et al. 2007).

A number of vitamin and mineral deficiencies, most notably iron, but also others, such as vitamin A, B vitamins, and zinc have been found to result in anemia (Christian and West 1998; Koury and Ponka 2004; Sim et al. 2010; K. West, Gernand, and Sommer 2007). The World Health Organization notes that these micronutrient deficiencies often coexist (Micronutrient Initiative 2009). One promising strategy to ensure that young children are receiving adequate amounts of nutrient-rich food is to add micronutrient powders (MNPs) to their diets.

The World Health Organization (WHO) recommends distributing MNPs to children 6–23 months of age if the prevalence of anemia in a country is greater than 20 percent (World Health Organization 2011), recommending that the composition include iron, vitamin A, and zinc, with the option of additional vitamins and minerals at recommended nutrient intake levels.

Uganda has made great progress in reducing rates of anemia in children. Between 2006 and 2011, the prevalence of anemia in children 6–59 months fell by 24 percentage points, and it declined among all age subgroups. Despite these improvements, the prevalence of anemia among children remains high at 49 percent and, as it is common, the highest levels of anemia are found in younger age subgroups. To continue reducing anemia, Uganda will need to focus anemia reduction efforts on children 6–23 months of age.

Several attempts have been made to introduce MNPs in Uganda in the past five years. Following the regional UNICEF/CDC MNP workshop held in Lusaka, Zambia in 2012, the Uganda Ministry of Health initiated the most recent process to introduce MNPs in Uganda by establishing a micronutrient technical working group (MN-TWG) in July 2012. This group is comprised of representatives from UN bodies (REACH, UNICEF, WFP, WHO), USAID projects (Community Connector, SPRING, and Harvest plus), Uganda Health Marketing Group, Makerere University, and other development partners. The MN-TWG was tasked to further explore the potential for the introduction and rollout of MNPs in Uganda.

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1 In 2009, MNPs were recommended (but not implemented) as a way to curb micronutrient deficiencies observed in the chronically food insecure populations of the Karamoja Region. In 2011, another attempt to introduce MNPs was initiated by the Uganda Health Marketing Group (UHMG), which planned to market MNP through the private sector. Unfortunately, insufficient resources subverted implementation of the activity.
2 This group was originally founded by the USAID-funded project AFFORD and works to create high quality strategic health communication and accelerating health market growth in Uganda.
3 This MNP research is aligned with the Constitution of the Republic of Uganda (1995), the National Development Plan (NDP, 2010/11-2014/15), the Uganda Nutrition Action Plan (2011–2016), National Health Policy (NHP II, 2010), Health Sector Strategic Investment Plan (HSSIP, 2010/11–2014/15), the Public Private Partnerships for Health Policy (2011), the Infant and Young Child
The introduction has been organized in two stages. In the first stage, MN-TWG partners will undertake implementation research studies on MNP distribution in identified districts to gauge acceptability of MNP and document distribution options in eight pilot districts. Based on lessons from the MN-TWG pilot process, the second step will consist of the national introduction of MNPs, led by the MOH and in collaboration with other stakeholders. In preparation for the implementation research studies and eventual national programming, the MN-TWG participated in development of micronutrient policy guidelines, formation of a draft implementation framework, and implementation of formative research on MNP distribution in Uganda.

Formative research conducted by MN-TWG members with support from the University of British Columbia formed the basis for national branding of the MNP sachets for the Ugandan context. Additionally, the Centers for Disease Control and Prevention (CDC) provide support to MN-TWG research efforts, including design of a monitoring and evaluation (M&E) framework for the pilot. In Namutumba, the SPRING team conducted formative research to identify key messages for tailoring the communications strategy to key audiences. Separate distribution models exist in each of the districts to address the various questions posed by Uganda’s MN-TWG. Final results will be shared at the end of the study to provide joint recommendations to the MN-TWG and MOH.

**Statement of the Problem**

The prevalence of anemia among young children is considered a severe public health problem in Uganda as defined by the World Health Organization. The Uganda Ministry of Health is interested in implementing MNP at national scale. However, there is no data available on the most appropriate delivery platform to distribute micronutrient powders in the context of Uganda.

**Justification of the Problem**

There has been significant progress implementing MNP interventions globally, with 22 countries having tried their use by 2011 (M. E. Jefferds et al. 2013), ballooning to over 60 interventions in 43 countries by 2013 (Ruth Situma 2015). The Uganda Ministry of Health is exploring the introduction of MNPs as part of the government’s strategy to address high levels of anemia and micronutrient deficiencies in children 6–23 months. Despite the efficacy of MNPs, research into effective distribution methods is still needed to inform the government’s efforts, especially for sustaining coverage, since a number of studies showed short-term improvement on anemia-related indicators, but the gains diminished over time (Gibson, Ferguson, and Lehrfeld 1998).
Conceptual Framework

The SPRING conceptual framework (Figure 1) relies on the national-level support for the research agenda through providing the policy support necessary to implement the MNP pilot across the country (including Namutumba District). Basic training, mobilization, and orientation activities need to take place hand-in-hand with delivery of the MNP to distributors in Namutumba District to ensure that a firm groundwork is laid for the uptake of MNP via the two delivery arms. To measure the functionality of these activities, SPRING will rely on numbers that look at output indicators like MNP delivery and household knowledge. Without these pieces, the outcome of proper, regular consumption is not an achievable goal. Data collected throughout this process will allow the team to develop findings regarding comparative coverage, adherence, and cost-effectiveness across the two distribution arms.

LITERATURE REVIEW

Nutritional Interventions to Address Anemia

Anemia is caused by a multiple factors, most notably iron and other nutrient deficiencies, malaria, helminthes, other infectious diseases, and hemoglobinopathies (Balarajan et al. 2011).

Meeting the nutritional needs of young children is particularly important because their rapid growth results in higher nutrient requirements (Bhutta et al. 2008; Bhutta et al. 2013). There are several interventions to improve infant and young child feeding, including exclusive breastfeeding for the first six months of life, continued breastfeeding and appropriate introduction of diverse complementary foods with high vitamin and mineral content for children ages 6–23 months, provision of micronutrient supplements, and enrichment of staple and complementary food through fortification. In Uganda, as in many developing countries, the diets of children ages 6–23 months are usually inadequate for providing sufficient amounts of micronutrients. Children’s dietary patterns are often limited to plant-based foods with insufficient content of some vitamins and absorbable amounts of minerals. The inclusion of animal-source foods, good sources of those micronutrients that are low in plant-based diets, to fill the nutrient gap is often not feasible in low-income countries (Murphy and Allen 2003; Ruel et al. 2004).

Micronutrient interventions, particularly vitamin A supplementation, zinc supplementation, and large-scale fortification of foods with iron, folic acid, iodine, and vitamin A are among the most cost-effective global development efforts (Horton, Alderman, and Rivera 2008). However, few countries have effectively implemented iron and other micronutrient-delivering strategies for small children at scale.
Implementation is often hindered by low adherence and acceptance of supplements, supply issues, poor public-private sector partnerships, safety concerns, and weak health systems.

Uganda is currently implementing a number of interventions at the national and subregional level to ensure an adequately balanced diet in children through the promotion of dietary diversification, vitamin A supplementation through Child Health Days Plus (CDP), bio-fortification, and mass food fortification. While these interventions provide additional intake of micronutrients, none can fully address the iron and other micronutrient needs of children 6–23 months. Although fortified oil is widely consumed, fortified flours will not reach all children because of Ugandan’s low flour consumption and limited accessibility to fortified foods in rural areas (Kyamuhangire et al. 2013; A. West 2011). In addition, only seven percent of children 6–59 months age took iron supplements in 2011 (Uganda Bureau of Statistics (UBOS) and ICF International, Inc. 2012), making it unlikely that children will receive their required daily iron intake. Compounding these issues are the poor complementary feeding practices in Uganda that consist of infrequent feeding of low caloric, starch-based porridges by caretakers who have limited knowledge of infant and young child feeding practices.

A promising strategy when the coverage or efficiency of food based interventions are limited is using MNPs, which are mixed in the child’s food, in a strategy popularly called ‘point-of-use fortification’ or ‘home-fortification’. MNPs are packets that contain dry powder fortified with nutrients that can be added to any semi-solid or solid food to increase the foods nutritional value. On a global level, the efficacy and effectiveness of MNP to improve iron status and reduce anemia has been demonstrated through numerous studies in various settings, and many of these findings are summarized in the 2011 Cochrane Review by De-Regil et al (De-Regil et al. 2013). These studies have ranged in country and scale, testing the effectiveness and efficacy of the powers against other forms of micronutrient supplements. MNP were developed originally to treat anemia and iron deficiency, and now include various other nutrients depending on the needs of the community. The most common formulation of MNP currently used contains fifteen micronutrients, which provides one recommended nutrient intake of each micronutrient per dose for children ages 6-59 months (World Food Programme et al. 2011). MNP has proven to be a more effective method of micronutrient fortification than iron drops or syrups, even though the efficacy of the two treatments remains comparable (Zlotkin et al. 2003; Zlotkin et al. 2001). This is due to the decreased side effects and higher acceptability among children and mothers seen with the use of MNP. The MNP can be added to foods with little to no effect on color, taste or texture of the food, as opposed to the metallic taste of liquid iron supplements (Zlotkin et al. 2001).

On a global level, the efficacy and effectiveness of MNP to improve iron status and reduce anemia of young children has been demonstrated through numerous studies in various settings using formulations containing at least iron, zinc, and vitamin A (De-Regil et al. 2011). MNPs are safe and effective if implemented correctly and home fortification allows families to continue to use home-prepared or purchased complimentary foods as the basis for the child’s diet.
Delivery of MNPs

In 2002, the World Health Organization (WHO) and the United Nations Children’s Fund (UNICEF) issued a global strategy for Infant and Young Child Feeding (IYCF) to improve feeding practices (WHO 2015). The IYCF programming guide and framework has been updated since then, with a continuous effort to improve feeding practices at the community level. Key components of the IYCF strategy include improving knowledge and capacity for proper breastfeeding and complementary feeding techniques. Integration of IYCF and MNP programs is a potentially cost effective way to implement these two methods of increasing child nutrition and health.

Some programs have successfully integrated the distribution of MNP into existing nutrition programs. These interventions take advantage of established networks and distribution channels to help get MNPs to families in need with some using both distribution centers and community health workers to supply the product to mothers (Loechl et al. 2009; Hyder 2004). The combination of quality service delivery and effective behavioral change communication strategies are considered ideal platforms to ensure MNP interventions reach the community (Loechl et al. 2009; Olney, Rawat, and Ruel 2012; Sun et al. 2011; UNICEF and CDC 2009). The use of Child Health Days (CHD) to provide multiple services to children at one point in time have been increasing over the past decade, and can help countries achieve high and equitable coverage of essential health and nutrition services (Palmer et al. 2013).

A study in Bangladesh found health workers preferred integrated MNP distribution (Hyder 2004). In Niger, many community members voiced a preference for delivery through pharmacies and health centers, since they trusted these locales to have non expired products, keep a stable and fair price, and provide additional counseling to mothers on child feeding and nutrition (Tripp et al. 2011). A study in Kenya showed the use of community vendors and whole-sale MNP distribution offices led initially to unbalanced access to the MNP packets as well as resale in the community by untrained vendors (Suchdev et al. 2010).

Communications strategies should ideally involve inter-personal communication as well as possible print materials and messages delivered through the media (UNICEF and CDC 2009). The WHO recommends that MNP programs should include a behavior change communication strategy to integrate the MNP use with other nutritional programs (Lazzarini 2013; De-Regil et al. 2011). This recommendation is supported by the current literature found on delivery strategies of MNP, and multiple studies have seen positive results from this combination of interventions (Loechl et al. 2009; Hyder 2004; Olney, Rawat, and Ruel 2012; Sun et al. 2011; UNICEF and CDC 2009; Suchdev et al. 2010; Osei et al. 2014). Including easily-referenced information for mothers and caregivers as part of MNP packaging was associated with increased correct use of MNPs (M. E. D. Jefferds et al. 2010).

Mothers were typically pleased with the preparation and effects of the MNP product, with concerns around side effects negated by including warning of possible side effects in preparation and feeding instructions (Loechl et al. 2009; Osei et al. 2014). Provision of instructions prior to distribution of the MNP, as well as reminders at a distribution centers or from health workers, increased caretaker satisfaction with the product (Osei et al. 2014). Across studies, repetition and multiple sources of instructions appear to yield higher satisfaction among caregivers.
varied across communities and should be tailored to each MNP intervention (Osei et al. 2014; M. E. D. Jefferds et al. 2010).

Willingness to pay for MNP was touched on briefly in some studies, all showing that mothers were amenable to paying for this type of product. The amount mothers were willing to pay ranged from US$0.005 to US$0.05, which is good news since the estimated cost has been shown as US$0.02-0.03 (Tripp et al. 2011; Osei et al. 2014). Interviews and home visits have also shown that some families are already spending extra money to buy special foods (i.e. yogurt, eggs, beans, oranges) for their children and would be willing to put this money towards MNPs instead (Tripp et al. 2011).

**RESEARCH OBJECTIVES**

**General objective**

This research activity will use a randomized cluster design to assess the effectiveness and cost-effectiveness of two MNP delivery mechanisms implemented by the Ministry of Health (MOH) in Namutumba District to inform the choice of MNP delivery method for use in the national distribution.

**Specific Objectives**

Despite global use of MNPs, very little guidance is available to programmers interested in efficacy of various distribution methods or the costs related to implementation. This implementation study seeks to improve performance of the MNP delivery methods and provide country-specific evidence on:

1. Coverage and adherence$^4$ performance of two delivery mechanisms for MNPs: (1) MOH-supported health facilities and (2) VHTs in the community.
2. Cost analysis and a cost-effectiveness comparison between two MNP delivery channels.

**METHODOLOGY**

To address its two research questions, the SPRING team will pursue a two-pronged research methodology. The first prong will address Objective 1, using a regular monitoring, a qualitative midline, and a quantitative endline to describe coverage of and adherence to MNP consumption regimens. Additionally, costing data will be collected regularly throughout the planning and distribution period to address Objective 2. Data for both objectives will be collected jointly to answer questions of effectiveness and cost-effectiveness. Implementation of the two delivery methods is randomly assigned by subdistrict (see “Randomization of subcounties” below), while outcomes will be determined at the household and individual levels. Data collection will rely on a continuous, monthly stream of routine monitoring data collected at the household level, in addition to qualitative data collected during a

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$^4$ Coverage means percent of eligible children who have received a box of MNP during the study. Adherence refers to receipt and use of the MNP in line with guidelines for proper consumption. See “Study Variables” for more information on the types of coverage and adherence measured.
midline exercise, and quantitative data collected at midline. In addition, SPRING will rely on program records to estimate total costs.

To better address the research questions, data collection teams will include Global Positioning System (GPS) coordinates each time that data are collected. The integrity of this study design and finalization of data collection tools rely on collection of regular and quality monitoring data throughout the entire study period. These data will be shared by monitoring staff regularly to ensure the whole team is aware of the progress of implementation.

**Study Design**

Following a cluster randomized design, this study will compare outcomes between individual children and households residing in a subcounty randomly assigned to one distribution method and individual children and households randomly assigned to another distribution method. The MOH’s implementation will follow two distinct distribution plans (see Figure 2), which SPRING will track to compare costs and program process and outputs (coverage and adherence) over a nine-month implementation period. During this implementation, caregivers will receive MNP for all children 6-23 months of age, and caretakers will be encouraged to add one MNP sachet every two to three days (three to four times per week), with no more than one sachet given per day per HFTAG and the Uganda MN-TWG guidelines (World Food Programme et al. 2011). The MNP formulation will also follow HF-TAG and the Uganda MN-TWG recommendations of providing 15 vitamins and minerals at the recommended nutrient intake (RNI) doses (World Food Programme et al. 2011).

*Figure 2: MNP Distribution Diagram*
Implementation Arms

In the health facility arm, MOH staff in all health centers II-IV will distribute MNP to eligible children who come into the facility. Additionally, facility-organized outreaches (immunization, nutrition assessment, etc.) will incorporate MNP distribution and counseling into their activities. In the community arm, it will be VHTs, instead, who are distributing the MNP to eligible children in their villages. These two distribution modes are assigned randomly to each of the six subcounties in Namutumba district, and are described below in more detail.

**Health facility arm:** Health workers play an active role while VHTs take a passive role. This approach mimics the routine VHT / health worker interaction routinely applied on HIV / ART and MNCH programs and will be used in Namutumba, Kibaale, and Magada subcounties.

*Health worker active roles:*
- To receive and store MNPs at the health facility.
- Monitor MNPs stock movement and replenishment schedules using MNP stock tools and systems.
- Distribute MNPs to mothers of children 6-23 months during routine clinic visits and outreaches.
- Include MNP messages in IYCF counseling during routine visits and provision of MNP, including discussion of adherence and use.
- Provide nutrition assessment to children visiting health clinic to collect MNP refill, in line with current practices.
- Assess for adverse events and manage accordingly.
- Collect routine data using MNP tools and systems.
- Health assistants supervise VHT according to MOH routines, including discussion of MNP with caretakers.

*VHT passive roles* (these will be sensitized and not trained on the full MNP curriculum)
- During routine household visits, follow up with caretakers to remind them on their return dates, identify and report any adverse events, emphasize key messages, and prompt caregivers to collect and use MNP, following visit guide.
- Refer adverse cases to the health facility.

**Community arm:** VHTs play an active role while health workers take a passive role in distribution. This mode will be implemented in Bulange, Ivukula, and Nsinze subcounties.

*VHT active roles:*
- Maintain a list of eligible children in their community.
- To collect MNPs from the VHT coordinator / health assistant stationed at the health facility where MNPs will be stored.
- Distribute MNPs, MNP enrollment, adherence, and reminder cards to each eligible household according to the distribution schedule.
- Conduct monthly household visits to assess for adverse events, and manage and refer accordingly, emphasize key messages, address acceptability issues. Use of counseling guide.
- Collect routine data using MNP monitoring tools and systems.
- Report routine data to Health Assistants/M&E Assistants in a timely manner.
Site Selection

SPRING’s work will track implementation of the pilot in Namutumba, a rural district located approximately three hours from Kampala (see Error! Reference source not found.). Namutumba is one of the “1,000 Days” districts, and there are multiple ongoing activities focused on children between six and 23 months in the district. The MOH delivers services and interventions through health facilities. There are no hospitals in Namutumba, but the district does contain Health Centers IV-I.5 Community mobilization activities will be conducted to prepare communities for participation in the MNP pilot and distributing MNP to all children 6–23 months of age in the district.

MNP provision is only one part of a broader complementary feeding strategy in Namutumba District. Due to acute malnutrition epidemics in recent years, is a priority issue for district government and partners focused on ensuring that families have sufficient food to prevent similar episodes of malnutrition. As such, many partners are implementing various packages of infant and young child nutrition (IYCN) activities in the district. Existing MOH IYCN activities in Namutumba center on routine IYCN promotion, focusing mainly on exclusive breastfeeding. MNP distribution will include elements of IYCN training to provide messaging on the need to maintain continued breastfeeding, provide an adequate variety of foods, feed the recommended number of meals, and ensure adequate volume of food.

MNP programming will be folded into existing IYCN work in Namutumba. From 2013 to September 2015, SPRING focused on supporting the DHO to strengthen systems for promoting IYCN as per the 2010 WHO guidelines, especially in the context of HIV prevention. All activities used the MOH IYCN materials and job aids, which had been revised to follow NACS and the baby-friendly hospital initiative (BFHI).

5 Health Center IVs are at the subdistrict level and ideally have an MD on staff. Health Center IIIs are at the subcounty-level and ideally have an MD on staff but are often staffed only by a clinical officer. Health Center IIs are at the parish level and staffed by nurses. Health Center Is are located at the village level and consist of the volunteer health teams (VHTs); VHTs must be able to read and write.
Other IYCN and related activities in Namutumba are conducted in the entire district by the World Health Organization (WHO), Action for Development, Action AIDS, and the USAID-funded STAR-EC. The WHO recently started a project in Namutumba that will use Optifoods software to identify and develop complementary foods for Uganda based on locally available foods. This activity is expected to concur with the MNP pilot in Namutumba, and it is anticipated that the findings, along with SPRING’s operational research will produce results useful in guiding the direction of MNP formulation in the Ugandan context. Action for Development is supporting food security and livelihood projects among women’s groups in Namutumba that aim to increase access to foods. Action AIDS works to improve livelihoods and food security by offering training and improved agriculture technologies and high-value crops and animals. STAR-EC runs mother-to-mother groups that train women to mentor and provide peer support on a number of topics, including IYCF, in their communities.

Throughout the study SPRING will be in regular communication with Ministry of Health officials to identify any issues that may affect the supply of MNP to the study population. In addition, SPRING staff will be in regular communication with district officials to understand the evolving landscape of partners and programs working in Namutumba to identify any possible demand changes exogenous to the study. However, at the current time there are no other programs operating in Namutumba that are working in the area of MNP distribution or communication. To triangulate information shared through district and national health channels, SPRING will also be asking caretakers where they have received messages related to MNP distribution, both during the midline and endline activities.

**Malaria programming in Namutumba**

According to WHO guidelines, iron provision (including MNPs) should be implemented “in conjunction with measures to prevent, diagnose and treat malaria” (World Health Organization 2011). Current malaria control and prevention interventions in Namutumba are provided by MOH’s malaria control program, which includes distribution of long-lasting insecticide treated nets (LLINs), as well as community screening, identification, and referral of malaria cases to facilities by VHTs. Abt Associates conducted an indoor residual spraying program in Namutumba in 2015. Given the existence of malaria prevention and control programs in Namutumba, the MOH programming in Namutumba meets the WHO guidelines for MNP distribution in Uganda.

**Randomization of subcounties**

A randomized group design will be used to assess differences between the two delivery channels. SPRING staff and district health officials randomly divided the subcounties of Namutumba District into two groups for implementation of the two distribution arms. Subcounties were randomly assigned to either facility or community distribution arms in a raffle process that took place in November 2015. SPRING staff led twelve Namutumba District officials in the randomization exercise during a training-of-trainers (TOT) workshop. Each subcounty name was written on twelve pieces of paper and shuffled together, resulting in 72 (6*12) pieces of paper. Each of the twelve district participants chose one ballot from the group, with the ballots reshuffled between each choosing. One point was awarded per ballot

6 The MNTWG has approved the current MNP formulation, so any research findings suggesting a different formulation would have to go through a separate approval process before being put into place.
chosen. After all participants had chosen a ballot, the totals were calculated with the three highest scores assigned to the health facility arm. The final results of the randomization exercise are shown in Table 1.

Table 1: Results of subcounty randomization exercise

<table>
<thead>
<tr>
<th>Sub-county</th>
<th>Exercise score</th>
<th>Assigned distribution arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Namutumba</td>
<td>3</td>
<td>Health facility</td>
</tr>
<tr>
<td>Kibaale</td>
<td>3</td>
<td>Health facility</td>
</tr>
<tr>
<td>Magada</td>
<td>3</td>
<td>Health facility</td>
</tr>
<tr>
<td>Nsinze</td>
<td>2</td>
<td>Community based</td>
</tr>
<tr>
<td>Ivukula</td>
<td>1</td>
<td>Community based</td>
</tr>
<tr>
<td>Bulange</td>
<td>0</td>
<td>Community based</td>
</tr>
</tbody>
</table>

The community distribution arm (Bulange, Ivukula, and Nsinze subcounties) will implement the MNP program solely through VHTs, while the facility distribution arm (Kibale, Magada, and Namutumba—including Namutumba TC—subcounties) will distribute through health facilities only (see Figure 4). Orientation, mobilization, and training activities for the MNP pilot will take place district-wide, creating a strong enabling environment for both types of distribution. Additionally, orientations will take place at the national and district levels with partners and leaders to introduce the plans for the pilot in Namutumba and ensure buy-in from all key stakeholders.

Training for MNP distributors

Two types of trainings will ensure that all stakeholders receive an appropriate level of skills and knowledge for their role in the MNP pilot. Those with an “active” role in their subcounty will receive training on MNP supply channels and monitoring systems in addition to the basics of MNP use and benefits. In the facility-distribution subcounties this includes staff at health facilities who are in key clinics for reaching target children, as well as those involved in child health days and immunization outreaches. In the community-distribution subcounties, the active participants are identified VHTs from each village who will participate in distribution. Trainings will use training manuals and job aids developed by MN-TWG, approved by MOH, and tailored to the Namutumba implementation.

A shorter training program will be provided to those involved in “passive” roles for MNP programming: VHTs in the facility-distribution model and health facility staff in the community distribution model. This training will focus on basic knowledge and messaging around MNP to ensure that if approached with a question about MNP use, the trained person is able to promote the proper practices and know when and how to refer the MNP user for more information. This shorter training will also be provided to opinion leaders at the subcounty-level to ensure their participation in encouraging proper MNP use. Trainings will use training manuals and job aids developed by MN-TWG, approved by MOH, and tailored to the Namutumba implementation.
Communications Strategy for MNP

Social behavior change communication (SBCC) is a critical component of the pilot that will be used to improve child nutrition knowledge and skills, as well as to increase demand and motivation for improved complementary feeding practices. Due to the novelty of MNPs in Uganda, there is a strong need for stakeholder mobilization and sensitization at all levels of the system: national, regional, district, subcounty, and village. Using findings from the formative research, the MN-TWG has developed a community mobilization and communication strategy for MNP distribution. This strategy fits within the national SBCC for nutrition strategy, which is ongoing at the national level and was launched in November 2015. All national-level tools and materials are tailored for local settings.

The MNP communications plan has four broad objectives for ensuring effective uptake and proper use of MNP:

1. Creating an enabling environment for MNP use by promoting acceptance of MNP as an effective nutrition and health intervention and dispelling misconceptions and misinformation.
2. Ensuring reliable and user-friendly supply of MNP for caretakers, delivery of information with a patient and respectful attitude, and provision of proper instructions with confident responses to mothers’ questions and concerns.
3. Creating informed demand among caretakers and other family members.
4. Ensuring proper and safe use of the product at home, without displacing recommended IYCF and WASH practices.

The strategy includes community mobilization/sensitization meetings, development of communications and messaging materials, MNP counseling, and mass media efforts. The communications strategy will be implemented across the entire district, with generic messages around MNP use and encouraging people to collect the MNP from their health center or local VHT. Rather than belonging to one arm or another, the communications strategy aims to create a supportive enabling environment for MNP across Namutumba District.

Data collection framework

In order to appropriately track outcomes at the household and child level, SPRING will rely on a three-pronged approach of collecting regular monitoring data, qualitative data during a midline exercise in the third month of the study, and through a quantitative survey at the end of the nine month study. Additionally, SPRING will rely on program records to track MNP stock movement and costs related to the distribution of MNPs.

Assuming that distribution through MOH channels will begin in January, a qualitative review of the program will take place around April (after three months of distribution) and an endline survey in October (after nine months of distribution). Routine costing, qualitative, and quantitative monitoring will take place throughout the distribution period. SPRING will identify both direct and indirect costs of the MNP distribution through the addition of cost-related questions in qualitative and quantitative data collection tools, in addition to the collection and review of program cost data.
Figure 5: Monitoring and evaluation timeline

Monitoring MNP distribution in Namutumba

Basic MNP monitoring will mirror existing MOH systems so it can be easily incorporated and adapted to current systems when MNP distribution expands to other districts. In addition to the basic information collected through MOH forms and processes and available to the SPRING research team, SPRING will collect more detailed monitoring data to inform development of midline and endline data collection. This additional monitoring is specific to the research agenda and will not be continued during national roll-out, as it would be too burdensome for regular collection.

Through MOH forms and reporting systems, all entities receiving MNP will be responsible for documenting distribution in a way that mirrors existing stock tracking at the facility- and VHT-level, so distributors will already be familiar with the process. In addition, the forms developed by the MN-TWG mirror forms already in use by facilities, outreach teams, and VHTs so that training to use these forms correctly will not be burdensome. Health facility staff will record MNP distribution in a facility-based distribution log that details the name, age, and sex of the child, as well as indicating whether the child is a new MNP client or has received MNP before and how often, based on the information on the MNP child card, when available. At the community level, VHTs will record MNP distribution in a child register detailing the name, age, and sex of the child, as well as dates of each MNP distribution and type of counseling provided with the MNP.

Facility distribution logs will be summarized monthly and shared with district leadership, as well as SPRING staff for monitoring the distribution at the household level. Similarly, VHTs will summarize the child registers monthly, delivering the reports to the local health facility through normal reporting channels. From there, the report will be shared with district leadership and SPRING staff. The monthly summaries will include counts for each reporting facility/community of MNP boxes distributed to new and existing clients in the reporting period. SPRING and district staff will have access to these reports for basic program monitoring purposes on a monthly basis.

The research-focused monitoring that SPRING conducts, separate from the regular MOH monitoring, will consist of regular visits by SPRING staff to households throughout both distribution arms to conduct short data collection tools (Appendix 1). These visits will focus on use of MNP within the household,
feeding practices related to MNP, costs of accessing MNP, and coverage of the communications messaging. Through existing relationships and a formal monitoring system, SPRING will seek partner organization and institution feedback about the MNP distribution program to highlight difficulties with distribution or key areas of success that should be further explored in the mid- and endline surveys. These data will be used to ensure adherence with the research design. The findings will be included in final reports and shared with stakeholders to guide future implementation of MNP programs.

Through existing relationships and a formal monitoring system, SPRING will seek partner organization and institution feedback about the MNP distribution program to highlight difficulties with distribution or key areas of success that should be further explored in the mid- and endline surveys. These data will be used to ensure adherence with the research design. The findings will be included in final reports and shared with stakeholders to guide future implementation of MNP programs.

Study Population
The intended users of MNP are children in Namutumba District, aged 6-23 months, but proper delivery of the MNP will rely on a number of stakeholders across the district, all of whom will be part of this operational research study. Caretakers of eligible children will be the primary population for the data collection efforts, but SPRING will also include health facility staff and VHTs as MNP distributors. While the implementation was randomized at the level of the subcounty, the study outcomes of interest will be measured within these key populations, namely eligible children and household with eligible children.

Monitoring
SPRING will collect data regularly from selected households with eligible children (age 6-23 months) throughout both arms of the study in Namutumba district.

Qualitative
SPRING will conduct a qualitative midline assessment after two months of distribution of MNPs through facilities and village health teams commences. SPRING will collect qualitative data from selected caretakers of children age 6-23 months, VHTs, and health facility staff throughout Namutumba district to investigate reasons for use or nonuse of MNP by caretakers, as well as effectiveness of the communications strategy.

Endline
The endline survey will include caretakers of children age 6-23 months throughout Namutumba district.

Sample Size
Monitoring
Each parish will be visited for collection of monitoring data every other month, with one household selected per parish. Households with more than one eligible child will complete a checklist for each child. This means that each month, SPRING M&E Assistants will conduct 37 household checklists for a total of 333 monitoring visits over the course of the research period. The goal of the monitoring work to
identify any important issues of fidelity of research design, as well as to gather regular information regarding reach, use, and adherence, and costs related to MNP.

**Qualitative**
The assessment will consist of key informant (KI) interviews with non/low-user and regular/high user caregivers and focus group discussions (FGDs) with VHTs and facility health workers (HWs). As detailed below, SPRING staff will interview eight caretakers of children 6-23 months per distribution arm. Four of these will be non/low-user and four will be regular/high users. Additionally, four FGDs will be held with five to ten VHTs and HWs per distribution arm. In total, SPRING will conduct eight KII and 16 FGD or until saturation is reached.

**Endline**
Using a design effect of two, 95 percent confidence interval, power of 0.8, a 90 percent response rate, and assuming coverage rates of 60 and 70 percent for the facility and community intervention arms, respectively, the minimum sample size for each arm would be 793 children, for a total sample size of 1,586 (see Equation 1). A total of 40 clusters (census enumeration areas) will be sampled from each distribution arm, leading to total sample size of 1,600 (20 interviews per cluster).

\[
n = \frac{Z_{\alpha/2} \sqrt{\frac{Z_{\alpha/2}^2}{2} \cdot Z_{1-\beta}^2 \cdot (P_1(1 - P_1) + P_2(1 - P_2))}}{(P_1 - P_2)^2}
\]

*Equation 1. Sample size calculation formula*

*Formula from Gorstein et al. 2007.*

**Sampling Procedure**

**Monitoring**
Villages will be randomly selected from each parish in the SPRING office by population proportional to size (PPS) sampling. Once villages are chosen, SPRING staff will travel to each village, meeting with village leadership and VHTs to develop an up-to-date roster of eligible households in the village. From this roster, the M&E Assistant will use a random number table to select one household to visit. If there is not a respondent at home for that household, the M&E Assistant will travel to meet up with a respondent if they are within the village. If the respondent for the chosen household is not available to participate, the M&E Assistant will use the household roster to randomly select a replacement household. This will continue until the checklist is completed.

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7 These assumptions are based on other implementation experiences. Angdembe et al found mean adherence to MNP of 67% (among rural Bangladeshi children 6-23 months), and defined low vs. high adherence by a 70% cutoff (Angdembe et al. 2015). In Nepal, Mirkovic et al found that any consumption of MNP rose from 56.5% to 63.6% between three and fifteen months of MNP implementation that was added to existing IYCF frameworks (Mirkovic et al. 2013). The Bangladesh experience represents an intensive, community-based approach to MNP distribution, while the Nepal work included some facility-based distribution.
Qualitative
For each type of data collection, locations will be purposively selected for further selection of participants. Locations (villages, subcounties, or facilities) will be chosen by SPRING staff with input from the DHO offices to represent each of the following categories:

a. Rural area where access to health facilities is limited
b. Quasi-urban area where health facilities are relatively easy to access
c. Area where monitoring data suggests good coverage and adherence
d. Area where monitoring data suggests poor coverage or adherence

It is important to note that participating villages/parishes/facilities will be chosen in such a way as to ensure that there is no overlap. The reason for this is to ensure that a variety of experiences are represented in this data collection exercise and that participants do not perceive that they are being asked to correct information provided by other respondents.

Findings from this activity will be used to improve the messaging and communications materials, as well as distribution activities in the district. Some basic quantitative data will be collected to understand MNP distribution and use (i.e. number of sachets consumed within a household), but this survey will not be sampled to provide specific estimates of these indicators at the district or intervention level.

Key Informant Selection
SPRING research staff will conduct interviews with four KIs from each distribution model, chosen by SPRING staff according to the four categories above. Once villages are chosen, SPRING staff will use VHT registers to rank households in the village as high MNP users (report above average adherence and consumption) and low MNP users (report below average or no adherence and consumption), creating two lists per village. Note that the villages chosen for KIs should not be located within subcounties chosen for the VHT FGDs nor within the catchment area of facilities chosen for the HW FGDs. One household will be randomly selected from each list to participate in a KII. If the caretaker of the MNP eligible child is unavailable for the interview or does not consent to take part, a replacement respondent will be chosen randomly from the list until an available, consenting respondent is identified.

Focus Group Discussion Participant Selection: VHT
FGDs for the VHTs will take place in four different parishes per distribution model (eight communities in total). The communities should be chosen according to the sampling process described above; note that the subcounties chosen for VHT FGDs should not include villages chosen for the KIs nor facilities chosen for the HW FGDs. Once a parish is selected by SPRING staff, one VHT from each village will be chosen to participate in the FGD. This participation should be allocated randomly with the participating VHT chosen for each village by a simple method, such as a coin toss. Participation in the FGD should be understood as part of a research agenda, without any basis on performance of the participating VHT. If the chosen VHT is unavailable or unwilling to participate in the FGD, the second VHT from that village will be invited.
Focus Group Discussion Participant Selection: HW
Using the same four categories for selection as the previous qualitative data collection activities, SPRING staff will select four health facilities per distribution arm to participate in the focus group discussions. Note that the facilities chosen for HW FGDs should not include villages chosen for the KIIs in their catchment area nor be located in parishes chosen for the VHT FGDs. Up to 10 participants will be identified per facility, including staff from outreach services, clinics reaching target children and caretakers, and pharmacy/logistics staff.

Endline
The endline survey will be cross-sectional, population based, cluster sampled and representative of the target population of children 6 to 23 months of age in each distribution arm: facility and community. A multistage cluster sampling design will used to obtain representative data at the group level.

In the first stage of sampling, a total of 40 clusters per distribution arm will be selected using population proportional to size (PPS) sampling, which will provide a total of 80 clusters (enumeration areas) selected overall. The clusters will be selected from the 2014 Population Census sample frame. Based on the 2014 National Population and Housing Census Provisional Result Report (Uganda Bureau of Statistics 2014), SPRING estimates that there are 8,129 children 6 to 23 months of age among the 136,538 people living in Namutumba district.

The second stage of sampling includes conducting a census in each of the selected clusters to identify all households with children 6 to 23 months of age. Because of the small age range of the survey population, we assume it is more efficient and less costly to have small advance teams update cluster maps and carry out a census to identify, select and locate the selected children. At the first stage, enumeration areas will by defined by villages. The second stage of sampling will include a visit to the local council chairman (LC1) of the selected villages to obtain household listings. A line list of all children 6 to 23 months will be created and simple random sampling will then be carried out to select 20 children 6 to 23 months of age in each cluster. More than one child may participate from one household.

For the purposes of this selection procedure, a household is defined as “all people who have lived in the house for the past 6 months eating from the same cooking pot and intend to stay in the household.” A household will be considered eligible if a child between 6–23 months resides in the household, the child’s primary caretaker is present at the time of enrollment, and consent is provided. Data collection teams will be organized such that each team will complete one cluster each day by collecting data for a total of 20 children per cluster. In each cluster, households of selected children will be visited and mothers/caregivers will be invited to participate in the survey. Community mobilization and sensitization will be conducted at the subcounty level through meetings with key political, health, and nutrition leaders approximately one week prior to survey implementation.

Study Variables
To assess the effectiveness and cost-effectiveness of each distribution method, SPRING will rely on a series of quantitative and costing indicators. These key indicators, or variables, are defined below:
MNP coverage: Percent of eligible children in the intervention area who have ever received a box of MNP sachets during the nine-month study.

MNP repeat coverage: Percent of eligible children in the intervention area who have received the appropriate number of boxes of MNP sachets. The appropriate number of boxes of MNP sachets is one box per two months since the intervention began OR since the child turned six months old, whichever is smaller.

Adherence: Percent of eligible children whose caretakers report giving MNP:

- three to four times a week in the previous two weeks
- only once per day the last time MNP were given
- mixed into complementary foods the last time MNP were given

Total costs: Total direct, indirect, and fixed costs, including purchasing, transportation, storage, training, communication, routine monitoring, and others related to the distribution of MNP, by study arm.

Average costs of MNP distribution: Total costs divided by total boxes of MNP distributed.

Average costs per person of MNP coverage: Total costs divided by number of children who have received at least one box of MNP sachets.

Average cost per percent increase in MNP coverage: Total costs divided by percent of MNP coverage.

Average costs per person of MNP repeat coverage: Total costs divided by # of children who have received the appropriate number of boxes of MNP sachets.

Average cost per percent increase in MNP repeat coverage: Total costs divided by percent of MNP repeat coverage.

Average costs per person of MNP adherence: Total costs divided by # of caretakers who report giving MNP according to standards.

Average costs per percent increase in MNP adherence: Total direct and indirect costs divided by percent of MNP adherence.

Incremental cost-effectiveness ratio: \( \frac{\text{Arm 1 cost} - \text{Arm 2 cost}}{\text{Arm 1 output} - \text{Arm 2 output}} \), where “cost” refers to each of the average costs calculated and “outputs” refers to each of the MNP indicators listed above.

DATA COLLECTION

Training of research assistants

To ensure data quality, all data collectors will participate in at least five days of training with SPRING staff that includes methodological issues of data collection, as well as technical information regarding MNP distribution and use. Data collectors will be supervised during their period of performance, with
supervisors - overseeing interviews and/or performing spot checks. M&E Assistants are SPRING staff and data collection methods, including random selection of respondents, will be part of their onboarding procedure. KIIs and FGDs will be conducted by research staff trained in qualitative methods, as well as proper MNP use. Qualitative data collection teams will consist of at least two staff: the lead interviewer and a note-taker. This team will be trained together to understand their roles. Similarly, endline data collection teams will be trained in quantitative methods, including the use of the endline survey tool. All data collectors will be trained by costing consultants hired by the SPRING project to advise on this work and analysis. During data collector training the data collection teams will translate the English version of the questionnaire into the local languages used for data collection. This process will consist of the entire group of data collectors reviewing the tools question-by-question and suggesting translations to the group for each of the languages spoken in Namutumba district (Lusoga, Luganda, Rusiki, Lulamogi). As a group the data collectors will ensure they are in agreement with each proposed translation before proceeding to the next question. In addition the endline survey questionnaire includes a question about the language in which the survey was conducted.

**Tools**

**Monitoring**

The M&E Assistants will use the Household Checklist available in Appendix A: Household Monitoring Checklist to collect and report on monitoring data. The checklist will be administered at the household or a nearby location convenient to the respondent. As appropriate, community leaders, community health volunteers and other local health facility staff will help promote the data collection and explain the importance of the monitoring data to mothers. SPRING will secure all necessary permissions and carry out community mobilization as needed. Each M&E Assistant will travel with an introduction letter endorsed by the district chief administrative officer (CAO).

**Qualitative**

The KIIs and FGDs will follow the interview/FGD guides available in Appendix B: Midline Qualitative Data Collection Tools. These interviews and FGD will focus on key successes or challenges faced in the MNP distribution to identify areas for program improvement. Specifically:

- **KIIs with caretakers** will identify specific examples of barriers and enablers to MNP use, as well as how and why caregivers made choices regarding MNP use. Interviews will also explore caregivers’ thoughts on how to improve the uptake of MNPs in their communities. Key areas of investigation include:
  - What are the barriers to proper MNP use?
  - What are the enablers of proper MNP use?
  - What are the costs associated with MNP use?
  - Overall effectiveness of the community’s delivery mechanism.

- **FGD with VHTs and HWs** will focus on the following issues:
  - What are the barriers to proper MNP delivery and use?
  - What are the enablers of proper delivery and use of MNPs?
  - What are the key areas for improvement?
- What is the main feedback you receive from caretakers when you speak to them about MNPs?
- What are the costs associated with MNP delivery, distribution, and use?
- Overall effectiveness of the MNP delivery

All FGD and KII participants will sign consent forms for their participation (see Appendix C). Any FGD participant who does not provide consent to participate will be removed from the activity, and replaced with a similar representative. If the KI does not give consent to participate in data collection, the interview will end immediately and another respondent will be randomly selected for participation.

**Endline**

The endline household survey is based on the surveys used in other districts involved in the MOH pilot to ensure comparability of data, but this tool has been revised for the context of the Namutumba programming and SPRING’s other research objectives (see Appendix D). The standardized household based questionnaire, administered to the child’s mother or primary care giver, will gather information on household characteristics, demographics, micronutrient powder knowledge and practices, recent child morbidity, infant and young child feeding practices, diet, coverage of health services and exposure to additional interventions. Self-reported data of MNP use will be supplemented with direct counts of remaining MNP sachets in the household, when available. Households will answer additional questions about their experiences with the MNP and plans to continue use after the study period, including any costs associate with use of the MNP. The survey will also ask questions about where households obtained MNPs in order to document any spillover from other implementation methods. Multiple versions of the tool will be developed that are identical, except for the price points provided in question K14 regarding household’s willingness to pay (WTP) for MNP. Three different amounts provided for these questions will be developed and assigned randomly based on results from the qualitative data analysis. Each survey questionnaire will be clearly identified by a letter on the cover page, corresponding to the suggested amount in the WTP section of the questionnaire. This version indicator will be included in the final data analysis file.

The questionnaire will be administered at the household or a nearby location convenient to the respondent. As appropriate, community leaders, community health volunteers and other local health facility staff will help promote the survey and explain the importance of the survey to mothers. SPRING will secure all necessary permissions and carry out community mobilization as needed. Each data collection team will travel with an introduction letter endorsed by the district chief administrative officer (CAO). If any clusters have less than the target number of eligible children, then all eligible children will be approached for enrollment. There will be no replacement of children if less than the target number of children are available or if mothers/caregivers refuse to participate in the survey. There will be no replacement of clusters if community leaders refuse to participate in the survey or clusters are inaccessible due to natural disasters. It is assumed that the buffer included in an estimated individual response rate of 90% will address any issues of refusals or inaccessibility.
Pre-testing

In order to finalize these tools, SPRING staff will use results from monitoring data collected during the implementation to ensure any emerging issues are included in the guides. Additionally data collectors will pretest the tools during training to identify any needed updates. The first round of pre-testing will take place as data collectors are introduced to and walk through the tool during the first half of their training. In the second half of training, data collectors will proceed to local communities to test the KII and endline tools. The FGD interview guides will be pretested with a chosen group of health facility staff and VHTs. After pre-testing, data collectors will discuss any difficulties or confusion and suggest necessary edits before the tools are finalized. For the endline survey, the contractor will pre-test the questionnaire to finalize the instrument prior to data collection and share all suggested changes with SPRING for approval prior to finalizing the questionnaire.

Field editing of data and missing data

All data collection teams will be supervised by a data collection supervisor, responsible for daily review of the collected data. Any discrepancies will be discussed with the data collector and either addressed immediately or the data collection team will return to the participant for further clarification.

Monitoring data will be reviewed by supervisors on a rolling basis to identify any areas of concern, within one week of data collection. For the qualitative data collection, supervisors will review the notes from FGD and KII daily to ensure that any errors can be corrected and addressed in following data collection activities. During the endline data collection, questionnaires will be collected and reviewed by each of the team members before leaving the cluster. Any errors in completing the questionnaires will be corrected in the field. All questionnaires will be reviewed for consistency and completeness by the supervisor in the evening. Protocols on quality assurance will be followed, including enumerator standardization before data collection begins and equipment standardization before and throughout data collection.

DATA MANAGEMENT AND ANALYSIS

Data management

Notes taken from the semi-structured key informant interviews will be typed and saved as Microsoft Word files on the day of the interview. These files should be shared with the MNP research team as often as possible, preferably on a daily basis, depending on internet connectivity, to avoid loss of data. On occasions when permission is granted by the key informant, the interviews will be recorded, transcribed and saved on the day of the interview. Monitoring and endline data will be entered into data entry forms through Epi Info, version 7 (CDC, Atlanta, GA, USA) that only allow pre-set responses, prompting incorrect data to be reentered. A data dictionary will be developed that defines each of the variables and acceptable values. All monitoring and endline data will be stored and analyzed using Stata statistical package, version 12 (StataCorp, College Station, TX, USA).

Quality assurance will be an integral part of the study. It will include the following broad strategies:
- Recruiting of competent and experienced field team members
- Developing an FGD/KI guide for FGDs/KIs to ensure that all questions and themes are thoroughly explored with participants
- Developing detailed survey questionnaires for collection of high quality endline data
- Explaining the purpose of the data collection to all categories of participants
- Obtaining oral consent prior to data collection activities
- Adopting systematic procedures for data management.
- Providing adequate supervision during the data collection process to ensure that protocols and procedures are followed.

**Data Analysis**

Monitoring data will be analyzed on a continual, rolling basis, with monthly reports generated as data are entered into the system, with results shared no later than the 10th day of the following month. Unweighted results will be summarized as conditional and unconditional means, medians, and standard deviations (SD) for continuous variables and as frequencies for categorical variables.

Analysis of midline qualitative data will be based on a set of pre-identified topic areas that will form the basis for the midline report. In addition, the qualitative survey and monitoring data will be used to complement quantitative findings in the final report. Interview transcripts will be coded based on the pre-identified themes of interest.

For endline data, socio-demographic characteristics, health-seeking behaviors, and infant and young child nutrition practices of the study subjects will be summarized as conditional and unconditional means, medians, and standard deviations (SD) for continuous variables and as frequencies for categorical variables. All analysis will take into account the complex design of the survey using appropriate software. Data will be analyzed based on “intention to treat,” which is defined by residence in subcounties randomly assigned to one of the two distribution methods. Differences in MNP use and complementary feeding practices between intervention groups will be tested with the Pearson chi-squared test. Unobserved, potentially confounding variables at the individual, household and district/county/parish levels will be controlled for in a regression analysis. This is particularly important given that the design strategy is randomized at the subcounty and not household or individual-level. Cost data will be combined with data on acceptability, coverage, and adherence to determine the most cost-effective mode of delivery.

The key study outcomes focus on receipt and use of MNP, a product only available at the beginning of the study. Therefore, SPRING is confident that use of MNP is limited only to the study period and there will not be issues of previous use or prior knowledge to undermine the final results. Additionally, SPRING’s previous work in Namutumba included annual household surveys that looked at many socioeconomic and health-related characteristics across the district (Alexis D’Agostino et al. 2014, SPRING 2016, SPRING Forthcoming). These data were collected using the lot quality assurance sampling (LQAS) methodology, which allow for comparisons of sub-district results to the district average. These findings can be used in final analyses to control for intra-district differences.
ETHICAL CONSIDERATIONS

The study protocol is being provided to the Institutional Review Board at Makerere University School of Public Health. Once approval is received, the approved protocol will be submitted to the Uganda National Council of Science and Technology (UNCST) in Kampala for ethical approval. Letters of introduction will also be provided by the MOH in Kampala and endorsed by the CAO for use by field data collection teams.

All data collectors will receive written consent from participants in the FGDs or KIIs (see Appendix C) and verbal consent from caretakers participating in the household checklist or endline survey because of the minimal risk associated with the study (see data collection tools for notification of verbal consent). Participants who do not provide agreement to participate will not take part in the research activity. The data collected by SPRING will be kept confidential and will only be accessed by the research team members. Electronic data will be stored on password protected computers and all hard copies will be stored in locked file cabinets in the SPRING office. These data will be accessible only to the research team. No names of participants will be used in final reports without the consent or prior approval of respondents. Qualitative data will be attributed to participants only by identifying their respondent type (caretaker, VHT, etc), data type (FGD or KI), and description of their community (rural, VHT distribution, etc.) when relevant. Survey data will be reported only in the aggregate, no lower than subcounty level, to ensure respondents cannot be identified. GPS data will be used only to compute final results or describe coverage of MNP in the aggregate. No raw GPS coordinate data will be shared in final reports.

Perceived Risk
There is no perceived risk to participants. Data collected by the research activities are not sensitive in nature.

Potential Benefits
There are benefits associated with participation in the research activities including reduction of anemia among children 6-23 months and providing information that may be used to guide or improve rollout of the MOH MNP pilot.²

DISSEMINATING RESULTS

The dissemination of study results will be shared with policy makers, the districts that participated in the study, and the scientific community. Dissemination to the three key target audiences will occur as follows:

- As part of the M&E plan, regular progress reports on activity implementation will be prepared by the SPRING team and shared with MN-TWG, and district staff implementing the intervention to address problems and improve performance. These reports will address implementation

² For more detail on the proven benefits of MNP use see De-Regil et al. 2011, De-Regil et al. 2013, Zlotkin et al. 2003, and Zlotkin et al. 2001.
challenges and promote best practices. Summary bulletins on program implementation in each district will be prepared quarterly and shared in the coordination meetings. SPRING will participate in quarterly meetings with national- and district-level stakeholders to share regular updates on research findings and activities.

- Final results of the pilot will be documented and shared with MOH, district and other partners through a technical meeting in early 2017. These results, aggregated with final results from other pilot implementation partners, will be used to inform discussions regarding implementation, costs, and predicted outcomes of a scaling up plan in Uganda.

- SPRING staff will also develop articles for submission to peer reviewed journals that will focus on the lessons learned around delivery of MNP, and estimated costs of the two delivery strategies.

The study investigators will be responsible for ensuring the outcomes of the study are communicated effectively. Partner institutions and sponsors involved in this collaborative research will be acknowledged in all dissemination materials. SPRING staff will take the lead on publications, while co-investigators and other partners will have the opportunity to serve as authors on these publications. A person who qualifies as an author will not be included or excluded in publications without their permission in writing. To be included as an author one must have made a substantial scholarly contribution by being involved in one of the following: conception, design or implementation of the study, and/or analysis and interpretation of findings, and/or drafting or significantly revising reports or manuscripts.
REFERENCES


APPENDIX A: HOUSEHOLD MONITORING CHECKLIST

Instructions: Complete the following sheets with members of households with a child 6-23 months.

Subcounty: ____________________________________

Village: _________________________________

GPS Coordinates of household location:________________________

Date: _____________________________________

Enumerator: ________________________________

Ask to speak with the main caretaker of the child 12 to 23 months of age. Read the informed consent to the participant. If they give informed consent then proceed with the interview. If more than one eligible child lives in the household, complete a questionnaire for both children.

The USAID-funded SPRING Project and Ministry of Health would like to know about your experiences with Micronutrient Powders. Any information you provide that identifies you will be kept strictly confidential by the research team. Once information that identifies you has been removed, the remaining information you provide may be shared for additional review and analysis. Do you agree to take part?

Consent provided?    ________ Yes (continue questionnaire)

          ________ No (end questionnaire, proceed to next household)

Ask the following questions about child age 6-23 months:

<table>
<thead>
<tr>
<th>Use of Vitamin and Mineral Powder</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What is the age of [child]</td>
<td></td>
</tr>
<tr>
<td>2. How many boxes of Vitamin and Mineral Powder have you ever received for [child],</td>
<td></td>
</tr>
<tr>
<td>including the current one?</td>
<td></td>
</tr>
<tr>
<td>3. Do you have an enrollment card? Show an example.</td>
<td></td>
</tr>
<tr>
<td>4. Do you have a reminder card? Show an example.</td>
<td></td>
</tr>
<tr>
<td>5. Do you have a sticker? Show an example.</td>
<td></td>
</tr>
<tr>
<td>6. Where did you receive the most recent box of Vitamin and Mineral Powder?</td>
<td></td>
</tr>
<tr>
<td>1=Home, 2=outreach clinic, 3=Health facility, 4=None received</td>
<td></td>
</tr>
<tr>
<td>7. When did you receive the most recent box of Vitamin and Mineral Powder?</td>
<td></td>
</tr>
<tr>
<td>if they provide number of weeks or months, calculate number of days and write the answer.</td>
<td></td>
</tr>
<tr>
<td>8. How many sachets has [child] taken in the past 14 days (2 weeks)?</td>
<td></td>
</tr>
<tr>
<td>Yesterday counting back 2 weeks and/or mention dates</td>
<td></td>
</tr>
<tr>
<td>9. How many sachets remain in the box? Ask to observe the box of sachets</td>
<td></td>
</tr>
<tr>
<td>10. Do you know when to pick up the next box of MNP?</td>
<td></td>
</tr>
</tbody>
</table>

□ Yes
□ No
### Acceptability of Vitamin and Mineral Powder

12. If child has not taken any Vitamin and Mineral Powder, why not?  
   1=Does not like, 2=do not give it, 3=None received

13. Does [child] finish the food with the Vitamin and Mineral Powder added during the meal?  
   □ Yes  □ No

14. Does the child like the food with the Vitamin and Mineral Powder added to it?  
   □ Yes  □ No

15. What are problems have you had with [child] accepting the food with Vitamin and Mineral Powder added to it?  
   __________________________________________

16. Is the child eating the usual portion, more or less when the Vit./Min Powder is used?  
   1=Usual, 2=More, 3=Less

17. What changes have you noticed in your child?  
   __________________________________________

### IYCF Practices and Malaria Control

18. Did [child] breastfeed today?  
   □ Yes  □ No

19. Is [child]’s food separated from the food for the rest of the family?  
   □ Yes  □ No

20. Please show me with your hand approximately how much food the child eats.  
   6-12month child should receive almost a hand full; 12-23 month children should receive a full handful or more. Is the amount adequate?  
   □ Yes  □ No

21. Describe the type of food you last added the Vitamin and Mineral Powder to.  
   Is this the correct type of food? It should be soft, thick, and not too hot.  
   □ Yes  □ No

22. Did the child sleep under an ITN last night?  
   Ask to observe the ITN.  
   □ Yes, ITN observed  □ Yes, ITN not observed  □ No

### Exposure to Communications Campaign

23. Did you hear any MNP messages last week?  
   □ Yes  □ No

24. Where did you hear the MNP message?  
   Check any that apply.  
   a. Radio  
   b. Drama group  
   c. Video  
   d. Health worker  
   e. VHT  
   f. Community leader  
   g. Friend  
   h. Family member  
   i. Neighbor  
   j. Other: ______________

25. Any other comment or question?
APPENDIX B: MIDLINE QUALITATIVE DATA COLLECTION TOOLS

[See attached files]
APPENDIX C: CONSENT FORM FOR FGD AND KII PARTICIPANTS

Please read the information below, sign at the bottom, and return it to the SPRING research team. Objectives This research project is organized by the USAID-funded Strengthening Partnerships, Results, and Innovations in Nutrition (SPRING) Project. We are collaborating with the Ministry of Health to carry out research on the implementation of micronutrient powders (MNP) in Namutumba District. The results of this study will be used to help improve distribution of the MNP in Uganda.

You have been selected for this [interview/focus group discussion] by our staff because of your experiences with MNP. We would like to invite you to be part of this research and answer a few questions. You may take time to talk with others or think about whether or not you want to take part in the [interview/discussion]. You can also choose which questions to answer or not answer. If you do not want to participate, nothing will happen to you as a result.

Confidentiality
The information you provide will be kept strictly confidential and will not be shared with anyone other than members of our survey team. Once information that identifies you has been removed, the remaining information you provide may be used or shared for additional review and analysis. To collect information we will take notes and record during the discussion. Recordings will only be used to verify the final notes.

Potential Risks or benefits of this study
There are no foreseeable risks to you as a result of your participation. You can also refuse to answer any questions that may make you feel uncomfortable or embarrassed or ask to stop the [interview/discussion] at any time. Your views are very important and you may feel good about participating in the survey to help improve the situation of your community members.

Compensation
The [interview/discussion] will take about [45 minutes/one hour] to complete. While your views are very important to our research team, we will not provide you with any compensation for this time.

If you have any questions about the study, you can also contact our office listed on the paper given to you.

Consent to participate in data collection
I have read, or have had read to me, this form, which describes the research. My questions about this activity have been answered by the research team. I agree to be a participant in this survey.

Date Interview Location Participant’s Signature for Consent OR Thumb print and Signature of witness

Contact Information for the SPRING MNP Study
Alexis D’Agostino (MPP): SPRING Project. Email for corresponding researcher: adagostino@jsi.com.
Henry Wamani (PhD): Makerere University School of Public Health, Kampala, Uganda

Questions and contact
To reach the research team conducting this study, please contact the SPRING Project: Plot 10. Budongo zone, Muyinda Road, Budongo Village, Namutumba District. Tel 0392-177-916.

For any questions on the IRB review of this study, please contact Dr. Suzanne Kiwanuka Chair of the School of Public Health, Research and Ethics Committee, Makerere University College of Public Health, P.O. Box 7072 Kampala, Uganda, Tel: 0393 291397/ 0701 888 163.
APPENDIX D: ENDLINE DATA COLLECTION TOOL

[See attached file]
APPENDIX E: CONSENT FORM FOR ENDLINE PARTICIPANTS

Please read the information below, sign at the bottom, and return it to the SPRING research team.

Objectives
This research project is organized by the USAID-funded Strengthening Partnerships, Results, and Innovations in Nutrition (SPRING) Project. We are collaborating with the Ministry of Health to carry out research on the implementation of micronutrient powders (MNP) in Namutumba District. The results of this study will be used to help improve distribution of the MNP in Uganda.

You have been randomly selected by our staff to participate in this survey. We would like to invite you to be part of this research and answer a few questions. You may take time to talk with others or think about whether or not you want to take part in the survey. You can also choose which questions to answer or not answer. If you do not want to participate, nothing will happen to you as a result.

Confidentiality
The information you provide will be kept strictly confidential and will not be shared with anyone other than members of our survey team. Once information that identifies you has been removed, the remaining information you provide may be used or shared for additional review and analysis.

Potential Risks or benefits of this study
There are no foreseeable risks to you as a result of your participation. You can also refuse to answer any questions that may make you feel uncomfortable or embarrassed or ask to stop the [interview/discussion] at any time. Your views are very important and you may feel good about participating in the survey to help improve the situation of your community members.

Compensation
The survey will take about one hour to complete. While your views are very important to our research team, we will not provide you with any compensation for this time.

If you have any questions about the study, you can also contact our office listed on the paper given to you.

Consent to participate in data collection
I have read, or have had read to me, this form, which describes the research. My questions about this activity have been answered by the research team. I agree to be a participant in this survey.

Date Interview Location Participant’s Signature for Consent OR Thumb print and Signature of witness

Contact Information for the SPRING MNP Study
Alexis D’Agostino (MPP): SPRING Project. Email for corresponding researcher: adagostino@jsi.com.
Henry Wamani (PhD): Makerere University School of Public Health, Kampala, Uganda

Questions and contact
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For any questions on the IRB review of this study, please contact Dr. Suzanne Kiwanuka Chair of the School of Public Health, Research and Ethics Committee, Makerere University College of Public Health, P.O. Box 7072 Kampala, Uganda, Tel: 0393 291397/ 0701 888 163.
APPENDIX F: TRANSLATED CONSENT FORM

EBIGEMAGANA KUKWIKIRIZAGANIA KWA FGD NI KII ABENIGIRAMU

Nkusaba okusoma ebigemegana kubiino ghansi, ghandika amaina oteku omukono kulupapula luno era olwiizeyo ku spring

EBIGENDELERWA

Kuno okunonenkereza kwe kitongole Kwa tegekeibwa aba USAID Kwa tebwamu sente era kwaigumiza okukolera aghalala ebivamu no kwiwabuliriza mururungo (SPRING)

Iffe tulikolera ghalala nekitongole kye byo bulamu okukola okunonenkeleza kwe enkozeesa eye’byobilungo obwobuwinga (mnp) mu Namutumba disutirikit. Ebiva mumusomo guno bidha kukozeebwa okuyamba okwongera okusansania Kwa MNP mu Uganda, olondeibwa nabakozi baife okwetaba mukunonenkereza kuno .Twidha kwenda okukwaniriza obe omu kwiife kukozenekereza kuno era oilemu ebibuzo ebitontono .Oyinza okutwala akaile okwogera nabandi okusobozesa okulowoza oba oyinza okwenda okwetaba mukunonenkereza oba tiwandyewe. Osobola okulonda ekibuzo ki ekyokwilamu oba no butailamu ezira kidha kumuuka nibwooba’nga tiwenigiire mu kunonerezu kuno.

EBIKUMIBWA NGA BYAKYAMA

Amaliifa googya okugha gaga kumubwa nkani okusigala nga gayama, era ezira member nkani muna kibina yeena yeena ye bagya kuganhegeraku okutolaku oyo gwe tukakalabya naye omulimo guno Ogwokunonenkereza. Era amaliifa agakwogerak gatoolebwagho agasigaire gayinza okunhanhibwanhanhibwamu nkani okugayizibwamu mungeri eyendhawulo neriso erye nkaliriza.

EBIGWA TIBIRAZE OBA EBIGANULWA MU MUSOMO GUNO

Eziila ebigwa tibilaze ebyalengerwagho ebiiyinza kukutukaku oluvainuma lwokwetaba mumusomo guno.

Era ighe osobola okwegania ghaloba okwiiramu ekibuzo kyona kyona ekibuzibwa bwekibanga kikubisisa bubu, ooba oli ghaidembe obutetaba mukukubagania bidhubo kisera kyona kyona.

Ebidhuba byo bya muwendho inho era oyinza okughulira (mule) obulungi mubyokwetaba mukunonenkereza olwo kuyamba mukulongoosa embeera edha Bantu bomukitundu kyo.

OKULIYILIRA

Okukubagania ebidhubo kuno kwiidha kuba Kwa Danika 45 (Ana naitaanu)

Aye aghalala nokubanti ebidhuubo byo bya mughendo eri etiimu ekola kubokunonenkereza teidha kukusasula nkani okuligha obwire bwo bwomaze kumukuzi guno.

Wooba olina ekibuzo ku musomo oyinza okwidha kuyafesi yaiye eteleibwa kulupapula olukugheleibwa.
OKWIKIRIZA OKWETABA NO KUGHA OBWEYAMO MU KUKUNGAANIA AMALIIFA

Nsomye, mpuliire nga basoma obughandiike buno obwinhongola ku byo kunonenkereza.

Ebibuuzo byange kunsonga eno biiribwamu nabanonenkereza.

Nolwensonga eyo ngahye okwetaba mu kunonenkereza kuno

…………………………………                        ……………………………………       ……………………………………………………………

ENAKU, OMWEZI, NOMWAKA          EkiffoWEBAGEZESEIBWA          OKUTAKU

OMUUKONO,
O GWAGEZESEIBWA
MUKWIKILIZA
OBA EKINKUMU KYE
NOKUTAKU EKINKUMU
NOMUKONO GWO
MUNTU ABAILEWO

ENDAGILIRO NEBIGEMAGANA ELI OKUSOMA KWA SPRING (MNP)

Alex D’Agastino (MNPp) spring project email Eli omuntu gwemugemagana naye mukunonenkereza adagastino@jsi.com. Henry wamani (PhD) makerere university school of public health, Kampala, Uganda

EBIBUZO NENDAGILIRO

Okutuka Eli ekikunsu ekinonenkereza ku kusoma kuno, osoobola okukoza endagiliro , the spring project plot 10 ekiketezo kye budongo, kulugudo lwa muyinda , Namutumba, olukomo 0392177916 Eli ebibuzo ku bakugu kukwiilamu okwetegereza mu kusoma kuno tukusaba ogemagane ni DR Suzanne kiwanuka akulila eisomero eligemagana nebyobulamu ebyabuli muntu.

Abanonenkereza nabaali kukakiko akebyo buwangwa, makerere university college eyo byobulamu ebyabuli muntu akasanduku 7072 Kampala, Uganda, olukomo 0393291397/ 0701888163
APPENDIX G: CVS OF INVESTIGATORS

[See attached files]