Feasibility and effectiveness of a delivery model for home fortification of children aged 6-24 months in rural Tamil Nadu, India: A pilot study

ICTPH NUTRITION INTERVENTION – PHASE I
DRAFT RESEARCH PROPOSAL

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Abstract

Child undernutrition including stunting, wasting, and micronutrient deficiencies is a leading cause of child mortality and morbidity in low- and middle-income countries. The period between 6 and 24 months of age is a critical stage during which nutritional deficiencies can cause deleterious and irreversible effects on a child's growth and cognitive development. Micronutrient deficiencies, particularly iron deficiency, have a direct impact on the nutritional status of children and are the leading cause of anaemia in non-malarial regions. The Indian National Health and Family Survey-3 conducted in 2005-2006, found that anemia among children less than three years of age is extremely widespread. Results from Tamil Nadu show that 72.7 percent of children aged 6-35 months of age are anaemic and the prevalence has actually increased from the NFHS-2 at which time 69.1 percent of this age group was anaemic. A successful short-term strategy to reduce IDA in children aged 6-24 months has been the use of Sprinkles home fortification powder. Despite the evidence of its effectiveness, research on the delivery of Sprinkles through a market-based model is limited. This study will seek to evaluate the process of delivery of Sprinkles through its sale at a rural micro health centre coupled with social marketing messages and education delivered through a system of community health workers called SughaVazhvu Guides and nurses. The coverage (sale and use) of Sprinkles will be quantitatively evaluated and qualitative data from surveys with caregivers of children aged 6-24 months will also be evaluated to identify potential bottlenecks and barriers in the delivery pathway. Secondary outcome measures related to mother's perceptions of child health and factors associated with compliance will also be analyzed. Blood hemoglobin levels will also be measured and evaluated for those children whose caregiver purchases Sprinkles.

Background

Child undernutrition is a leading cause of child mortality and morbidity in low- and middle-income countries. Undernutrition represents a combination of deficiencies in protein, energy, and micronutrients which most commonly cause anthropometric deficits but can also lead to more severe effects depending on the duration and severity of deficit. Even mild undernutrition can increase a child's risk of mortality with worsening levels of weight-for-age, mortality rate increases logarithmically and case fatality rates for children with diarrheal disease or pneumonia (the two leading causes of under-5 mortality) is higher for undernourished children compared with well-nourished children (Merson et. al 2006). Nutritional deficits and subsequent impairments in child growth and development can affect school readiness and performance, employment potential later in life, and thus the potential of individuals to break from the cycle of poverty (Black 2008).

The period between 6 and 24 months of age is a critical stage during which nutritional deficiencies can cause deleterious and irreversible effects on a child's growth and cognitive development. Iron deficiency is considered to be the most common micronutrient deficiency in the world and anaemia is the most frequent clinical classification of this deficiency (Merson et al. 2006). Estimates of the global burden of anaemia range from 1.3 to 2 billion children, women, and men and approximately half of these cases can be attributed to iron deficiency. *Nutritional anaemia* includes not just iron deficiency, but also a deficiency of other vitamins especially folate, Vitamin A and Vitamin B_{12}. Studies have shown that infants with iron deficiency anaemia (IDA) score lower on tests of motor and mental development and are at-risk for long-term developmental disadvantages compared with non-anemic infants (Lozoff 1991). The Indian National Health and Family Survey-3 (NFHS) conducted in 2005-2006, found that anemia among children less than three years of age is extremely widespread. Results from Tamil Nadu show that 72.7 percent of children aged 6-35 months of age are anaemic and the prevalence has actually increased from the NFHS-2 at which time 69.1 percent of this age group was anaemic (NFHS 2005-2006).

Typically, in low-income regions the iron density of food is between 4.5-7.5 mg per 1,000 kcal and largely is composed of non-heme iron from grains, fruits, and vegetables, which is poorly absorbed (ACC/SCN 1992). Other reports suggest that, depending on the region, diets in India usually contain an adequate amount of iron (26 mg), but the absorption of iron is only 1-5 percent of this intake (ICMR 2000). Phytates in foods, tannins in teas, calcium in dairy products and greens, and animal protein from milk, cheese, yogurt and egg whites inhibits the absorption of non-heme iron (Merson et al. 2006).

When complimentary foods do not provide the recommended intake of micronutrients, research recommends micronutrient supplementation as a strategy to combat micronutrient deficiencies in children under five (Bhutta 2008). In non-malarial regions, iron supplementation for children of this age group can be used as an effective strategy to reduce iron deficiency anaemia and should be coupled with long-term strategies as well. The goal of iron supplementation is to restore normal levels of iron storage and hemoglobin levels (ODS NIH). Supplemental iron is available in two forms - ferrous and ferric. Ferrous iron salts are the best absorbed forms of iron with each type of ferrous iron salt containing a different amount of elemental iron available for absorption by the body - ferrous fumarate (33%), ferrous sulfate (20%), and ferrous gluconate (12%) (Hoffman 2000, ODS NIH). Iron supplementation for children can be delivered through a variety of methods including but not limited to iron drops, iron tablets, and microencapsulated powder. Conventional methods such as tablets and drops often have low adherence rates due to unpleasant side effects and difficulties with use however results have been inconsistent (Geltman 2009, Zlotkin 2001). Of these methods, microencapsulated powder has been a well-received and effective method to raise blood hemoglobin and reduce anaemia prevalence among children (Hirve 2006, Adu-Afarwuah 2008).

In India, national programs have attempted to tackle anaemia among the population. For instance, the National Nutritional Anaemia Prophylaxis Programme recommends routine iron supplementation (20mg) and folic acid (100mcg) for 100 days per year for children aged 6-60 months regardless of anaemia status (Pasricha 2009, Hirve 2006). However, due to practical difficulties, the system has failed to deliver as expected (Kapil 2002, Vijayaraghavan 1990). Likewise, iron drops are available through the Integrated Child Development System and Anganwadi Centres across India yet utilization is low (Nair 2009). Iron drops are often difficult to use, cause uncomfortable side effects, and have an unpleasant taste lending to their unfavorable use.

Sprinkles are a microencapsulated powder developed by Micronutrient Initiative which are a safe, easy to use, flavorless micronutrient powder that is added to complementary foods. The powder is contained in sachets and it is recommended that 60 sachets be used over a course of 60-120 days. Evidence has shown that a short course (60 days) delivery of Sprinkles Anemia Formulation (with 12.5 mg iron) effectively raises blood hemoglobin levels and reduces the prevalence of anemia among children for at least six months. Despite the evidence of its effectiveness, research on specific delivery models of Sprinkles is limited, especially in the Indian context. In order to ensure the feasible and effective delivery of a proven strategy to improve nutrition is achieved, research is needed to evaluate the effectiveness of a delivery model and identify potential bottlenecks and barriers in the delivery pathway.

This research will be beneficial to support efforts toward achieving both national and international targets to reduce child malnutrition in India. Further, results from this research are necessary to inform scalable programs to reduce child undernutrition both in Tamil Nadu as well as across other areas of rural India which are cost-effective, feasible, acceptable, and sustainable. Results from this research will be published and disseminated to beneficiaries in the participating community as well as the scientific community.

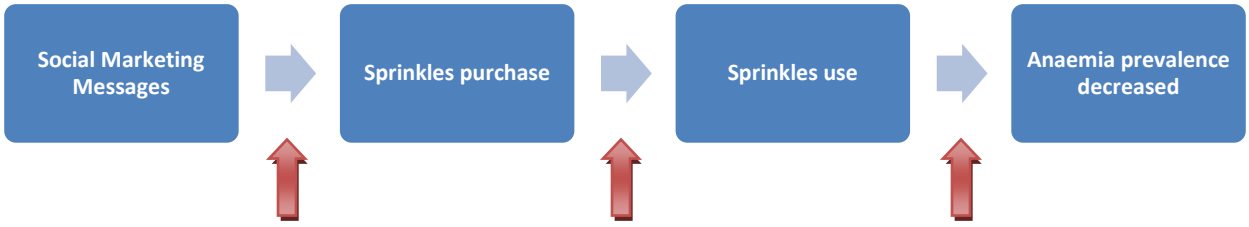
Disease Burden and Cost-Effectiveness

A review of studies utilizing home fortification of complementary foods with micronutrient powder found that in children under 2 years of age, hemoglobin levels increased 5.68 g/L (95% CI, 1.78–9.57) and iron-deficiency anaemia was reduced compared with controls (relative risk 0.54, 95% CI, 0.42–0.70) (Bhutta 2008).

Cost-benefit analysis has been conducted on the use of Sprinkles for children aged 6-12 months based off of data from the Sprinkles Pakistan Study (see Sharieff 2006). Computer modeling of the number of child febrile illness and diarrhea episodes as well as hemoglobin levels were used to conduct probabilistic analysis to view the impact of combined zinc and iron home fortification on lifetime earnings (Sharieff 2008). Results showed that when both direct and indirect costs are taken into account costs for children receiving Sprinkles ranges between $2.40-$108 USD ($10.51-$473.04 international dollars) and costs for children receiving placebo range between $0.3-$117 USD ($1.31-$512.46 international dollars) depending on risk level of the child. Home fortification with Sprinkles was found to be associated with higher lifetime earnings due to decreased mortality rates and higher IQ scores so that for every 10 million children reached by the nutrition intervention, there is a 95% chance that losses in earnings prevented by Sprinkles are in the range of $1.7 to $19.3 billion USD ($7.45 to $84.62 billion international dollars).

Theoretical Framework

Hypothesis: The distribution of Sprinkles through rural micro health centres coupled with social marketing and education activities is a feasible and effective means for reducing anaemia among children aged 6-24 months old.



This research will serve to assess potential bottlenecks and barriers at each stage of the above diagram.

Research has shown that social marketing techniques can be used to effectively incite behavior change and encourage health behaviors. Through these techniques, we assume that targeted messaging can be used to encourage the purchase and use of a nutritional home fortification powder which has been show to benefit the health of children 6-24 months of age.

Product Information

Sprinkles can be used both for the prevention and treatment of anaemia in children based on the Anaemia Formulation shown in Figure 1. Though it has been developed for children aged 6-24 months, it has been shown to be effective for children up to the age of 5 years without increased risk of toxicity. Sixty Sprinkles sachets should be distributed over the course of 60-120 days, however in areas where malaria is endemic, the short-course 60-day regimen is recommended. The provision of 60 sachets should be repeated every 6 months until a variety of mixed foods (containing iron and other micronutrients) are being eaten.

Micronutrient	Amount
Iron	12.5 mg
Zinc	5 mg
Folic Acid	160 µg
Vitamin A	300 µg RE
Vitamin C	30 mg

Figure 1: Sprinkles Anemia Formulation

Suggested use
Sprinkles can be easily mixed with a child's normal foods. The melting point of the lipid encapsulation is 60 degrees Celsius so it is recommended that food be cooled to below this temperature before mixing in the Sprinkles powder. Sprinkles can be put into liquid, but the capsules will not mix and will float on top.

Potential side effects
Stool consistency does not change in the majority of infants and children receiving Sprinkles but stool color often changes to a dark or black color in all infants receiving Sprinkles on a regular basis. Some very young infants who have not previously been exposed to any complementary foods containing micronutrients may develop loose stools or even mild diarrhea. The diarrhea does not lead to dehydration, but is a valid concern to parents and health care providers. The diarrhea lasts for approximately one week and then will not recur. Parents have reported that diarrhea quickly disappears in these young infants, who are transitioning from breastfeeding to complementary feeding, if 1/3 - 1/2 of a Sprinkles sachet is used.

Loose stools may be caused by a change in bowel flora (microorganisms) associated with the introduction of iron into the diet or possibly the impact of ascorbic acid on bowel peristalsis in infants, who previously had received only very small amounts of ascorbic acid in their diets (in breast milk). Since loose stools have only been observed in infants transitioning from exclusive breastfeeding to complementary feeding, loose stools may possibly be unrelated to Sprinkles, and instead related to the change in stool pattern with the introduction of complementary foods. Likely, the microencapsulation of iron and presence of food during Sprinkles intake accounts for the fewer and less severe cases of diarrhea and constipation than other iron supplements.

There is no elevated risk of Vitamin A toxicity in children receiving Sprinkles as well as a twice yearly Vitamin A supplement. Children with thalassemia trait are not at a greater risk of complications with additional iron in the diet and iron supplementation will neither correct nor improve anaemia due to this trait. In children with iron deficiency and thalassemia, iron supplementation will improve blood Hb levels to a certain point and then will level off.

Research Objectives

To evaluate the feasibility of combining social marketing with the activities of a local health centres and community health workers to promote the sale and use of Sprinkles micronutrient powder in rural Tamil Nadu and its effectiveness on reducing the levels of anaemia among children aged 6-24 months.

Primary objectives:
- Evaluate the feasibility of distributing Sprinkles through rural micro health centres.
- Monitor Sprinkles coverage (sales and use).
- Assess caregiver's perceptions of the delivery model

Secondary objectives:

- Measure the effectiveness of Sprinkles use on the prevalence of anaemia among children 6-24 months whose caregiver purchases Sprinkles.

Primary outcome measures:

1) Feasibility
   a) Enrollment at household level through population level screening package (PLSP)
   b) Fortnightly follow-up by SVGs
   c) Delivery of messages by SVGs at household
   d) Delivery of product (through RMHC, to household)
2) Acceptability
   a) Response rate (# enrolled/# contacted)
   b) Drop-out rate (# drop outs/# enrolled at baseline)
   c) Compliance levels (#children completing course/#children whose caregiver purchased Sprinkles)
   d) Adverse side effects
   e) Ease of use, challenges, and mother's perceptions of product

Secondary outcome measures:

1) Effectiveness
   a) Mean change in Hb levels among children whose caregiver purchases Sprinkles
2) Mother's perceptions of child's health (activity level, pica, symptoms of anaemia
3) Factors associated with compliance (e.g. caregiver's education level, income, awareness levels, etc.)

Study Design and Research Methods

Type of study design
Process evaluation with cross sectional baseline and end line surveys

Study area and participants:
This study will be carried out in Karambayam, Thanjavur district, Tamil Nadu. Karambayam and surrounding villages are not endemic for malaria (GOTN 2010). Sprinkles micronutrient powder will be distributed through Karambayam's rural micro health centre (RMHC) which serves five villages (Ambalapattu, Ettupulikadu, Karambayam, Sembalur, and Vappankadu) with a total population of around 11,000 and is staffed by two nurses and one physician. A network of 13 SughaVazvhu Guides (SVGs), local community health workers, conducts risk screening of the population through a population level screening package (PLSP). Each SVG is responsible for a population of around 1000 people (150-250 households each) in a given geographical location whose households have been mapped by GIS markers (Figure 3).

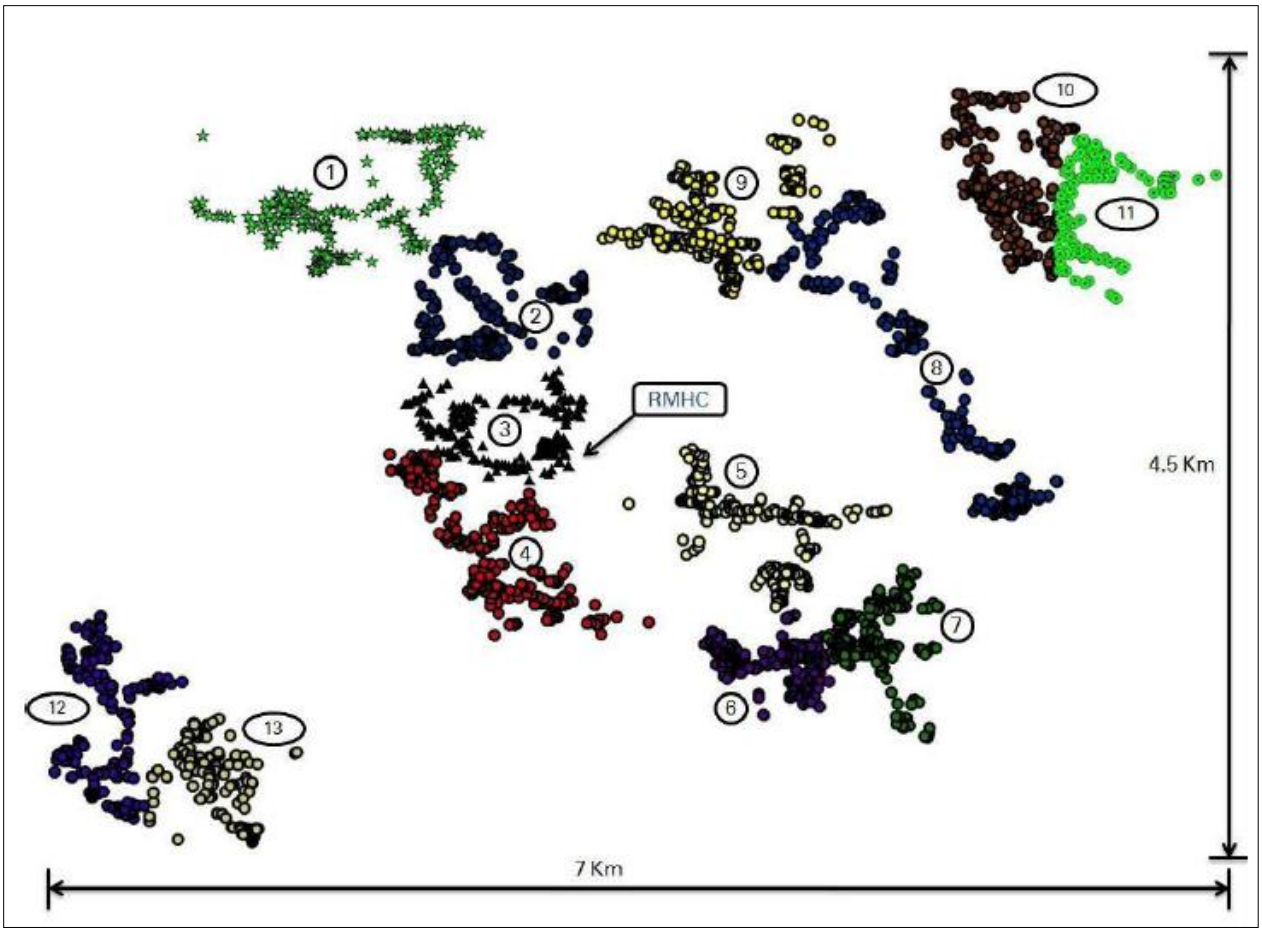


Figure 2: Area allocation of 5 villages served by Karambayam RMHC
The five village catchment of the RMHC - Karambayam (illustrated area 2-5); Ettuplikadu (6-7); Sembalur (8); Ambalapattu (1 & 9-11); Veppankadu (12-13). Source: Johar, Z (2010). ICTPH Health System Approach.

Children between the ages of 6 and 24 months will be invited to participate in the study based on deliberate sampling techniques and will be identified on a rolling basis through the PLSP as they are identified in the field. The PLSP data is collected through optical mark recognition (OMR) forms which will then be scanned and the data transferred to an Excel sheet. This data can be sorted by date of birth and identification number in order to identify eligible children. PLSP data collection began during October 2010 and is planned to continue over the next 6 to 7 months. If there are an inadequate number of children identified through this method, we will use a snowball technique to identify children not covered by PLSP. Subsequent families surveyed by PLSP, SVGs, and other clinic staff will be asked if they know of children age 6-24 months, a list of these families will be compiled, and those not already recruited for the study will be visited by the SVGs.

NOTE: ICTPH baseline survey identified 282 children less than 2 years of age living in three villages – Alakkudi, Karambayam, and Nattuchalai

Formative research:
Qualitative data was gathered from exploratory focus group discussions (FGD) and individual interviews with mothers of children aged 6-24 months was used to determine and explain the factors that influence choices and behaviors in our target population. This information was used to design educational and social marketing messages to increase awareness of childhood anaemia and encourage the purchase and use of Sprinkles as a means to prevent and treat anaemia. As the intervention progresses as we gain more

information from mothers on their perceptions and practices, these messages can be modified in an evolving process. Sample educational and social marketing messages can be found in Annex III.

Training:
SVGs, nurses, research personnel and other relevant individuals will be trained to enroll research participants, in proper data collection techniques, social marketing and education communication, and proper use of Sprinkles home fortification powder. Sessions will be conducted over two days during regularly scheduled "Thursday Case Discussions". Training will be conducted by the senior researcher and field coordinator with active learning techniques. Follow-up training will be conducted at designated intervals and SVGs will be able to meet with nurses, other clinic personnel, and research staff to discuss any concerns or questions.

Informed consent:
Prior to enrolling in the study, SVGs will explain research activities, risks, implications, and obtain written consent from caregivers. SVGs will have one copy of the research proposal in Tamil which can be shown to potential participants. The SVG will keep one copy of the consent form and give another copy to the study participant along with contact information for research/clinic personnel in case of concerns or questions during the course of the study.

Baseline Survey:
After providing consent and enrolling in the study, caregivers of children aged 6-24 months will be administered a short baseline survey by the SVG. This survey will collect demographic and socioeconomic information; knowledge, attitudes and practices regarding child nutrition and anaemia; child health history (i.e. previous history of worms, previous infections). Additionally, caregivers will be asked to provide their mobile number, if not already available through the PLSP, for the intention of follow up activities.

Education activities:
Following enrollment and baseline survey, SVGs will deliver educational messaging to caregivers regarding micronutrient deficiencies, particularly iron deficiency anaemia. SVGs will inform caregivers of the risks associated with anaemia in a child's growth and development as well as inform the caregiver that there are supplements which are available at the RMHC which can help to prevent and treat anaemia in children. SVGs can demonstrate the ease of use of Sprinkles at the household level and compare to use of iron drops and tablets. These messages will be designed to build demand for health seeking behavior and for interventions that can mitigate the effects of anaemia on children's health with the aim of encouraging caregivers to visit the RMHC to purchase Sprinkles. Sample messages can be seen in Annex III.

Activities at the RMHC:
When caregivers visit the RMHC to purchase Sprinkles, nurses will assess the child's nutritional status including blood hemoglobin level and anthropometric measurements. Children identified with severe malnourishment, Hb levels less than 7g/dL, children with chronic illness that prevents normal feeding practices, and children with infection based off of the recommendations located in Annex II. Children who are identified with these conditions will not be eligible for this study and will be referred for proper treatment at the RMHC or, if required treatment is not available at the RMHC, the child will be referred to the PHC. After proper treatment, the child may be eligible for Sprinkles use and can be enrolled in the study if the caregiver chooses to do so. Additionally, children with blood Hb levels greater than 10g/dL will not be eligible for the study based off of this normal Hb level.

Children without these conditions will be eligible for the study. Nurses will provide social marketing messages through interpersonal communications and printed materials directed toward caregivers about

child anaemia and available iron supplementation options. Because research has shown that Sprinkles are a highly acceptable and effective mode of supplementation in India compared to iron drops and tablets (Hirve 2006), nurses will state the benefits of using Sprinkles compared to the alternatives. The goal is to increase knowledge and demand for Sprinkles to encourage their purchase and use. Sample messages can be seen in Annex III.

Further, deworming treatment will be offered to children who visit the clinic regardless of their enrollment in the study. Deworming treatment will be included in each purchase of Sprinkles sachets and will be administered by nurses based on clinical guidelines. Drug and dosage will be based on the below WHO/UNICEF recommendations listed in Figure 3 below. The purchase price of Albendazole tablets (400mg) in the RMHC is 2 rupees.

Treatment Group	**Drug and Dosage**	**Duration**
	Albendazole (400 mg tablet)	
Children 12-23 months	½ tablet	At least annually; optimally 2 times/year**
Children 24 months and older	1 tablet	At least annually; optimally 2 times/year**

Figure 3: Recommended helminth treatment in India
** Where hookworm prevalence is 20-30 percent
Adapted from: WHO/UNICEF (2004) *How to add deworming to vitamin A distribution*. Geneva: WHO and Galloway, R. (2003) *Anemia prevention and control: What works.* Washington DC: The World Bank, UNICEF, WHO, FAO, USAID, CIDA, and the Micronutrient Initiative.

If at any point during the study, a child is determined to be at-risk for malnourishment or infection based off of reported side effects, the SVG will refer the child to the RMHC for further assessment and will advise the caregiver to cease the use of supplementation until the child's condition is determined.

Sprinkles Distribution:
Sprinkles Anemia Formulation micronutrient powder will be utilized for this study with the product specifications listed previously. Prior to the start of this study, 50,000 Sprinkles sachets will be purchased from Hexagon Nutrition Pvt. Ltd in Mumbai. Sprinkles can be purchased from the wholesale manufacturer at 1 rupee per sachet. A 60-day short course delivery of home fortification at 1 rupee per sachet will thus cost 60 rupees plus any minor incidental costs (such as deworming treatment) which are to be determined. Sprinkles sachets will be stored at the SughaVazhvu pharmacy where they will be assembled by pharmacy staff in packages along with journal.

If the mother decides that Sprinkles is a good option for the child and wishes to purchase, a receipt will be drawn up and she will be directed to the payment center. After she has paid, the nurses will provide the mother with the supply of 60 sprinkles sachets will be distributed to caregivers in a plastic, re-sealable bag. An additional re-sealable bag will also be included and caregivers will be asked to save used Sprinkles sachets as a means for monitoring compliance in the extra bag. A record of sales will be obtained through the RMHC's Electronic Health Record data in order to monitor sales coverage.

Caregivers will be given a journal in which to record any side effects suffered by their child, which can be discussed with an SVG at follow up visits. Journals can also be used to record any feedback on service delivery (i.e. related to marketing, affordability, accessibility, ease of use, etc.). Additionally, a calendar or logbook will also be included in the journal on which caregivers can record the days that Sprinkles was used as another means to monitor compliance. Caregiver will also be notified of the date on which she can expect an SVG to conduct a follow up visit.

If a caregiver decides that she wishes to utilize an alternate form of iron supplement available at the RMHC, she will be provided with these supplements using the payment procedure as mentioned before and provided with directions on usage. If the caregiver decides that she wishes to seek treatment elsewhere or at a later date, she will be given a letter, drafted in Tamil, which states the results of the child's nutrition assessment and recommendations for care. In this way, the caregiver can present this letter to the proper authorities at other centers in order to inform them of the child's previous care so that she can obtain desired supplements or follow up.

Monitoring Compliance and Follow-up Visits:
SVGs will visit study participant's households on a *fortnightly* basis to monitor compliance, collect morbidity data, and encourage Sprinkles use. Follow-up visit reminders will be sent to caregivers' mobile phones 2 days prior to the SVG visit. Compliance will be monitored by collecting used Sprinkles sachets from the caregiver and recording the number in a log book. Journal entries made by the caregiver will be reviewed and any side effects noted in the log book. Children with signs of infection or other serious side effects will be advised to stop Sprinkles use and will be referred to the RMHC for evaluation by a health professional. Data on Sprinkles sales will be collected from the RMHC on a bi-weekly basis by research personnel and the inventory assessed to cross-check recorded sales.

SVGs will also conduct follow up visits with enrolled children and caregivers who do not visit the clinic to provide a second round of educational messaging to caregivers with the aim of encouraging their visit to the RMHC to purchase and use Sprinkles.

Endline Evaluation:
1) For enrolled children whose caregiver purchased Sprinkles, surveys will be readministered to assess changes in outcome variables at the end of the 60-day Sprinkles regimen.
    a) Semi-structured, qualitative interviews with a sample of caregivers who completed the study will be conducted to assess the perceived barriers and bottlenecks in the system of delivery.
    b) Caregiver exposure and recall of educational and social marketing messages will be recorded.
2) Semi-structured, qualitative surveys will be administered to caregivers who did not complete the study to identify reasons for drop out and potential barriers and bottlenecks in the delivery system.
3) Children's blood Hb levels for those children whose caregiver purchased Sprinkles
4) Retrospective surveys will be given to SVGs and nurses to identify any barriers and bottlenecks in service delivery from their perspective.

6 month Follow-up:
At this point, it is recommended that another 60 day course of Sprinkles be administered for children between the ages of 6-24 months. SVGs will follow up with study participants to provide educational information again and encourage a second regimen of Sprinkles. Hb levels will be recorded at the RMHC and a survey of caregiver's perceptions and child's health will also be taken at the household level.

Study population

Target population
Children aged 6-24 months

Sample size
Qualitative, semi-structured baseline and endline surveys will be given to caregivers whose children participate in the study. Based off of baseline data from 2008, 282 children between ages 6-24 months were identified. For a 95% confidence interval and 5% confidence limit with a design effect of 1, the

required sample size will be 163 children between the ages of 6-24 months which was calculated using OpenEpi.

Based off of previous Sprinkles effectiveness studies in India, we assume a 1.0 g/dL increase in Hb levels will be achieved by completion of a 60-day course of Sprinkles (Hirve 2007). We account for a dropout rate of 20% to reach statistical significance at $\alpha = 0.05$ and ß = 0.90. The sample size required to detect a 0.5% change in mean Hb levels from baseline (see Bhutta 2008) for children whose caregiver purchases Sprinkles at the clinic is 93 based off of the following calculation to detect within-subject increases in mean Hb level:

$$N= (Z_{\alpha} + Z_{1-\beta})^2 \sigma^2/|\mu_0 - \mu_1|^2$$

$1- \beta$ = the desired power
α = the significance level
σ = the population standard deviation
$|\mu_0 - \mu_1|$ = the difference in the means

Type I error 5%, $Z_{\alpha}= 1.645$
Power 90%, $Z_{1-\beta}= 1.28$
$|\mu_0 - \mu_1|$ =difference to be detected=0.5
σ= SD at baseline= 1.5
$n= (1.645+1.28)^2(1.5)^2/(0.5)^2 = 77$
N=77.0

Assuming 20% attrition rates:
0.20 * 77.0 = 15.4
77.0 + 15.4 = 92.4
93 = N

Eligibility:

- Ages eligible: children aged 6-24 months
- Sex eligible: male and female
- Healthy volunteers accepted

Inclusion criteria:

- Age 6-24 months old at enrollment
- Permanent resident of villages served by Karambayam clinic

Exclusion criteria:

- Severely malnourished children requiring hospitalization (identified through middle-upper arm circumference less than 115mm or weight-for-height less than -3SD)
- Severely anaemic children (identified by Hb less than 7 g/dl)
- Children with normal levels of Hb greater than 10g/dl
- Children with infection identified through clinical diagnosis
- Children with chronic illness which impairs feeding ability

Data Collection and Planned Analysis Procedures

This study proposal will be submitted to the proper Institutional Review Board of ICTPH prior to beginning any activities. Confidentiality will be ensured by using an identification number assigned to each caregiver and child. All records will be stored in a locked, secure place within the research facility. Only authorized research personnel will have access to these records.

Surveys have been developed following formative research (FGDs, interviews) with caregivers of children age 6-24 months in the catchment area. Cross-sectional surveys will be administered at baseline, mid-line, end-line, and follow-up. Qualitative interviews will be conducted with caregivers at mid-line and end-line points to identify barriers and bottlenecks in the service delivery model.

Surveys will be administered in paper format. Collected data will be double-entered and cleaned and will be analyzed in STATA and a backup file of the raw data will be saved in Excel.

Limitations of Study

Offering deworming treatment to all children at the clinic level can potentially confound the results in improvements of Hb levels since helminth infections are another cause of anaemia in children. This could make it difficult to determine if any improvements in Hb levels are due to Sprinkles, Sprinkles and deworming, or deworming alone.

Ethical Considerations

There are minimal risks involved for the participants in this study. Risks, benefits, and assurance of confidentiality will be listed in consent form. Caregiver consent will be obtained for children participating in the study. Participants will be given a copy of the consent form along with contact information for researchers in case of concerns or questions. Consent and information forms will be available in both English and Tamil language.

No child will be denied care and treatment based off of their enrollment status and participation in the study.

Annex I: Micronutrient Information

The following micronutrients are described due to their relevance to child health, development, and survival as well as their inclusion in the Sprinkles Anemia Formulation. Recommended daily intake amounts of selected micronutrients are included in Figure 4.

Vitamin A – Vitamin A is an essential micronutrient that contributes to vision and cell proliferation and differentiation. Vitamin A deficiency is the leading cause of preventable pediatric blindness, is associated with increased short-term risk of child mortality, and is associated with poor growth. Vitamin A deficiencies can increase the severity of malaria infection which can exacerbate anaemia. Vitamin A deficiency can be prevented by three strategies: supplementation, fortification, and diet diversification.

Iron – Iron plays a central role in oxygen transport to cells through its binding with Hb during erythropoiesis. Iron also plays a role as a cofactor of enzymes involved in cellular respiration, division, neurotransmission, immunity, and growth. Non-heme iron in grains, vegetables, nuts, and fruits is not easily absorbed and largely constitutes the iron available in diets in low-income regions. Iron deficiency can be prevented through supplementation, fortification, as well as diet diversification.

Zinc – Zinc is a constituent of more than 200 enzymes and many transcription proteins that regulate nucleic acid synthesis; metabolism of proteins, lipids, and carbohydrates; and cell differentiation. These functions give Zinc an important role in a broad range of activities throughout the body. Absorption is lowest in high grain and vegetable diets and greatest in breastmilk and meat. Zinc deficiency can increase the severity of malaria infection which can exacerbate anaemia. Direct supplementation with zinc, especially in combination with other micronutrients, provides the most immediate approach for improving zinc status among mothers and children. Zinc supplementation may prevent morbidity and mortality related to diarrheal illnesses.

Vitamin C – Vitamin C is a water-soluble antioxidant necessary for growth and development. Vitamin C is a necessary for the formation of collagen for production of scar tissue, skin, tendons, ligaments, and blood vessels. It is also necessary for the repair and maintenance of skin, teeth, and bones. Vitamin C is an antioxidant which can block some damage caused by free radicals. Vitamin C also enhances the absorption of iron.

Folic Acid – Folic Acid is a B vitamin which is necessary for making new cells in the body. A deficiency in folic acid can lead to anaemia. During pregnancy, folic acid is important for prevention of neural tube defects in the fetus.

Iodine – Iodine is an essential component of thyroid hormones that control cellular metabolism and neuromuscular tissue growth and repair. It is ingested as iodide or iodate and once in circulation, nearly all iodide is oxidized to iodine. Deficiencies in iodine and subsequent thyroid hormone production at certain points of organogenesis can lead to irreversible mental retardation and other developmental defects. Goiter is the most common clinical sign of iodine deficiency. Salt iodization has been the longest-standing, most cost-effective approach to reducing IDD, but in areas where this is not practical, such as in Thanjavur where iodized salt consumption is very low despite it being sold in stores, supplementation has been shown to be an effective method to prevent IDD. NOTE: Iodine is not included in the Sprinkles Anemia Formulation.

Age	Vitamin A (µg/day)	Iron (mg/day)	Zinc (mg/day) Condition 1*	Zinc (mg/day) Condition 2**	Iodine (µg/day)	Vitamin C (mg/day)
0 to 6 months	400	11	4	5	110	40
7 to 12 months	500	11	4	5	130	50
1 to 3 years	300	7	3	3	90	15

Figure 4: Recommended Dietary Allowances of Selected Micronutrients for Infants and Children

*Under usual conditions of a mixed or refined vegetarian diet

**Under usual conditions of an unrefined cereal-based diet

Source: Michael H. Merson, Robert E. Black, Anne J. Mills (ed.). International public health: diseases, programs, systems, and policies. Second edition. Jones and Bartlett Publishers, Inc. 2006; MedlinePlus, National Institute of Health. Available at: http://www.nlm.nih.gov/medlineplus/medlineplus.html.

Risk of Toxicity

There is the potential for iron toxicity because very little iron is secreted from the body. Research has found that child death has occurred following the ingestion of 200 mg of iron (Corbett 1995). Tolerable upper limits (UL) of iron intake have been established even though there are times that a health professional might prescribe a daily intake greater than the UL in cases of iron deficiency anaemia to replenish iron stores. For children and infants aged 7-12 months and 1-13 years old, UL for iron is 40 mg per day (ODS NIH).

Annex II: Recommended Guidelines for Supplementation Programs

WHO Child Growth Standards

Growth standards were revised in 2006 based off of cohorts of children from different ethnic origins raised in optimal conditions and measured in a standardized way. Studies have shown that there may be some ethnic differences among groups, but for practical purposes they are not considered large enough to invalidate the general use of the WHO growth standards population as a standard in all populations.

Growth charts are available online at: http://www.who.int/childgrowth/standards/en/

Identification and treatment of anaemia in children 6-24 months

International standards have been developed to identify anaemic individuals based on hemoglobin levels and hematorcrit levels shown in Figure 5. Guidelines for the treatment of anaemia among children aged 6-24 months can be found in Figure 6.

Age or Sex Group	Hemoglobin below (g/dL)	Hematocrit below (%)
Children 6 months – 5 years	11.0	33
Children 5-11 years	11.5	34
Children 12-13 years	12.0	36
Non-pregnant women	12.0	36
Pregnant women	11.0	33
Men	13.0	39

Figure 5: Hemoglobin and hematocrit cutoffs used to define anaemia in people living at sea level
Source: International Nutritional Anemia Consultative Group (INACG). Guidelines for the Use of Iron Supplements to Prevent and Treat Iron Deficiency Anemia.

Prevalence of anaemia in children 6-24 months	Dosage	Birth weight category	Duration of treatment
Less than 40% of population	12.5mg iron + 50µg folic acid daily	Normal	6-12 months
		LBW (<250g)	2-24 months
Greater than or equal to 40% of population	12.5mg iron + 50µg folic acid daily	Normal	6-24 months
		LBW (<250g)	2-24 months

Figure 6: Guidelines for iron supplementation to children 6-24 months of age
* Iron dosage is based on 2mg per kg body weight per day
Source: International Nutritional Anemia Consultative Group (INACG). Guidelines for the Use of Iron Supplements to Prevent and Treat Iron Deficiency Anemia.

Identification of severe anaemia

Severe anemia is defined clinically as a low hemoglobin concentration leading to cardiac decompensation, that is, to the point that the heart cannot maintain adequate circulation of the blood. Where severe anemia is relatively common (prevalence 2 % or more of a population group), its detection and treatment in primary care facilities is necessary to prevent morbidity and mortality from severe anemia. Iron deficiency is not the only cause of severe anemia. Other possible causes include malaria, folate deficiency, hemoglobinopathies such as sickle cell anemia or thalassemias, and the anemia of chronic disorders such as HIV infection, tuberculosis, or cancer. In primary care settings, health care workers should know when to refer individuals who do not respond to oral iron therapy or who are at urgent risk of serious complications.

a) Hemoglobin: Less than 7.0 g/dL

b) Hematocrit: Less than 20%

c) Assessment of pallor: If any of the three areas - inferior conjunctiva of the eye, the nail beds, and the palm - is abnormally pale, the individual should be considered to be anaemic.

d) Kwashiorkor and Marasmus: Any child with these conditions should be considered anaemic.

Note: Kwashiorkor is a condition that develops after a child is displaced from the breast and children aged 2-3 years are at highest risk. Clinical signs include edema; milder wasting; reddish hair changes; enlarger liver; dermatosis ("flaky-paint rash); a state of misery and disinterest in food. Marasmus usually occurs in infancy and is marked by severe wasting that is clinically evident and is accompanied by a weight-for-height Z-score usually below -3 SD; a "baggy" skin appearance; moderate to severe stunting; soft, sparse hair; absence of edema; alertness; and hunger. Children with either condition are at high risk for corneal xerophthalamia due to Vit. A deficiency (Merson et al. 2006).

Once a child has been identified as being severely anaemic, it should be determined by the nurse or doctor whether the child can be treated at the RMHC or if they should be referred to the PHC. Guidelines for the treatment of severe anaemia can be found in Figure 7. Iron supplementation should not be given to children with kwashiorkor or marasmus until after they have started gaining weight and regaining an appetite which usually occurs following a 14 day nutritional rehabilitation regimen.

Age group	Dosage	Duration of treatment
0-2 years	25mg iron + 100-400µg folic acid daily	3 months
2-12 years	60mg iron + 400µg folic acid daily	3 months
Adolescents and adults, including pregnant women	120mg iron + 400µg folic acid daily	3 months
• After 3 months of therapeutic supplementation, pregnant women and infants should continue preventive supplementation regimen		

Figure 7: Guidelines for oral iron and folate therapy to treat severe anaemia
Source: International Nutritional Anemia Consultative Group (INACG). Guidelines for the Use of Iron Supplements to Prevent and Treat Iron Deficiency Anemia.

Follow-Up Care for Children with Severe Anaemia

Follow-up of children undergoing treatment for severe anaemia should occur at 1 week and 4 weeks. If the condition has worsened at the 1 week follow-up or if no change is seen at the week 4 follow-up, the individual should be referred to a primary health center.

Identification of children aged 6-60 months with severe acute malnutrition (SAM)

a) Using weight-for-height (wasting): Cut off of -3 standard deviations below WHO child growth standards

- Children with a weight-for-height below -3 SD based on the WHO standards have a high risk of death *exceeding 9-fold* that of children with a weight-for-height above -1 SD
- Specificity of >99%

b) Using middle-upper arm circumference (MUAC): Less than 115 mm

- Specificity of >99%
- It is important to note that children identified through weight-for-height and MUAC are not always the same (only about 40% selected by the one criterion were also selected by the other).

Therefore, BOTH measurements should be used as independent criterion for SAM identification.

c) Bilateral Oedema: Clinical sign

Helminth Control

In populations with endemic hookworm, anthelminthic therapy should be given presumptively to anyone with severe anemia, because treatment is safe and much less expensive than diagnosing hookworm infection. Anthelminthic treatment to school children without prior screening is currently recommended in the school setting and combined with iron-folate supplementation in antenatal care. Three schistosomes can cause anemia: *Schistosoma mansoni* and *S. japonicum*, which are intestinal parasites, and *S. haematobium* (endemic to Africa and Middle East), which infects the bladder and urinary tract.

Treatment Group	Drug and Dosage				Duration
	Albendazole (400 mg tablet)	**Mebendazole (500 mg tablet)**	**Levamisole (40 mg tablet)***	**Pyrantel (250 mg tablet)***	
Children 12-23 months	½ tablet	1 tablet	2.5 mg/kg	10 mg/kg	At least annually; optimally 2 times/year**
Children 24 months and older	1 tablet	1 tablet	2.5 mg/kg	10 mg/kg	At least annually; optimally 2 times/year**
Pregnant women	1 tablet	1 tablet or 100 mg twice daily for three days	2.5 mg/kg; best if dose repeated on next two consecutive days	10 mg/kg; best if dose repeated on next two consecutive days	One treatment in second trimester. If hookworm prevalence is 50%, one dose in the each of the second and third trimesters.
Lactating women	1 tablet	1 tablet or 100 mg twice daily for three days	2.5 mg/kg; best if dose repeated on next two consecutive days	10 mg/kg; best if dose repeated on next two consecutive days	At least annually; optimally 2-3 times/year**

Figure 8: Recommended treatment for helminthes

* Scales are needed to obtain the correct dosage for these drugs

** Where hookworm prevalence is 20-30 percent

Adapted from: WHO/UNICEF (2004) *How to add deworming to vitamin A distribution*. Geneva: WHO and Galloway, R. (2003) *Anemia prevention and control: What works.* Washington DC: The World Bank, UNICEF, WHO, FAO, USAID, CIDA, and the Micronutrient Initiative.

NOTE: In India, Albendazole is the preferred treatment course for helminth infections.

Annex III: Sample Educational and Social Marketing Messaging

As more information is gathered from our work in the field, these messages can be further adapted to be more effective. These messages will be translated into Tamil before they are delivered to caregivers.

1) Proper nutrition is important for your child's growth and development when they are between the ages of 6 to 24 months. A lack of iron and other micronutrients in your child's diet can lead to anaemia. Anaemia threatens growth and development so your child might not perform as well in school and be as healthy if they don't get enough iron.
2) Anemia is both preventable and treatable. Children can get iron from their diet if it has a lot of iron-rich foods like meat, fish, and green vegetables. If the diet doesn't give enough iron though, supplements can be given to your child to provide the adequate amount.
3) There are different types of iron supplements such as iron drops and iron tablets. These are available through programmes like ICDS at Anganwadi Centres and PHCs. These are effective at reducing anemia, but they are often difficult to use and have uncomfortable side effects.
4) Another option is a supplement called "Sprinkles". It can be used at your house and put into the meals that you feed to your child. It is effective at preventing and stopping anaemia. It has no flavor and no side effects which means your child will be more likely to take it and you don't have to change the foods you serve in your home. Sometimes children have minor side effects after they start taking Sprinkles like constipation or loose stool. After taking the Sprinkles for a few days, these side effects should go away.
5) Sprinkles is contained in individual packages. By giving a packet of Sprinkles to a child each day in one of his or her meals for 60 days, the anemia can be cured. In other words, 60 packets of Sprinkles is enough to protect a child against complications due to a lack of iron and other nutrients that can cause anemia.
6) Use Sprinkles once a day for 60 days for a healthy, smart child.
7) How to use:
    a) One packet of Sprinkles per day for 60 days is enough to stop and prevent anaemia in children age 6-24 months.
    b) Feed one packet of powder to your child each day for 60 days.
    c) Hold the packet from one corner and tear it.
    d) Add the Sprinkles powder to the cooked meal. Make sure to choose an amount of food that the child is able to consume before adding the Sprinkles. It is best to add it to solid food because the powder doesn't mix with liquids.
    e) Use a spoon to mix the powder into the food. Feed the food to your child.
    f) The food should be eaten within 2 hours after you mix Sprinkles in.

Annex IV: Research Forms and Sample Surveys

A. Informed Consent

Informed Consent Form for caregivers of children age 6-24 months for the research study entitled "Feasibility and effectiveness of a delivery model for home fortification of children aged 6-24 months in rural Tamil Nadu, India: A pilot study"

Name of Principle Investigator: Lindsey Peugh
Name of Organization and Sponsor: IKP Centre for Technologies in Public Health
Name of Project and Version: "Feasibility and effectiveness of a delivery model for home fortification of children aged 6-24 months in rural Tamil Nadu, India: A pilot study"

Part I: Information Sheet

Introduction
I am _____, and I work for SughaVazhvu Pvt. Ltd. based in Thanjavur. I am helping conduct a research study with IKP Centre for Technologies in Public Health which might help your child become and stay healthier. In our research we will talk to you and other mothers about child nutrition and suggest treatments which can improve your child's nutritional status. Whenever researchers study children, we talk to the parents and ask them for their permission. You do not have to decide today whether or not you agree to have your child participate in this research. Before you decide, you can talk to anyone you feel comfortable with. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

Purpose
It is possible that children in this region are not receiving adequate nutrients from food for proper growth and development. We are most interested in a micronutrient called iron and its inadequate intake in children 6-24 months which can cause a condition called anaemia. In this study, we will talk to caregivers of children aged 6 to 24 months about nutrition topics and suggest ways in which the child's anaemia status can be improved. We will also track the changes in a child's anaemia status throughout this study. We will use the information gathered to better understand if our messages and delivery of treatments to improve children's nutrition status is effective and feasible in this particular setting in India.

Type of Research Intervention
This research will look at how a specific nutritional supplement is delivered from the Rural Micro Health Centre which will be combined with messages at the household level. In order to study this, we will need to take measurements of your child's hemoglobin levels at the beginning and end of the study and record your observations of your child's nutritional status, side effects and perceptions of service.

Selection of Participants
We are particularly interested in including children between the age of 6 and 24 months in this study because this is a very important time during their growth and development. We are asking you to allow your child to participate in this study because they are in this age range and lives in the area serviced by the SughaVazhvu Rural Micro Health Centre in Karambayam.

Voluntary Participation
You do not have to agree to let your child participate in this study. You can choose to say no and any services that you and your family receive at the health centre and from the SughaVazhvu Guides will not

change. We know that the decision can be difficult when it involves your children. You can ask as many questions as you like and we take the time to answer them. You don't have to decide today. You can think about it and tell me what you decide later.

Procedure

Hemoglobin level: At the beginning and end of the research study, we will take a small sample of blood from your child. We will use this blood to measure the amount of hemoglobin, a component of blood which is important for certain body functions and also lets us know about the anaemia status of your child. We will also monitor how your child's anaemia status changes from the beginning of the study so we will have to take another blood sample after about 2 months time.

Evaluation at RMHC: Services will be offered at the Rural Micro Health Centre for evaluating the nutritional status of your child and will be provided by trained nurses.

Nutritional supplements*:* If your child is found to be anaemic, we will suggest available options for treating the condition called "nutritional supplements" which are all available at either the Rural Micro Health Centre, PHC, or in ICDS centres. It will be your own decision whether or not to utilize and administer such nutritional supplements.

Follow up visits: SughaVazvhu Guides will conduct visits to your home every two weeks if you decide to utilize a nutritional supplement. At these times, your child's health will be evaluated through a questionnaire to monitor any side effects or illnesses that your child is experiencing while taking the nutritional supplement.

Caregiver questionnaires: In addition to the information obtained from your child's participation, we will ask you, the caregiver, to complete a survey at the beginning and end of the research study as well as fill out short questionnaires during follow up visits regarding your perceptions of child nutrition and of the services offered in this study.

Duration

The time required for your child to participate in this study is minimal outside of normal daily activities. Household visits, including questionnaires and follow-up, will generally take 30 minutes.

Risks and Discomforts

Nutritional supplements often have minor side effects for children. These can include loose stools, changes in stool color, diarrhea, and teeth discoloration (in the case of iron drops).

Benefits

Preventing and treating anaemia in children aged 6-24 months can have long term benefits on a child's growth and development. Nutritional supplements have been shown to reduce the occurrences of anaemia in this age group when food does not provide adequate nutrients for a child.

Reimbursements

You and your daughter/son will not be provided with any payment to take part in the research.

Confidentiality:

We will not share information about you and your son or daughter outside of the research team. The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child will have a number on it instead of his/her name. Only the

researchers will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except staff members at ICTPH.

Sharing of Research Findings
At the end of the study, we will be sharing what we have learned with the participants and with the community. Information gathered during the study will be kept confidential even after the study period is complete. We will also publish the results in order that other interested people may learn from our research

Right to refuse or withdraw
You may choose not to participate in this study or have your child participate in this study. Choosing to participate or not will not affect either you or your child's future treatment at the RMHC or other activities provided by SughaVazhvu in any way. You and your child may stop participating in the study at any time that you wish without either of you losing any of your rights here.

PART II: Certificate of Consent
I have been asked to give consent for my daughter/son to participate in the research study entitled "Feasibility and effectiveness of a delivery model for home fortification of children aged 6-24 months in rural Tamil Nadu, India: A pilot study", which will involve my child providing a small blood sample and taking a nutritional supplement should I choose to do so as well as providing information about my child's health and perceptions of service. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.

Print Name of Parent or Guardian _____

Signature of Parent of Guardian_____

Signature of SVG taking consent_____

Date _____

If illiterate:
A literate witness must sign and caregivers who are illiterate should include their thumb print as well.
I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Signature of witness_____ Thumbprint

Who to Contact
If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:
Sangeetha Lakshmanan at 9500072391 or Lindsey Peugh at 9940096421

This proposal has been reviewed and approved by the IRB within ICTPH which is a committee whose task it is to make sure that research participants are protected from harm.

B. Sample Baseline Survey Questionnaire

SVG ID: **KAR** ☐☐
Child ID: ☐☐☐☐☐☐☐☐ Caregiver ID: ☐☐☐☐☐☐☐☐
Child's date of birth ☐☐☐☐☐☐☐☐ Caregiver date of birth ☐☐☐☐☐☐☐☐
Child sex: Female ○ Male ○ Caregiver sex: Female ○ Male ○
Caregiver mobile number ☐☐☐☐☐☐☐☐☐☐

Demographic questions:
1.1 Caregiver's years of education completed: 0 ○ < 5 ○ 5-10 ○ 10+2 ○ UG ○ PG ○
1.2 Marital status: Married ○ Widowed ○ Divorced ○ Separated ○ Deserted ○ Never married ○
1.3 Household income: 0-10000 ○ 10000-50000 ○ 50,000-100,000 ○ 100,000+ ○
1.4 Employment status: Works at home ○ Works outside of home ○ Seasonal work ○ Unemployed ○

Caring practices:
2.1 Did you receive antenatal care during pregnancy of [child]? Yes ○ No ○ DK ○
2.2 Did you consume iron folic acid tablets during your pregnancy of [child]? Yes ○ No ○ DK ○
2.3 Did you consume any other nutritional supplement during pregnancy of [child]? Yes ○ No ○ DK ○
2.4 Were you told during pregnancy of [child] that you were anaemic? Yes ○ No ○ DK ○
2.5 Have you ever been told that you are anaemic? Yes ○ No ○ DK ○
2.6 Ever breastfed [child]? Yes ○ No ○
2.7a Still breastfeeding [child]? Yes ○ No ○
2.7b How old was child (in months) when you initiated complimentary feeding? ☐☐ months
2.9 Exclusively breastfed infant 0 to 6 months old? Yes ○ No ○ DK ○
2.11a Received infant feeding information and support? Yes ○ No ○ DK ○
2.11b If yes, source of information:
Health facility ○ Health provider ○ Community health worker ○ Brother or sister ○
Brother- or sister-in-law ○ Mother ○ Grandmother ○ Spouse ○ Friend or neighbor ○ Other ○

Child health and nutrition:
3.1 How many meals does your child consume each day? ☐☐
3.2 How many snacks does your child consume each day? ☐☐
3.3 How often during the last week has your child eaten:
- Meat ☐☐
- Fish ☐☐
- Poultry ☐☐
- Beans ☐☐
- Eggs ☐☐
- Groundnuts ☐☐
- Dark green vegetables ☐☐

3.4 Yesterday, during the day or night, did [child] consume any [iron fortified solid, semi-solid or soft foods designed specifically for infants and young children available in the local setting]?
Yes ○ No ○ DK ○
3.5 Yesterday, during the day or night, did [child] consume any food to which you added a [nutrient powder]?
Yes ○ No ○ DK ○
3.6 Yesterday, during the day or night, did [child] consume any [list iron fortified infant/toddler formulas available in the local setting]? Yes ○ No ○ DK ○

3.7a Has your child experienced any episodes of worms in stool? Yes ○ No ○ DK ○
3.7b If yes, was it treated? Yes ○ No ○ DK ○
3.8a Has your child ever had malaria? Yes ○ No ○ DK ○
3.8b If yes, was it treated? Yes ○ No ○ DK ○
3.9 How many episodes of diarrhea has your child experienced in the last week? ☐☐
3.10 How many times have you had to administer Oral Rehydration Salts to [child]? ☐☐
3.11a Does your child currently receive iron supplements? Yes ○ No ○ DK ○
3.11b If yes, where do you obtain these supplements?
ICDS Centre ○ PHC ○ Private hospital ○ Charitable hospital ○ Drug Store/Pharmacy ○ Other ○
3.11c If no, what prevents you from giving your child these supplements?

I've never heard of iron supplements ○
I don't know where to get iron supplements ○
I don't think my child needs iron supplements ○
It is too difficult to travel to get iron supplements ○
It is too far of a distance to travel to get iron supplements ○
I don't have enough time to get iron supplements ○
Iron supplements are too expensive ○
Other ○

Mother's perceptions:
4.1 How would you describe your child's appetite?
Excellent ○ Good ○ Fair ○ Poor ○ No comment ○
4.2 How would you describe your child's activity level?
Very active ○ Active ○ Moderately Active ○ Occasionally Active ○ Inactive ○ No comment ○
4.3 Does your child often seem to be irritable? Yes ○ No ○ DK ○
4.4 Does your child often appear to be pale in color? Yes ○ No ○ DK ○
4.5 Have you ever heard of a medical condition called "anaemia"? Yes ○ No ○ DK ○
4.6 If yes, have you heard any information on how to prevent anaemia in children? Yes ○ No ○ DK ○
4.7 If yes, where did you obtain this information?
Health facility ○ Health provider ○ Community health worker ○ Brother or sister ○
Brother- or sister-in-law ○ Mother ○ Grandmother ○ Spouse ○ Friend or neighbor ○ Other ○

C. Sample Follow-up Survey Questionnaire

SVG ID: **KAR** ☐
Child ID: ☐☐☐☐☐☐☐☐ Caregiver ID: ☐☐☐☐☐☐☐☐
Date of Follow up: ☐☐☐☐☐☐☐☐ Date of Sprinkles start: ☐☐☐☐☐☐☐☐
Sprinkles packets used: ☐☐

1. Easy to purchase? Yes ○ No ○
2. Easy to use? Yes ○ No ○
3. Child likes? Yes ○ No ○
4. Mother likes? Yes ○ No ○
5. How do you think Sprinkles is affecting your child's health? Positively ○ Negatively ○ No Change ○
6. How do you think Sprinkles is affecting your child's activity level? Positively ○ Negatively ○
No Change ○

7. Side effects (number of episodes):
Diarrhea: _____ Vomiting: _____ Stool discoloration: _____ Loose stool: _____

8. Concurrent illness (number of episodes):
Fever: _____ Cough: _____ Cold: _____ Other: _____

Date of next follow up: ☐☐☐☐☐☐☐☐

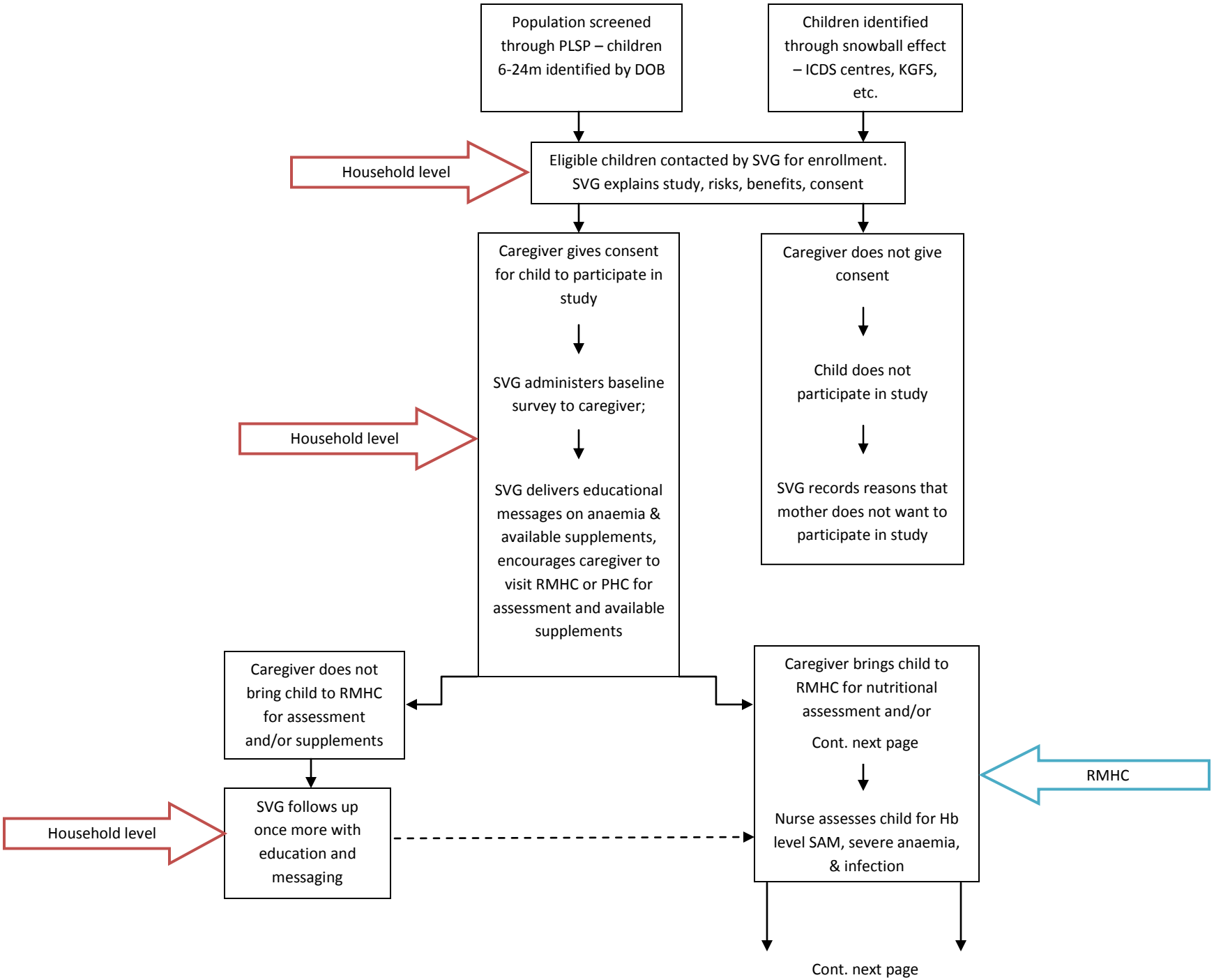
D. Caregiver Calendar/Journal

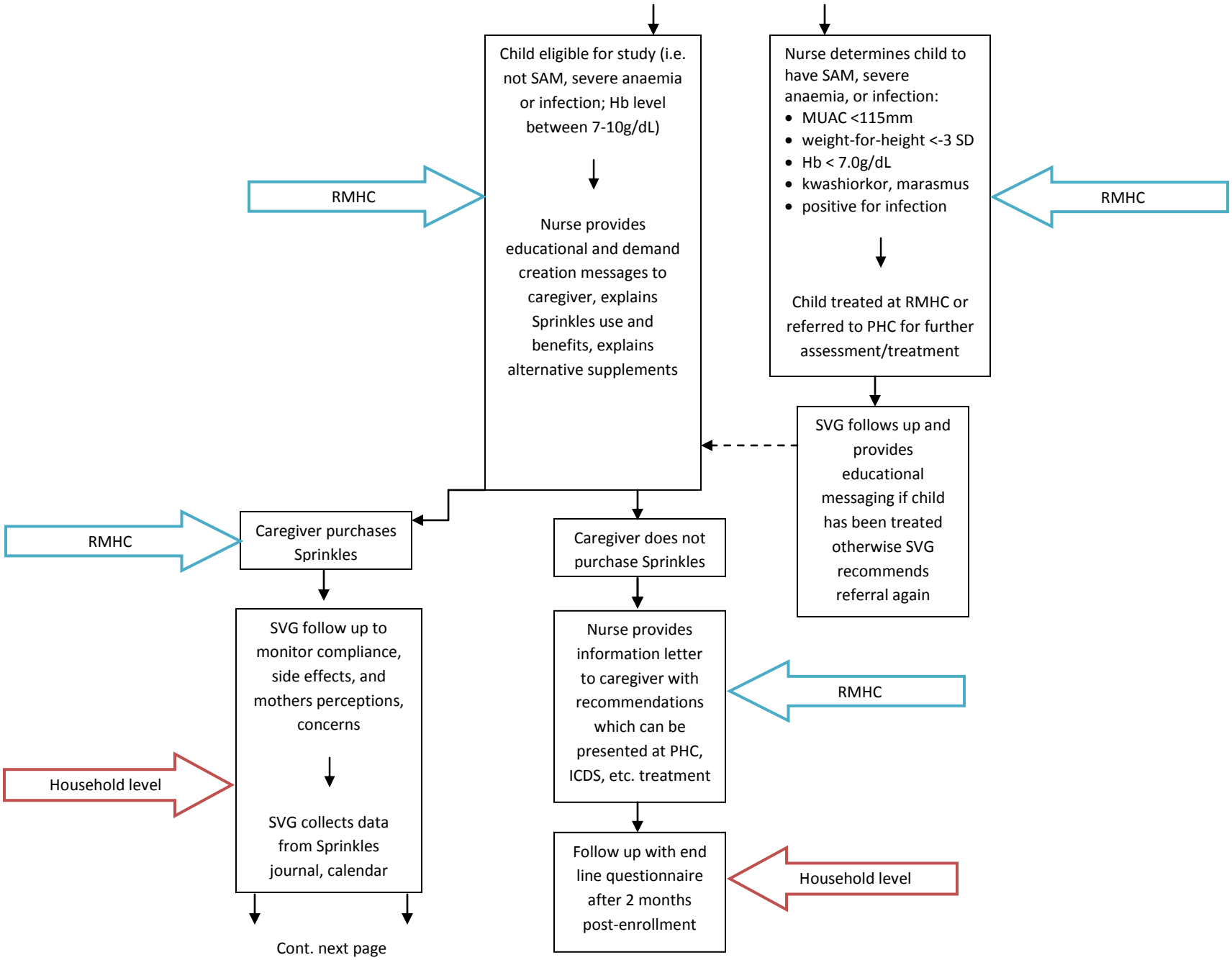
Sprinkles once per day for 60 days for a healthy, smart baby

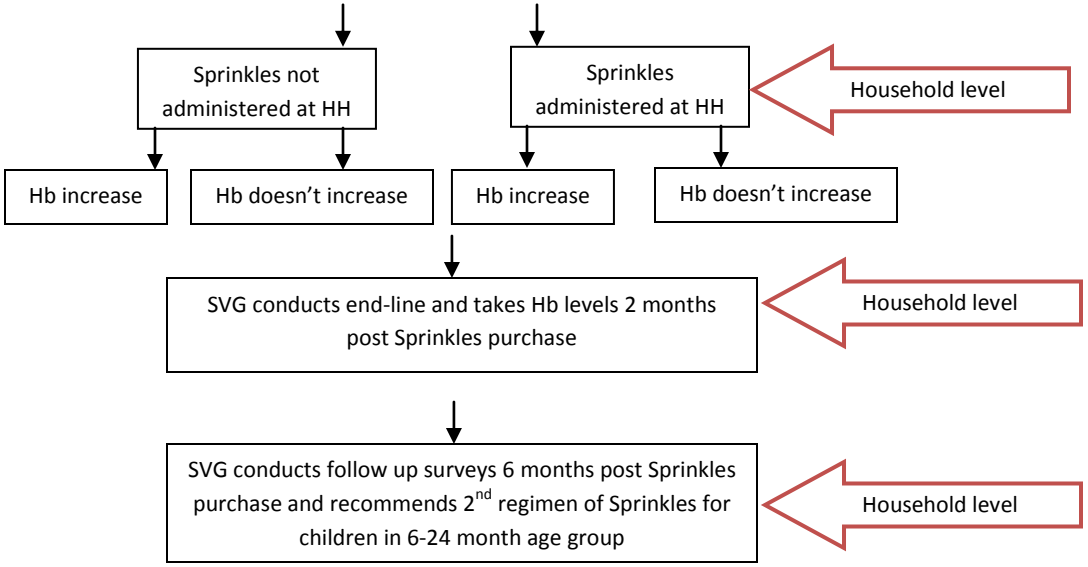
Directions: Use the calendar below to mark the days that you add Sprinkles to your child's food with an "X". If you notice that your child has any side effects or other illnesses while using Sprinkles, record those as well.

January 2011						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						1
2	**3**	**4**	**5**	**6**	**7**	**8**
9	**10**	**11**	**12**	**13**	**14**	**15**
16	**17**	**18**	**19**	**20**	**21**	**22**
23	**24**	**25**	**26**	**27**	**28**	**29**
30	**31**					

February 2011						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1	**2**	**3**	**4**	**5**
6	**7**	**8**	**9**	**10**	**11**	**12**
13	**14**	**15**	**16**	**17**	**18**	**19**
20	**21**	**22**	**23**	**24**	**25**	**26**
27	**28**					


Population screened through PLSP – children 6-24m identified by DOB
Children identified through snowball effect – ICDS centres, KGFS, etc.
Household level
Eligible children contacted by SVG for enrollment. SVG explains study, risks, benefits, consent
Caregiver gives consent for child to participate in study
SVG administers baseline survey to caregiver;
Household level
SVG delivers educational messages on anaemia & available supplements, encourages caregiver to visit RMHC or PHC for assessment and available supplements
Caregiver does not give consent
Child does not participate in study
SVG records reasons that mother does not want to participate in study
Caregiver does not bring child to RMHC for assessment and/or supplements
Household level
SVG follows up once more with education and messaging
Caregiver brings child to RMHC for nutritional assessment and/or
Cont. next page
RMHC
Nurse assesses child for Hb level SAM, severe anaemia, & infection
Cont. next page


Child eligible for study (i.e. not SAM, severe anaemia or infection; Hb level between 7-10g/dL)
Nurse provides educational and demand creation messages to caregiver, explains Sprinkles use and benefits, explains alternative supplements
RMHC
Nurse determines child to have SAM, severe anaemia, or infection:
MUAC <115mm
weight-for-height <-3 SD
Hb < 7.0g/dL
kwashiorkor, marasmus
positive for infection
Child treated at RMHC or referred to PHC for further assessment
RMHC
SVG follows up and provides educational messaging if child has been treated otherwise SVG recommends referral again
Caregiver purchases Sprinkles
RMHC
Caregiver does not purchase Sprinkles
SVG follow up to monitor compliance, side effects, and mothers perceptions, concerns
SVG collects data from Sprinkles journal, calendar
Household level
Cont. next page
Nurse provides information letter to caregiver with recommendations which can be presented at PHC, ICDS, etc. treatment
RMHC
Follow up with end line questionnaire after 2 months post-enrollment
Household level


Sprinkles not administered at HH
Sprinkles administered at HH
Household level
Hb increase
Hb doesn't increase
Hb increase
Hb doesn't increase
SVG conducts end-line and takes Hb levels 2 months post Sprinkles purchase
Household level
SVG conducts follow up surveys 6 months post Sprinkles purchase and recommends 2nd regimen of Sprinkles for children in 6-24 month age group
Household level

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