USING FORMATIVE RESEARCH TO DESIGN INFANT AND YOUNG CHILD

FEEDING INTERVENTIONS

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USING FORMATIVE RESEARCH TO DESIGN INFANT AND YOUNG CHILD
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Interventions using technology-based supplements to improve infant and young child feeding (IYCF) have only had a moderate effect on growth. The amount of formative research conducted prior to these interventions has been minimal suggesting that unknown contextual aspects may have affected the impact of these technology-based supplements. This dissertation explores the use of formative research to improve the design of IYCF interventions using technology-based supplements.

In CHAPTER TWO I examined the underlying contextual determinants of complementary feeding in two food insecure settings to identify appropriate intervention strategies. In CHAPTER THREE I tested the feasibility of one of the strategies developed in CHAPTER TWO by comparing how much infant feeding can be improved without and with the use of a lipid-based nutrient supplement. In CHAPTER FOUR I compared the information gained about the acceptability of a processed complementary food (PCF) from a short, one-day taste and a longer, 2-week home trial.

The results of CHAPTER TWO indicate that other determinants besides income poverty can help determine whether a food-based supplement is required and that nutrition education programs should be grounded in the larger indigenous ways of knowing about food and infant care. In CHAPTER THREE the results show that nutrient intakes can be significantly improved with barrier-specific counseling

messages via a transformative learning experience, but ultimately some type of supplement is necessary to ensure adequate iron and zinc intakes when there is a lack of animal source foods. In CHAPTER FOUR, the results confirmed that a longer home-based trial can identify pitfalls that could affect a longer intervention that were not found in a short, one-day taste test.

In CHAPTER FIVE I reviewed available formative research models and made recommendations to improve the feasibility of conducting such research in an era where more technology-based supplements are available. I conclude that formative research can be approached iteratively such that multiple layers of an intervention could be explored. I recommend that formative research for an intervention should be better documented to recognize the contextual decisions of intervention design and education interventions should begin to incorporate contemporary adult learning theory into their design.

BIOGRAPHICAL SKETCH

Keriann Hunter Paul was born in Bristol, Tennessee and grew up on the other side of the Blue Ridge Mountains in Hickory, North Carolina. She attended public schools in Hickory until she decided to follow in her older sister's footsteps and accept the greater challenge by attending the North Carolina School of Science and Mathematics in Durham, North Carolina. This formative experience enlightened Keriann about the world of science where she took classes in biochemistry, organic chemistry, immunology, and genetics.

After graduating from high school, Keriann won the prestigious Park Scholarship to North Carolina State University in Raleigh, North Carolina. She majored in Biochemistry and conducted most of her undergraduate research in the lab of Professor John Cavanagh which studied protein structure and dynamics. She had external experiences during the summers at the Mayo Clinic in Rochester, Minnesota and Syngenta Biotechnology, Inc. in the Research Triangle Park in North Carolina. During her last year, Keriann conducted an undergraduate research project on plant signal transduction pathways in the lab of Professor Wendy Boss.

Keriann had several other educational experiences that have directed her path. The Park Scholarship experience fostered and challenged her to excel not only in scholarship but also leadership and service. She co-founded a mentorship program to engage gifted middle-school aged females in intellectual pursuits other than school and grades. She took a course in permaculture which introduced her to many topics regarding sustainability, health, and agriculture. She also spent a semester abroad at the University of Leeds in the United Kingdom where she developed a love of travel and finding connections with people from all parts of the world.

After all these experiences, Keriann decided to pursue graduate studies in Food Science at Cornell University where she could apply her basic science background to

her interest in food and health. During her first semester at Cornell, Keriann attended a wide variety of seminars and courses which opened her eyes to the many opportunities for research beyond the laboratory. Thanks to her advisor in Food Science, Professor Dennis Miller, she was offered the opportunity to work on a human field study with Professor Rebecca Stoltzfus in the Division of Nutritional Sciences. Keriann was invigorated by the experience and continued working with Professor Stoltzfus for the rest of her dissertation.

Keriann's education is still in progress. During the course of her dissertation research, she became interested in Adult Education under the advisement of Professor Rosemary Caffarella. Upon completing of her dissertation, Keriann would like to be involved in nutrition research which focuses on ways to improve the health of communities using integrated principles of education, community development, and nutrition.

To my whole family, for encouraging me since I was a little girl.

To Lindsay, for giving me footsteps in which to follow.

To Aaron, for giving me my future

Advisors in the field

I would like to thank Boss Hamad Juma, Said Ali, Sabra Khalfan, Nadra Ali, and everyone else at the Public Health Laboratory-Ivo de Carneri for making my first international work experience so productive and painless. I would also like to thank Dr. Jean Humphrey, Dr. Allison Jenkins, and everyone else at ZVITAMBO for giving me the opportunity to work in such a wonderful country as Zimbabwe and get a lifetime of experience in just six months.

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I would like to thank my family for their continued excitement over all my life's decisions. I would like to thank the friends I have met at Cornell for giving me respite from the stresses of PhD research. Lastly, I would like to thank my best friend and love of my life, Aaron, for finding me relatively quickly, knowing how to take care of me when I need it, and sticking with me through the months and months we had to be apart.

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CHAPTER ONE

INTRODUCTION

THE PROBLEM

The face of child undernutrition

Childhood undernutrition continues to plague millions of children in the developing world. Thirty-two percent of all children in developing countries under the age of five are stunted (length-for-age z score ≤ -2.0) (1). In addition to stunting, undernourished children may also be underweight (weight-for-age z score ≤ -2.0) or wasted (weight-for-length z score ≤ -2.0), and experience poor cognitive development and lowered immune function (1). These outcomes increase the risk of mortality, which is why child undernutrition is currently responsible for 35% of global child deaths (1). The long term consequences of child undernutrition decrease the human capital of these countries by reducing reproductive, academic, and economic potential of the adult population (2). Subsequently, undernutrition contributes to the difficulty in achieving sustainable development and alleviating people from poverty. Understanding how to prevent child undernutrition is imperative to the future development of these countries.

The timing of growth faltering

Children suffer the immediate consequences of undernutrition early in life. Maternal undernutrition in pregnancy can lead to intrauterine growth retardation and possibly also pre-natal programming effects that can affect growth and health later in life (1,3,4). During infancy, a large portion of growth faltering occurs in the complementary feeding period (5). Complementary feeding is the process of infants

receiving increasing amounts of solid food in addition to breast milk (6). The onset of growth faltering generally corresponds to the time when mothers introduce complementary food, around the age of 6 months, and continues through infancy (5). Growth faltering usually slows after 18 months of age, but children do not experience substantial catch-up growth. Therefore, the first two years of life represent the most advantageous period to intervene to prevent the effects of undernutrition (7,8).

Growth faltering during complementary feeding

During the complementary feeding period, there are two direct causes of poor growth: inadequate nutrient intake and infection (1,6,9). Inadequate nutrient intake is due in part to poor quality diets containing inadequate energy (10-15) and micronutrients such as calcium, iron, zinc, vitamin A, and vitamin B6 (10,11,13,14,16,17). While zinc deficiency is directly related to stunting (18), other micronutrient deficiencies may affect growth by suppressing appetite thereby lowing overall food intake (3). In developing countries, these complementary feeding diets generally consist of thin staple porridges without a lot of nutrient dense foods such as vitamin-A rich fruits and vegetables and animal source foods (6). Another characteristic is the low bioavailability of nutrients such as iron and zinc due to consumption of cereal-based foods without additional absorption enhancers such as vitamin C and meat (10,16).

Infection can limit growth by interacting synergistically with undernutrition in a vicious cycle (19). Periods of infection contribute to undernutrition through decreased absorption of nutrients, anorexia, and other metabolic effects. Conversely, nutrient deficiencies themselves can lower immune function and increase one's susceptibility to infection. Complementary foods are often prepared and stored under unhygienic conditions which also lead to infection (20,21).

Underlying these immediate causes of inadequate nutrient intake and infection are poor caregiver feeding practices. Already mentioned practices are 1) feeding low energy and nutrient dense foods and 2) preparing and feeding foods in an unhygienic manner. There are other caregiver practices that often contribute to inadequate nutrient intake and infection. One, mothers may stop giving breast milk exclusively before 6 months of age to introduce these unsafe and non-nutritious foods thereby initiating the undernutrition and infection cycle in early infancy (5,9,22). Two, mothers may not be feeding their children in an active and responsive manner (23-25). Mothers who are not proactive feeders may not feed an undernourished child with a poor appetite simply because the mother perceives the child is not hungry (25). Additionally, mothers may not be responsive to the child's hunger and satiety cues and therefore neglect to feed the child frequently or force feed the child which can negatively impact later eating behaviors (25). The Guiding Principles for Complementary Feeding for the Breastfed Child is a seminal document that describes ten ideal practices that have been shown to have a substantial impact on the health and growth of an infant during this time (26). Understanding mothers' actual practices in comparison with the ideal complementary practices is important when assessing how children become undernourished.

INTERVENTION APPROACHES

Interventions seek to improve complementary feeding practices and/or the nutrient gaps in order to prevent growth faltering, micronutrient deficiencies, and morbidity. Previous intervention approaches have been: 1) food supplementation either at feeding centers or with food baskets to be taken home, 2) nutrition education to improve complementary feeding practices and to teach more nutritious preparations of local complementary foods, 3) market-based programs to support the purchase of

specific foods, 4) local processing of staple foods to improve nutrition such as germination of grains to decrease viscosity (and increase energy density) and decrease levels of anti-nutrients like phytate, and 5) micronutrient supplementation (6).

Complementary feeding interventions through 1997

Caulfield et al. reviewed complementary feeding interventions from the 1970s until 1997 and discussed the gains in weight and length growth associated with the different approaches (27). They reviewed efficacy trials that provided food supplementation via feeding centers or raw food ingredients delivered to families. Programs were also reviewed which provided complementary feeding education in the form of recipe trials to demonstrate more nutritious food preparations and communication strategies to disseminate complementary feeding messages. The conclusion was that these interventions improved ponderal and linear growth by 0.10 - 0.50 SD. While this range would not ensure normal growth for these populations, this degree of improvement would significantly reduce the prevalence of stunting and underweight.

Recent approaches

In the past decade, there has been a growing interest in developing and testing various technology-based, ready-to-use products for use in the home to prevent undernutrition. Interventions using these new products have taken place at home because their design was intended to mitigate some of the barriers to complementary feeding such as lack of time, knowledge, and resources. Other ready-to-use products had been developed in the past, such as the *Atole* drink used in the INCAP study in Guatemala during the 1960s and 1970s (8). While *Atole* is still manufactured and marketed as Incaparina® for at-home use in Guatemala, the efficacy study provided it

to mothers and children at special feeding centers (28). Below is a short description of these new products along with a summary of the trials using each of them.

Processed complementary foods (PCF)

Processed complementary foods are cereal porridges that contain some type of complementary protein source such as legumes or milk. They are often pre-cooked and fortified. These PCF provide a balanced set of macro- and micronutrients without requiring any extra time or cooking resources (29). PCF are similar in ingredients to the fortified blended flours used in food aid such as corn-soy blend (CSB). However, extrusion of the ingredients produces a completely cooked product that only requires the addition of water to reconstitute.

India (Bhandari et al., 2001). This randomized, controlled trial compared the effect on growth and morbidity from supplementation with a PCF verses nutritional counseling. There were 4 groups: a milk-based PCF supplement group, a nutritional counseling group, a no intervention group, and a visitation group (30). Children were in the study from 4 to 12 months of age. Changes in weight and length were the primary outcomes. Secondary outcomes were attained weight and length, dietary intake, and morbidity.

The growth effect was small and accompanied some negative outcomes. The children in the food supplement group gained 250 g more than the control (visitation group) during the 8 month intervention. There were no differences in attained weight or either of the length parameters. Children in the food supplement group had a lower breastfeeding frequency and a higher incidence of dysentery and fever than the control group. The higher overall weight gain was due to a significantly higher weight gain between the 6 and 9 month time points. This represents an effect size of 0.32, which corresponds to the range found in the Caulfield et al. review (27). They discuss

several potential factors for this small impact: over-reporting of supplement intake, unknown barriers to feeding beyond availability of food, and the higher incidence of morbidity caused by the decrease in breastfeeding or an unobserved contamination of the supplement during preparation.

Ghana (Lartey et al.. 1999). The objective of this study was to determine the effect on growth and micronutrient status from fortified complementary foods (31). This randomized, controlled trial had 5 groups: a PCF called Weanimix without micronutrients (control), Weanimix plus a high level of micronutrients, Weanimix plus a low level of micronutrients, Weanimix plus fish powder, and a traditional fermented maize porridge, *koko,* plus fish powder. Children were enrolled at birth, and mothers were encouraged to exclusively breastfeed until the child was 6 months of age. At 6 months, the children began receiving the trial foods, and the study continued until they were 12 months old. A cross-sectional study was conducted to compare anthropomorphic data of children not in the intervention with those who were. The primary outcomes were weight and length growth. The secondary outcomes were other anthropomorphic data, clinical chemistry measurements of micronutrient status, dietary intake, and morbidity.

Based on this randomized comparison, fortification with micronutrients did not improve growth, but there were significant improvements in micronutrient status. There were no significant differences among the groups for WAZ, LAZ, weight gain, length gain, and the other anthropomorphic measures. However, the average WAZ and LAZ for all of the intervention groups was significantly greater than the comparison group by 0.52 and 0.64, respectively. These values are slightly higher than the range in the Caulfield et al. review (27). The percentage of infants with low serum ferritin values, an indication of iron deficiency, was significantly higher in the two fish powder groups and the control compared to the fortified Weanimix groups.

There was a significantly greater change in plasma retinol, an indication of Vitamin A status, in the fortified Weanimix groups compared to the other groups. The authors reason that the provision of free, macronutrient dense food and attention to mothers in all the groups may have a greater impact on growth than simply fortifying food with iron, zinc, and vitamin A. They also suggest that perhaps the micronutrient deficiencies were not as severe as they assumed such that zinc and other supplements could not have an impact on growth.

South Africa (Oelofse et al., 2003). This randomized, controlled study looked at the effect of a fortified, commercial complementary food on micronutrient status, growth, and development in "disadvantaged" infants from 6 to 12 months of age (32). This study only had an intervention group which received the trial food and a control group which received a normal diet. Data were collected on anthropomorphic indices, micronutrient status, and psychomotor skills.

The results were only significant for micronutrient status. The decline in serum iron and serum retinol was significantly less in the intervention group. There was no difference in weight or length between the two groups, and no difference in psychomotor skills. The reasoning given for the lack of growth results was that the sample size was too small and some children refused to eat the trial food. The authors state that children in this area would have begun complementary foods at 3 months and may have been used to consuming more variety by 6 months thereby causing them to be tired of the trial food.

Nigeria (Obatolu, 2003). This randomized, controlled study looked at the growth effect from providing a maize and cowpea PCF to infants from a low socio-economic group compared to one control group, infants from a low socio-economic status not receiving the PCF, and one reference group, infants from a high socio-

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economic status not receiving the PCF. Children were supplemented from 4 to 18 months of age. Weight and length were the only outcomes measured.

Unlike the previous 3 interventions described, this intervention had a very substantial effect on weight and length compared to the other group of infants from the low socio-economic status. The intervention group achieved similar growth as the children from the high socio-economic group. The effect sizes were 2.99 for weight and 1.81 for length. These effect sizes are well away from the 0.10-0.50 range seen in other interventions. A recent review of complementary feeding interventions excluded this study on the grounds that the energy contribution from the supplement was exceptionally high (33).

Lipid-based nutrient supplements (LiNS)

Lipid-based nutrient supplements are derived from ready-to-use therapeutic foods used for at-home rehabilitation of severe acute malnutrition (34). They are typically a fortified peanut (or other legume) paste mixed with dry milk powder, sugar, and vegetable oil. These LiNS are very energy dense and can supply ~100 kcal plus the recommended nutrient intake of micronutrients in a small 20 g dose. LiNS has been touted for its technological superiority over PCF. Because of its high lipid content, the water activity (amount of available water to microorganisms in the product) is low thereby making it difficult for bacteria to grow in it unlike leftover reconstituted PCF (34). Secondly, LiNS is easier to manufacture than PCF requiring only a standing mixer to combine ingredients verses the more expensive extrusion technology needed to make PCF (35). Lastly, the high energy density of LiNS would enable mothers to feed smaller quantities fewer times a day than the same amount of energy from PCF and thus possibly prevent a displacement of breast milk in the diet

(6,36). Three studies have used LiNS to prevent undernutrition during the complementary feeding period.

Ghana (Adu-Afarwuah et al., 2007). This randomized study compared 3 types of home fortification: LiNS, Sprinkles, and Nutritabs and their effect on growth, morbidity, and motor milestones from 6-12 months of age (37). Sprinkles are sachets of powdered micronutrients, and Nutritabs are crushable tablets of micronutrients. The hypothesis was that adding more micronutrients (LiNS > Nutritabs > Sprinkles) in the presence of macronutrients (LiNS) would have the greatest impact on growth and micronutrient status. The primary outcome was growth, and the secondary outcomes were morbidity, dietary intake, and the motor milestone, walking independently at 12 months. A non-intervention group was measured at 12 months of age as an ethical alternative to a control group.

The LiNS had a significant impact on growth over the other two interventions, but not on morbidity or motor milestones. Children in the LiNS group gained significantly more weight (220 g) and length (0.5 cm) than the Nutritab group. The children in the LiNS group also had higher WAZ and LAZ at 12 months compared to both the Sprinkles and Nutritab groups. While there was a significant difference in WAZ between the LiNS group and the non-intervention group (Effect size=0.31), there was no significant difference in length. The authors concede that the lack of baseline data on the non-intervention group caused large standard deviations in the adjusted means and made it hard to see statistically significant differences. Another interesting result was that children receiving any type of micronutrient supplement were 2-3 times more likely to walk independently by 12 months than the non-intervention group. The only significant difference with respect to morbidity was a greater prevalence of cough in the Nutritab group compared to the other two groups.

To understand which nutrients were responsible for the growth effects, the authors did a path analysis. They discovered that the increase in weight was most likely due to the added energy (~80 kcal/day), and the increase in length was due to a higher level of essential fatty acids in the blood which would correspond to the essential fatty acids supplied by the LiNS. The effect size on WAZ was 0.31 and the effect size on LAZ was 0.26, although not significant, are again in the same range found in other interventions.

Malawi (Lin et al., 2008). This randomized study compared the growth outcomes from children receiving 40 g LiNS/day to children receiving 137 g maize porridge fortified with fish powder/day (38). Children received the supplements from 6 to 18 months of age. The primary outcomes were weight and length growth. The secondary outcomes were change in zinc and selenium status plus incidence of morbidity.

The only significant difference was a 110 g higher weight gain from 6 to 12 months in the LiNS group. There was no difference in length gain, change in zinc and selenium status, or incidence of fever, cough, and diarrhea. There was no comparison with a non-intervention group to determine overall effect on weight. The authors cite data from a previous survey to show that children from this area gained 90 g less than the LiNS group did during the same age interval. The authors conclude very generally that unknown nutrients and environmental factors played a role in the improved linear growth seen in other studies, such as the Ghana study by Adu-Afarwuah et al. (37), but not theirs.

Malawi (Phuka et al., 2008). This was another study in Malawi that included several of the authors on the Lin et al. study (39). This study compared the effect on growth and incidence of undernutrition in infants receiving 25 or 50 g LiNS/day verses 71 g fortified maize-soy flour. Children received the supplements from 6 to 18

months of age. The primary outcome was weight gain. The secondary outcomes were length gain, change in WAZ, LAZ, and weight-for-length z score (WLZ), the incidence of severe and moderate underweight, stunting, and wasting, change in head or middle upper arm circumference, and change in hemoglobin and serum ferritin concentration.

There were no significant differences in weight or length gain among the groups. There was a significantly lower incidence of severe stunting (LAZ < -3) in the 50 g LiNS/day (0/56) and the 25 g LiNS/day (2/56) groups than the maize-soy group (7/56). In children whose baseline LAZ was less than the trial median, there was a significant improvement in LAZ (0.4 SD) in the 50 g LiNS group verses the maize-soy group. The authors considered the non-significant differences in weight (100 g) and length (0.8 cm) gain to be in line with the range (0.1-0.5 SD) found in other interventions. However, they conclude that LiNS alone might only benefit those who are already stunted.

Home-based fortification

Home-based fortification, as mentioned above, is the delivery of single or multiple micronutrients in the form of a small sachet of powder (Sprinkles) or a crushable tablet (Foodlet) that can be added to complementary foods. Delivery of micronutrients through traditional drops, syrups, and pills is often associated with poor adherence rendering it less effective (40). Sprinkles were designed to be encapsulated micronutrients that could be added to complementary foods without changing the color or taste to make them more acceptable than tradition supplements (40). Sprinkles and Foodlets also deliver specific quantities of micronutrients required by the target age group, an advantage over centrally fortified foods (40).

Few studies have reported the effects on growth using home-based fortification. One was the LiNS study in Ghana described in the previous section which did not see a significant effect on growth in the Sprinkles and Nutritab groups (37). Other interventions similarly have had no effect on growth (41,42). Home-based fortification, while not improving growth, has had significant impacts on micronutrient status (41,42), anemia (40-43), and morbidity (44).

Complementary feeding interventions 1998-2007

Dewey et al. reviewed complementary feeding interventions from 1998 through 2007 to assess their affects on growth, micronutrient status, morbidity, and child development (33). This review included all the studies mentioned above, with the exception of the two LiNS studies in Malawi, as well as other interventions using education, food supplementation plus education, food fortification, and techniques to increase energy density. Again, the conclusion was that all of these interventions combined have a positive, but moderate effect on weight and length growth, ~ 0.25 SD. Food fortification, including home-based fortification, did not have an impact on growth, but it was effective at improving micronutrient status. Morbidity was either unaffected (as seen in most trials), positively affected (as seen in one Sprinkles trial), or adversely affected (as seen in one PCF trial) based on the type of intervention that was chosen. Positive effects on child development were found in the two reviewed studies that measured those outcomes, including the Adu-Afarwuah LiNS trial (37).

FOCUS ON FORMATIVE RESEARCH

The results from these technology-based interventions have not improved growth beyond the previous types of non-technology-based interventions. These products have a lot of innovative benefits, so it is still plausible that they could

contribute to better growth and prevention of undernutrition. The question is then *why were these interventions not more efficacious?* Many authors cite inadequate sample sizes (31,32), prenatal programming effects (3,30,45), and study design (38,46) as potential factors that negatively impacted their results. However, these authors also speculate about unknown contextual aspects that may have impacted the efficacy of the intervention.

The mention of unknown contextual aspects leads to the observation that these interventions were not designed using much, if any, formative research. Formative research is the process of collecting and analyzing qualitative and quantitative data to inform program planning on the contextual and practical aspects of potential interventions (47). Such aspects include current practices and knowledge on infant feeding as well as acceptance, compliance, and feasibility of the intervention. For the most part, developers of these technology-based interventions admit to having little understanding of the actual need for the specific product and of the complementary feeding behaviors around and beyond the product's use within their chosen context. Formative research would provide insight into both of these factors, and for this reason, it should be a valuable tool for designing infant and young child feeding (IYCF) programs using technology-based products.

Methods of formative research

Typically formative research begins with an assessment of the local diet, feeding practices, and infant feeding beliefs. Methods used for assessment include dietary assessment (e.g. 24 hour dietary recalls and food frequencies), ethnographic methods (e.g. observations, focus groups discussions, and interviews), or surveys. This assessment leads to the development of potential intervention options. These potential options may then be tested for acceptability and feasibility using methods

such as recipe trials, sensory tests, focus groups discussions, and short-term household trials.

Use of formative research in IYCF interventions

Formative research is usually cited in the development of behavior change interventions using nutrition education and/or social marketing techniques. Bentley et al. were some of the first researchers to detail the use of formative research in an intervention in Kwara State, Nigeria (48). The researchers used ethnographic studies to understand cultural beliefs around complementary feeding practices, recipe trials to develop nutritionally enhanced complementary foods, and focus groups to assess their acceptability. The researchers concluded that initiating a "dialogue" with mothers that connected nutrition with socio-cultural issues was important to designing a successful intervention. The end result was knowledge, trial, and adoption rates of 57%, 48%, and 17% respectively.

Formative research does not receive such a thorough description for other nutrition education interventions. The Caulfield et al. review noted that all the nutrition education programs that had significant effects on growth and complementary feeding practices included some type of formative research (27). A nutrition education intervention in Brazil developed counseling messages based on ethnographic studies of current practices and then tested the acceptability of them with interviews and household trials (49). The final evaluation showed that children in the intervention group had higher nutrient intakes and improved weight gain along with a non-significant improvement in length. An intervention in India was based on formative research that included quantitative and qualitative methods to assess current feeding practices, community characteristics, children's nutritional status, and household trials to test acceptability of messages (50,51). The results of this

intervention were an increase in energy intakes and an improvement in select feeding practices. A successful nutrition education intervention in Peru only mentions that formative research was completed. In the end, they found an improvement in feeding practices, dietary intakes, and weight and length growth (52). It is inappropriate to compare the outcomes of these studies because of differences in study design and outcomes. However, all of these studies were able to see a positive effect on complementary feeding and all of them used some aspects of formative research to develop their intervention.

Formative research for interventions using a specific food or product has relied on short-term trials to assess maternal and child acceptability. These studies are often simple one-day sensory tests where mothers, and sometimes children, taste the food and give reactions (53-56). Sometimes these studies are structured observations of infant consumption (53). The PCF study in Ghana was the only technology-based intervention reviewed here that mentioned assessing acceptability. They determined the PCF was acceptable to an infant if he/she ate any of a 250 g serving. One study in Bangladesh used a longer trial to assess the acceptability and feasibility of feeding LiNS, but this study was not (yet) followed by a published efficacy trial. Researchers asked mothers to feed LiNS two times a day for a week at home. Acceptability was assessed based on the disappearance of the supplement and recalls of supplement use (36). These trials have been limited to the use of the product alone without assessing the interaction with other feeding behaviors that might influence overall nutrient intake.

Models for conducting formative research

When formative research has been conducted, a variety of methods have been used. In order to streamline the process for non-researchers, several models have been

developed which incorporate these various methods: Designing a Community-Based Nutrition Program Using the Hearth Model and the Positive Deviance Approach-A Field Guide, Designing by Dialogue: A Program Planners Guide to Consultative Research for Improving Young Child Feeding, ProPAN: Process for the Promotion of Child Feeding, and the Preventive Approach (47,57-59). These formative research models utilize similar qualitative and quantitative methods such as observations, interviews, surveys, 24 hour dietary recalls, recipe trials, household trials etc. Despite the similarities, there are criticisms that some of these models are too impractical and inefficient to be implemented regularly. I will briefly describe these four models here, and later in CHAPTER FIVE, I will discuss a potential unified framework for a more feasible and efficient use of formative research.

The Hearth Model using the Positive Deviance Approach

The Hearth Model using the Positive Deviance Approach has been developed by several people over the past 40 years, so it is difficult to attribute it to a particular group or person. This field guide came out of work done by Save the Children, a large international humanitarian agency (60). The basic premise of this model is to identify solutions to child malnutrition that exist within the community using positive deviance. Positive deviance is defined as "adaptive responses for satisfactory child growth under harsh economic circumstances such as food scarcity" (61). In short, the objective is to find families with well-nourished children who are living in "harsh economic circumstances" and then identify the child feeding and care behaviors practiced by these families that deviate from the norm in that community. The nutrition program is then built around those practices with the goals of 1) rehabilitating malnourished children, 2) enabling families to sustain the rehabilitation at home, and 3) preventing malnutrition in future children. The manual has a

conceptual framework that describes the formative research process as well as the

design of the Hearth program (**Figure 1.1**).

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┌─────────────────────────────────────────────┐
│         Identification of Local Resources     │
│                                               │
│         •Village Health Committee             │
│         •Health Volunteers                    │
│         •Formal and Non-formal Health Resources│
└─────────────────────────────────────────────┘

┌─────────────────────────────────────────────┐
│    Situational Analysis of Malnutrition in Children │
│                                               │
│         •Baseline Nutrition Survey            │
│         •Focus Group Discussions              │
│         •Setting-up Program Goals             │
└─────────────────────────────────────────────┘

┌─────────────────────────────────────────────┐
│          Positive Deviance Inquiry (PDI)      │
│                                               │
│         •Identification of Successful Feeding │
│         •Caring and Health Seeking Practices  │
└─────────────────────────────────────────────┘

┌─────────────────────────────────────────────┐
│   Design of Nutrition Education and Rehabilitation │
│          Sessions (NERS) Based on PDI         │
│                                               │
│         •NERS Menu and Messages               │
│         •Positive Deviance Food Contribution  │
│         •NERS Protocols                       │
│         •Integration with Other Existing Programs │
└─────────────────────────────────────────────┘

┌─────────────────────────────────────────────┐
│               Hearth Components               │
│                                               │
│         •Counseling Caretakers                │
│         •Growth Monitoring Program            │
│         •NERS (Phase 1 only)                  │
│         •Vital Events Monitoring              │
│         •Community Management of NERS         │
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Figure 1.1: Conceptual Framework of the Hearth Model

The first step, before the conceptual framework, is to assess whether the site is appropriate for the program using very specific criteria, such as having a prevalence of malnutrition $\geq 30\%$, availability of affordable local foods, availability of mothers as potential volunteers, and presence of committed leadership in the community. This assessment is done by reviewing national surveys, doing informal market surveys, and talking with community members.

The first step in the conceptual framework is the identification of local resources. The model requires substantial community involvement in the planning and implementing of the program, so it is essential to first identify key community members that are motivated to do invest significant amounts of time and energy. The second step is the situational analysis. A baseline nutrition survey is conducted to identify malnourished and well-nourished children for the Positive Deviance Inquiry. Focus group discussions with community members help to identify the normal child feeding and care practices in the community. Lastly, program goals for that community are adapted from the 3 main goals of the Hearth Model.

A few well-nourished (Positive Deviant) and malnourished (Non-Positive Deviant) children are selected for the Positive Deviance Inquiry. The inquiry teams conduct household visits during meal times to observe and interview mothers and other family members. The field guide provides an example observation checklist and interview guide. After the interview, the teams summarize the feeding practices and care behaviors (including health seeking behaviors) for each family. The research teams then compare the findings from the Positive Deviant families with the findings from the Non-Positive Deviant families, and they identify the key Positive Deviant Behaviors and Positive Deviant Foods. A caveat is that these Positive Deviant practices must be accessible to everyone in the community.

The Hearth Model then describes the development of the Nutrition Education and Rehabilitation Sessions based on the Positive Deviance Inquiry. Health Volunteers conduct several sessions each month for mothers with malnourished children. Each session is devoted to a child feeding or care topic, and the messages are based on the Positive Deviant Practices in the community. At the same time, the Health Volunteers prepare supplementary feeds for the malnourished children to help with the rehabilitation. Mothers are required to contribute a Positive Deviant food each day so they can practice these new behaviors instead of just learning about them. Other aspects of the program include continued growth and vital events monitoring as well as community-based monitoring and evaluation of behavior change.

Designing by Dialogue

Designing by Dialogue came out of the work by the Manoff Group, a non-governmental organization which provides technical consulting on health and nutrition behavior change, and the Academy for Educational Development. The "consultative" principal of this model is working together with families to identify improved practices in child feeding. The core method is the household trial known as Trials of Improved Practices (TIPs). The methodology includes other aspects of formative research as well (**Table 1.1**).

Trials of Improved Practices are a series of household visits. In the first visit, current feeding practices are assessed using an in-depth interview and a qualitative 24-hour dietary recall. After the visit, the research team identifies the feeding problems and chooses potential improved practices to give to the mother. At a second visit, the research team member discusses the feeding problems and counsels the mother on the improved practices by providing motivation and information to overcome barriers. Then the research team member negotiates with the mother to try one or more of the

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Table 1.1 Designing by Dialogue Methodology

PHASE 1	Reviewing Existing Information and Designing the Research
Reviewing existing information	To gather and summarize available information. To identify key child feeding problems and possible household actions to solve the problems. To identify remaining research questions.
Designing the research	To select and tailor research components to meet the objectives and answer the research questions.
PHASE 2	**Formative Research Methods**
Exploratory research (in-depth interview and observations, recipe trials, focus groups)	To learn about current feeding practices and problems, as well as related beliefs and attitudes. To obtain advice from families on ways to solve feeding problems. To obtain opinions from influential people.
Trials of Improved Practices (TIPs)	To assess feeding practices and provide tailored recommendations. To test mothers' and children's responses to new feeding practices. To learn about motivations and constraints to improving child feeding practices.
Checking research (focus groups, key informant interviews)	To check the response of a broader or different sample to the recommendations or messages. To check the response of decision makers or program implementers to the recommendations.
PHASE 3	**Building a Bridge from Research to Action**
Analysis and presentation	To integrate all the information collected and analyzed during Phases 1 and 2 into one document. To interpret the findings and make recommendations on how to use the results. To share and discuss the results.
Using results for programming	To apply research results to program planning. To develop the program strategy and communications plan.

Adapted from Box 1.1 (47)

improved practices. After a few days, the team member completes a follow-up visit to assess whether the mother tried the new practices, what motivated her or prevented her from trying the practices, whether she will continue to try the practices, and whether she would recommend the practices to her friends. The outcomes of the TIPs include

identification of common feeding problems, the most acceptable improved practices, modifications made by mothers to the improved practices, and the motivations and barriers to adopting the improved practices. The experiences of these mothers can then be used to develop the overall nutrition messages that will likely have the most impact on the community.

The manual is divided up into the different phases of the research. There is an emphasis on tailoring the research to include only the necessary elements in an effort to be flexible and time efficient. However, TIPs is regarded as an essential element that should not be skipped. The manual provides succinct descriptions of each method and step-by-step instructions for completing them. Question guides and worksheets are provided to guide data collection, data analysis, and reporting. Examples from actual project reports are also included for each type of method. Overall this manual has been well referenced in the complementary feeding literature (9,30,58).

*Pro*PAN

*Pro*PAN was developed by the Pan American Health Organization (PAHO). The authors state that *Pro*PAN is the most comprehensive manual to date because it provides step-by-step instructions on quantitatively identifying nutritional and dietary problems, qualitatively describing why they occur, and developing an intervention with a monitoring and evaluation plan. The conceptual model for *Pro*PAN has four modules: 1) Assessment, 2) Recipe Creation Exercise and Test of Recommendations, 3) Design of the Intervention Plan, and 4) Monitoring and Evaluation (**Figure 1.2**).

The first module, Assessment, begins with some review of available documentation to "identify the general nutrition situation." After that the General Survey and 24 hour dietary recall are implemented to identify actual practices and nutrient intakes in the population. These surveys are intended to be statistically

Figure 1.2 _Pro_PAN conceptual model (58)

representative of the population so they require a large sample size. After the quantitative assessment, market surveys, semi-structured interviews, opportunistic observations, and food attribute exercises are completed with smaller samples to qualitatively assess the actual practices and feasible options for behavior change.

The second module, Recipe Creation Exercise and Test of Recommendations, has guidelines on completing recipe trials and household trials. The household trials are a series of three visits. In the first, an interviewer collects basic information to understand the mothers' current practices and to avoid giving a recommendation that the mother already practices. Then the interviewer asks mothers to try a recommendation for a week. A follow-up visit assesses whether the mother is trying the recommendation and whether there are any facilitating factors or constraints. The interviewer continues to motivate the mother to try the recommendation. A final interview assesses the overall experience and asks mothers if they have any suggestions about promoting this recommendation in the community.

The third and fourth modules, Design of the Intervention Plan and Monitoring and Evaluation, are the shortest modules. The module on designing the intervention gives intervention plan options and general guidance on their design and implementation. Examples of interventions include: training, development of health services norms, development of a nutrition and feeding communication plan to improve young child feeding, promotion of community participants, and coordination with strategic allies. The module on monitoring and evaluation gives a thorough explanation of those concepts and why they are necessary in intervention design. Then the module describes how to develop frameworks for monitoring and evaluation activities.

The main tools offered by *Pro*PAN are question guides, a software program, and matrices. The question guides are provided for the General Survey, semi-structure

interview, and household trials. The software program is for inputting and analyzing the data from the General Survey and the 24 hour dietary recall. The matrices are for summarization and prioritization of the data. The manual and software were originally developed and tested in Latin American and the Caribbean so the language is obviously targeted for those populations. However, PAHO and UNICEF are currently updating the manual so that it can be more easily used in other parts of the world.

The Program Theory Approach

This model was developed and used by a multi-institutional project in Haiti that was studying the effectiveness of a preventive verses recuperative program model to reduce child undernutrition (59). The overall design of the preventive approach was to include a food supplementation component along with a behavior change component to all mothers with children under the age of 2. They developed a formative research model to help design their behavior change communication (BCC) component. The steps of their formative research were:

1. Review existing communication materials.

2. Rapidly assess infant feeding practices.

3. Gather in-depth information on current feeding practices and their determinants using interviews with mothers, grandmothers, fathers, and program staff.

4. Conduct recipe trials to develop improved complementary foods.

5. Observe current program activities and identify potential delivery points for BCC.

6. Select priority behavior change communication actions using: a decision matrix, a program-planning matrix, and a BCC strategy matrix.

7. Develop BCC materials and training plans by reviewing previous program communications and pre-testing recommendations using interviews to assess comprehension, believability, perceived importance and benefit, and potential to change behavior.

The developers of this approach cite their matrices as the stand-out component for this model (P. Menon communication). The decision matrix is used to compare actual practices with ideal practices and identify the facilitators and constraints to performing the promoted practices. The program-planning matrix highlights the facilitators and constraints for each promoted practice, the programming options within the current system, and the programming options that require new structures to be developed. The BCC strategy matrix lists the practices to be promoted, who the messages will be targeted to, when the messages will be delivered, where the communication will be delivered, how the communication will be delivered, and what is needed to help with the communication. Viewed together, the matrices are intended to help the program planner pull out the necessary data from the formative research and organize it into a fully-developed program theory.

OVERALL RESEARCH OBJECTIVE OF THE THESIS

The observation that interventions using technology-based products have not included in-depth formative research provides an opportunity to potentially improve the efficacy of future interventions that use them. This thesis addresses how conducting formative research can improve the design of infant and young child feeding interventions using these technology-based products in three ways. Chapter Two assesses complementary feeding in two settings (rural Zimbabwe and Pemba Island, Zanzibar, Tanzania) and determines appropriate intervention strategies. The comparison of two settings determines how important context is when choosing

intervention strategies. Chapter Three evaluates the feasibility of improving infant diets with provision of LiNS in the context of an improved underlying diet. Chapter Four compares the information around PCF acceptability and use that is gained from a one-day sensory study verses a longer, more in-depth household trial.

Specific research questions for Chapter Two

1. What are the nutrient gaps in the diets of 6-12 month old children in rural Zimbabwe and Pemba Island, Zanzibar, Tanzania?
2. What are the feeding practices causing the nutrient gaps?
3. How does the context at the household and local level influence feeding behaviors?
4. How does context determine what supplements and educational approaches would be appropriate?

Specific research questions for Chapter 3

1. What are the nutrient gaps in the diets of 6-12 month old children in rural Zimbabwe?
2. What are the feeding practices causing the nutrient gaps?
3. What improved practices are acceptable and feasible to mothers (including and not including LiNS)?
4. How much are nutrient intakes improved with and without provision of LiNS?

Specific research questions for Chapter 4

1. Will Pemban mothers feed a soy-and-rice-based PCF with and without added dry skim milk to their 10-15 month old infants?
2. Will infants consume at least 50 g dry product per day?

3. Will there be replacement of breast milk?

4. Will there be replacement of nutritious family food?

5. Will there be sharing among family members?

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CHAPTER TWO

BEYOND FOOD INSECURITY: COMPARING TWO SITES IN SUB-SAHARAN AFRICA TO DETERMINE HOW CONTEXT CAN HELP IMPROVE COMPLEMENTARY FEEDING INTERVENTIONS

ABSTRACT

The role of context has not been elaborated with respect to current recommendations for complementary feeding interventions apart from a gross distinction based on food security. Our objective was to compare two food insecure settings in Sub-Saharan Africa to determine how context influences complementary feeding practices and nutrient intakes and in turn the appropriate nutrient supplements and educational approaches. We conducted formative research using 24-hr dietary recalls, household interviews, and focus group discussions in rural central Zimbabwe (n=32 mothers) and Pemba Island, Zanzibar, Tanzania (n=44 mothers) to assess the context of complementary feeding for 6-12 mo. old infants. In both settings, there were high proportions of children not consuming the estimated required intakes from complementary food for all nutrients. Problematic feeding practices included poor dietary diversity and inadequate sanitation/hygiene in both settings, while Pemba had additional problems with breastfeeding and Zimbabwe with inadequate energy density. Beyond food insecurity, contextual determinants of practices included inaccurate indigenous knowledge, time-consuming maternal livelihoods, family eating behaviors, local agriculture, and the local ecosystem. A home-based fortificant would likely be sufficient for Pemban children because the ecosystem of the island provides sufficient sources of macronutrients. However, Zimbabwean children appear to need a fortified food-based supplement to overcome the poor agricultural and economic context leading to food insecurity. Both settings would require nutrition education,

but it should target the larger indigenous ways of learning and family eating behaviors in order to achieve the necessary behavior change. Assessing context more completely highlighted potential ways to improve the specificity and therefore the efficacy of complementary feeding interventions. A framework to guide future formative research is proposed.

INTRODUCTION

Child undernutrition remains a persistent problem throughout the developing world. A recent series in The Lancet described the current exposure and consequences of undernutrition for the world's children (1-5). Undernutrition leads to stunting, poor cognitive development, and increased morbidity and is responsible for 35% of child deaths under the age of 5 (1). Because long term consequences of undernutrition eventually result in the loss of human capital, preventing undernutrition is imperative to many nations' development (2).

Most child undernutrition occurs during the period of complementary feeding (6). Complementary feeding is the process of providing infants other liquids and solid foods in addition to breast milk (7). Ideally infants receive breast milk exclusively from birth to 6 months, and then are introduced to nutritious solids of increasing consistency while continuing to breastfeed until 24 months of age (8). Undernutrition is frequently caused by inadequate nutrient intakes and disease resulting from poor complementary feeding behaviors/practices (**Figure 2.1).** This complementary feeding period is therefore recognized as a critical time for intervention to prevent child undernutrition (9).

The series in The Lancet recommends complementary feeding intervention strategies to improve nutritional status based on two broad contexts—food secure areas and food insecure areas. Nutrition counseling using specific messages that
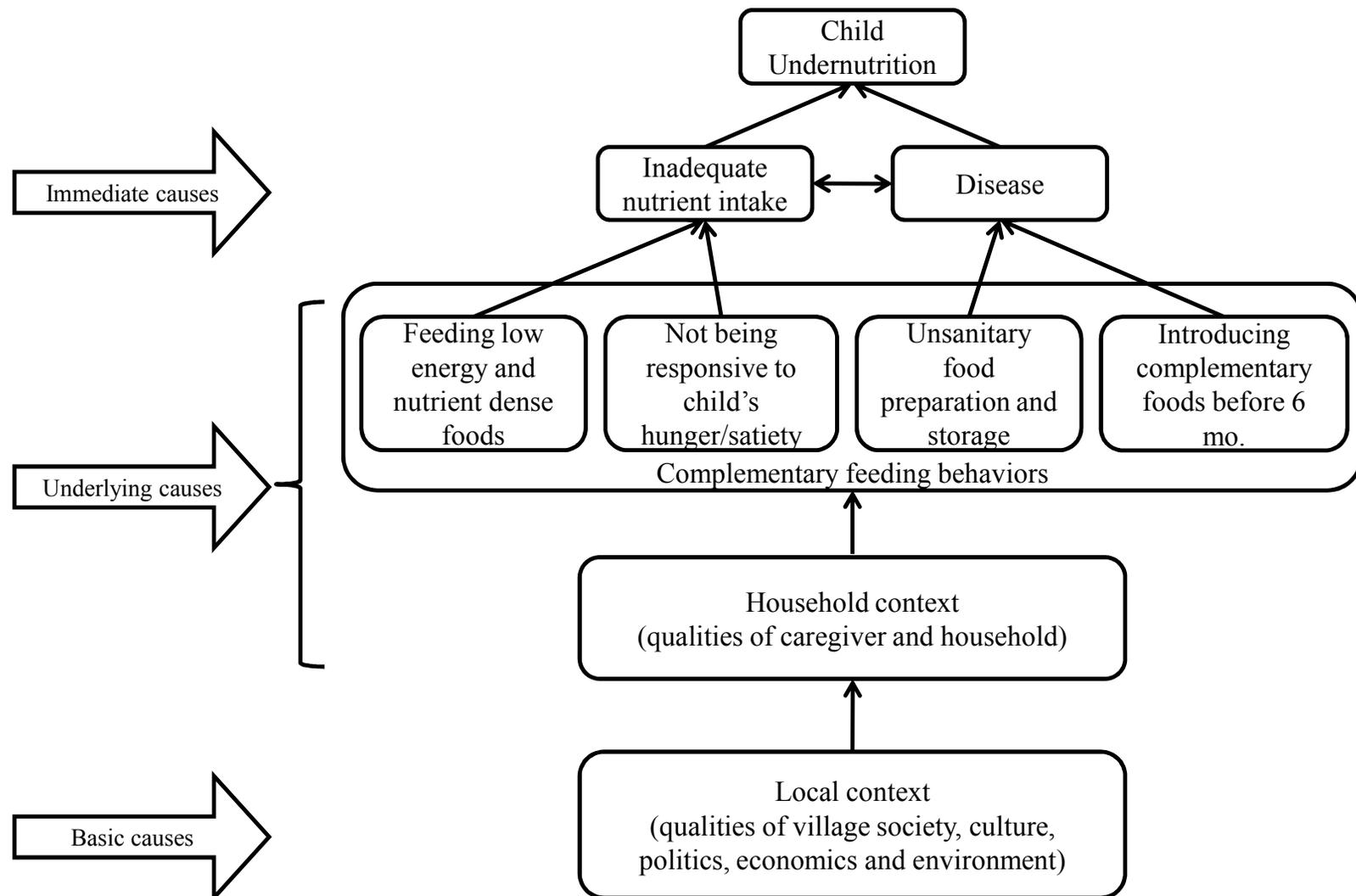
Figure 2.1 Modified UNICEF framework for child undernutrition focusing on the complementary feeding period

emphasize consumption of animal source foods and energy density is recommended for food secure areas. Nutrition counseling plus some type of food supplement with micronutrient fortification is recommended for food insecure areas. However, two reviews of these types of complementary feeding interventions showed a variable, but overall limited effect size (~0.1 to 0.5 SD) on ponderal and linear growth (10,11). Furthermore, other estimates in The Lancet series showed that we can reduce stunting by only 35.5% and deaths by 24.7% at 36 months of age if we implement all the "available" interventions (including pre-natal supplementation, breastfeeding promotion, disease prevention, and micronutrient supplementation) (3). A reasonable question is *what can we do to improve the efficacy of these interventions, particularly complementary feeding interventions?*

One response to that question has been that we need better supplements, an idea that has been pursued in recent technological innovations. Several types of products have been designed by food scientists to help meet specific nutrient needs or mitigate common causes of poor maternal feeding behaviors such as lack of time, resources, and knowledge (7,12). Examples of these products are processed complementary foods (PCF), fortified and pre-cooked blends of cereal and legume flours (13); lipid-based nutrient supplements (LiNS), typically fortified peanut butter, vegetable oil, and milk powder spreads (12,14); and home-based fortification using powdered micronutrients such as Sprinkles or crushable tablets of micronutrients known as Foodlets (15,16). Lipid-based nutrient supplements may be classified as home-based fortification or fortified food, because they deliver micronutrients as well as some macronutrients (15). Over the past decade, trials using PCF and LiNS have produced similar effects on growth compared to other food supplements and education (11,17-22). Home-based fortification with Sprinkles or Foodlets has had a significant effect on morbidity and micronutrient status but not growth (11).

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However, focusing on the variation instead of the overall effect highlights the possibility that contextual aspects other food security, defined by The Lancet series as per capita income per day > US$1 (3), are modifying the efficacy of the intervention. These contextual aspects may affect the appropriate choice of the supplement as well as the educational messages required, and the appropriate targets and channels for those messages. The authors of The Lancet series concede that the indicator for food security is "crude and arbitrary" (3), so we believe it is helpful to determine the benefit of understanding context more in-depth.

The role of context has been long recognized in discussions of child undernutrition, and elements of context are included as underlying and basic causes in the widely accepted UNICEF framework for child undernutrition (1). Context is a difficult word to define. In simple terms, context is the set of circumstances surrounding something. Its definition may be narrow and confined to immediate people and surroundings, or it may be expanded to include characteristics of the society, culture, physical environment, economy, and political system. Currently the recommended complementary feeding interventions target the most immediate causes of undernutrition—inadequate nutrient intake and complementary feeding practices— as opposed to other contextual aspects. This focus is understandable given the complex layers of context that might be relevant, and the drive to simplify and generalize global recommendations.

We decided to explore the context around complementary feeding in two sites that would be considered similar by the Lancet series' definition of "food insecure areas" and determine appropriate intervention strategies for them. Our specific research questions are:

1. What are the nutrient gaps in the diets of 6-12 month old children in these sites?

2. What are the feeding practices causing the nutrient gaps?

3. How does the context at the household and local level influence feeding behaviors?

4. How does context determine what supplements and educational approaches would be appropriate?

METHODS

Settings and participants

In preparation for future efficacy trials, formative research was completed to assess current infant feeding practices and nutrient intakes in two food insecure settings in Sub-Saharan Africa—Pemba Island, Zanzibar, in Tanzania and rural central Zimbabwe. Sites in each setting were purposively chosen. In Pemba the formative research took place in 3 villages—1 semi-urban village in the district of Wete and 2 rural villages in the district of Micheweni (1 inland and 1 coastal) during January 2006 and January 2009. In Zimbabwe the formative research took place in 2 small rural villages in the central district of Chirumanzu between November 2007 and April 2008.

Both settings were food insecure by the definition in The Lancet series. In Wete and Micheweni Districts, the average per capita incomes per day are $0.27 and $0.30[1], respectively, and the proportion of people living below the food poverty line is 24 and 33%, respectively. In Zimbabwe, the GDP per capita per day is $0.54, and the proportion of people living below the food poverty line was estimated at 69% in 2002 (23-26). Additionally, the two countries also have similar rates of undernutrition with regard to growth faltering and anemia (**Figures 2.2 and 2.3**) (27,28).

Mother and infant dyads were randomly selected from lists of eligible households provided by village health workers, health clinics, or other community

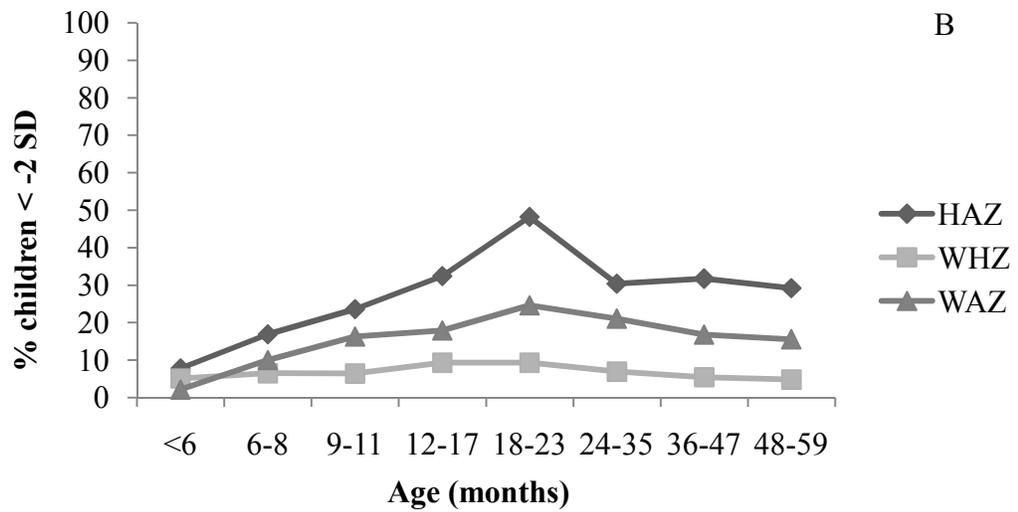[1] US dollar figures are based on mean exchange rates for 2004 and 2005.
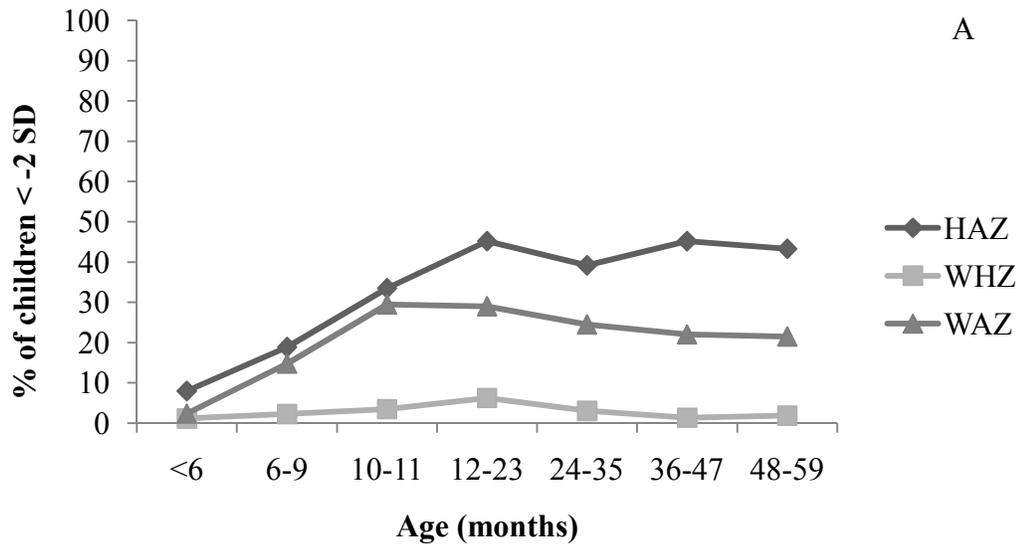
Figure 2.2 Growth faltering in children aged 0-59 months in A) Tanzania and B) Zimbabwe (27-28).
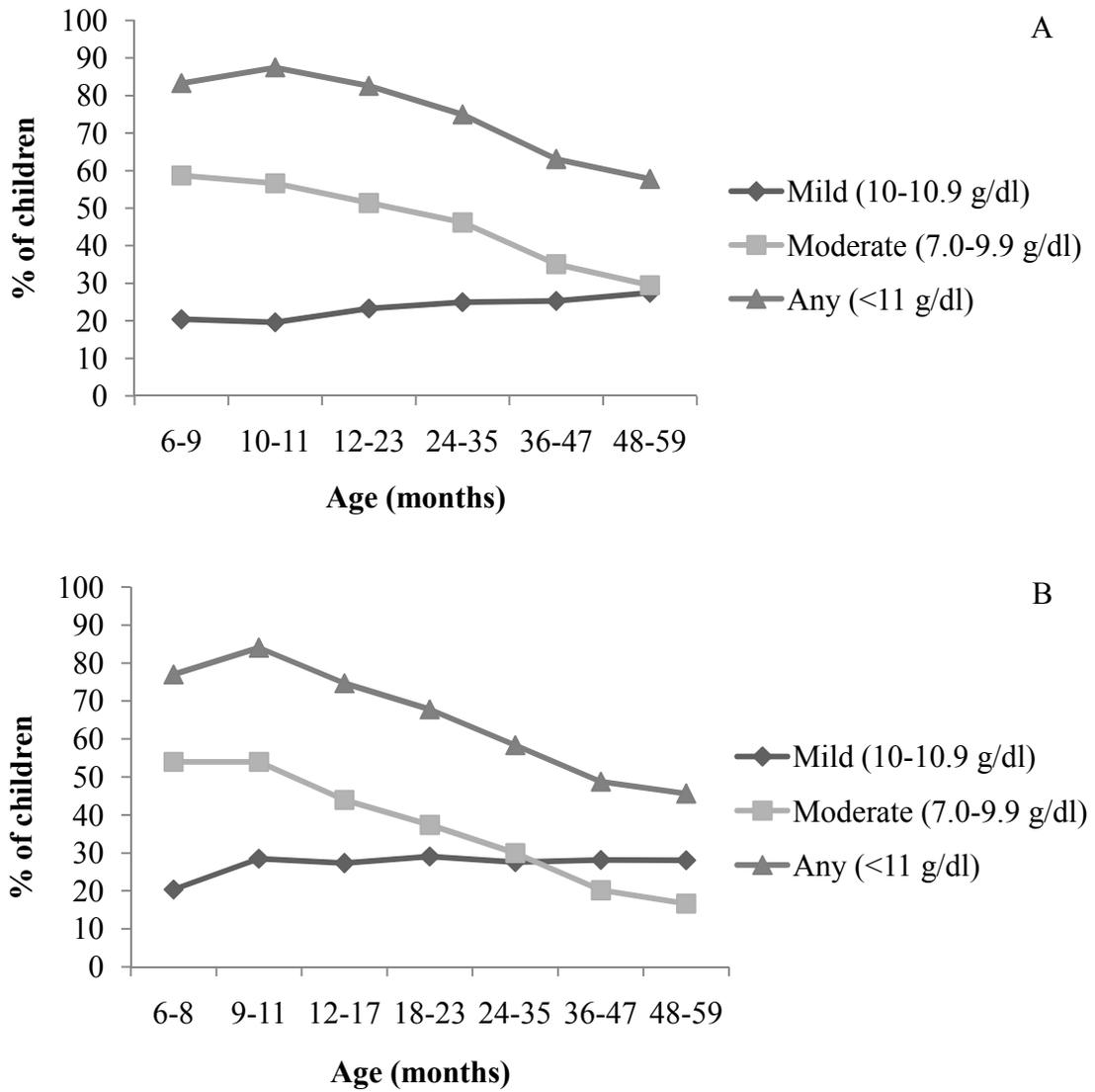
Figure 2.3 Anemia in children aged 0-59 months in A) Tanzania and B) Zimbabwe (27-28)

leaders. Eligible mothers had infants between 6-12 months of age and were actively breastfeeding. We chose this age group because it is the time when food supplementation has shown the greatest effects on growth (29) and because it is the most precarious time to achieve a healthy diet. The study was approved by the Medical Research Council of Zimbabwe, the Research Ethics Board of McGill University, the Zanzibar Ministry of Health, and the Institutional Review Boards of Johns Hopkins University and Cornell University. Informed consent was obtained from all participating families.

Data collection

     Identifying nutrient intakes. In both sites two 24-hr dietary recalls were conducted on non-consecutive days (Pemba, n=44 children and Zimbabwe, n=32 children).   Weights of food were collected using food samples or qualitative measures that were later reproduced and weighed. Local recipes were collected from mothers and replicated to measure ingredients and cooking yields. Pemban food intakes were transformed into nutrient intakes using a food composition table built from local, African, and USDA tables (30). Zimbabwean food intakes were analyzed using Nutrisurvey software (WHO), which included food composition data from similar tables plus other resources (31,32).

     Identifying complementary feeding practices and their contextual determinants. We collected information about infant feeding practices in two ways. In Pemba, focus group discussions were conducted initially (n=72 mothers) in 2006. In Zimbabwe, information about infant feeding practices was collected using in-depth household interviews (n=32) in 2007-2008. To capture information sought in the household interviews that was not discussed in the focus groups, the same interviews

were conducted in Pemba (n=36) in 2009 during the same time of year to minimize seasonal effects.

Data analysis

  Qualitative data. Initial focus group discussions in Pemba were summarized using fieldworkers' written observations and were translated from Swahili to English. Household interview responses in Zimbabwe and the Pemba follow-up study in 2009 were recorded verbatim and in English due to high English proficiency of interviewers. Text segments were labeled with codes pertaining to contextual determinants of infant feeding using Atlas.ti software (Berlin, Germany). The coded data were then tabulated and summarized by emergent themes (33). The Guiding Principles for Complementary Feeding the Breastfed Child document was used as a standard to compare feeding practices found in these two sites (8).

  Quantitative data. Nutrient intake and demographic data were included only for children with 2 completed 24-hr dietary recalls. Nutrient intakes were averaged over the two days for mean individual nutrient intakes. The median intake was used to describe the center of the data because of occasional outliers in the data. The proportions of children not meeting estimated nutrient requirements from complementary foods were based on estimated requirements from complementary foods given an average intake of breast milk (12,13,34-37). These two values were used to identify major nutrient gaps in the diet. To identify top sources of nutrients in each setting, total intakes from each food were averaged over the entire sample.

RESULTS

Demographics

      Maternal education levels were markedly different between the two settings, with Pemban mothers being markedly less educated than Zimbabwean mothers (**Table 2.1)**. Pemban mothers were also much more likely to be multiparous. Only 2.3% of mothers in Pemba had one child compared to 40.6% of mothers in Zimbabwe. Furthermore, 28% of mothers in Zimbabwe were single compared to 0 mothers in Pemba (data not shown). In both settings, most mothers were housewives and maintained gardens.

Table 2.1 Demographic characteristics of participants

	Zimbabwe	Pemba
	n=32	n=44
Age of Child, (m), %(n)		
6-8	37.5(12)	38.6(16)
9-12	62.5(20)	61.4(28)
% of males	62.5(20)	38.6(17)
Educational Level, %(n)		
No primary school	0	50.0(22)
Some primary school	0	13.6(6)
Completed primary school	25.0(8)	6.8(2)
Some secondary school	65.6(21)	29.5(13)
Completed secondary school	3.1(1)	0
%(n) 1st child	40.6(13)	2.3(1)

Nutrient intakes

     Energy. Energy was a problem nutrient in both settings, but for different reasons (**Table 2.2**). In Zimbabwe, 50% of 6 to 8 month old children and 30% of 9 to 12 month old children did not consume the estimated energy requirement. There was one child in the younger group that was still exclusively breastfed at 6 months, and two others who had barely been introduced to complementary foods at 6 months which partially would explain this high proportion. Despite the median food intakes being quite high (447.8 and 589.2 g/day), the low energy density of the complementary food (0.6 kcal/g) could also explain why these proportions were high. In Pemba, although median energy intakes were adequate, 37.5% of 6 to 8 month olds and 21.4% of 9 to 12 month olds were not consuming enough energy. In contrast to Zimbabwe, these proportions could be explained by low food intakes (median intakes: 203.3 and 314.3 g/day) of high energy dense (1.2 kcal/g) foods. The staple foods contributing to energy for these two settings differed: namely, rice and wheat in Pemba verses maize in Zimbabwe.

     Protein. Median protein intakes were adequate for most groups, but the proportion of children not consuming enough protein was $\geq 20\%$ for all groups except the 9 to12 month olds in Pemba (36). Additionally, in Zimbabwe, the main dietary sources of vegetable protein were not complementary. The top two sources of protein were stiff maize porridge followed by regular maize porridge. In contrast, the top two sources of protein in Pemba were rice followed by fish, an animal source protein, which is consumed daily in these island communities. However, the proportion of 6 to 8 month old children in Pemba that did not consume enough protein was still high, 37.5% (n=6). One of these children was exclusively breastfed, and four did not consume any fish on either day.

Table 2.2 Daily nutrient intakes from complementary foods

	Estimated Requirements for Complementary Food		Zimbabwe				Pemba			
	6-8 Months	9-12 Months	6-8 Months n=12		9-12 Months n=20		6-8 Months n=16		9-12 Months n=28	
			Median	% Below	Median	% Below	Median	% Below	Median	% Below
Episodes/day	2-3	3-4	2.5		3.4		2.8		3.0	
Food Intake (g/day)			447.8		589.2		203.3		314.3	
Energy (kcal/day)	200	300	179.1	50.0	383.5	30.0	270.9	37.5	432.7	21.4
Protein (g/day)	4.6	5	3.6	58.3	10.5	20.0	6.1	37.5	8.6	7.1
Fat (g/day)	0-7.6	1.7-12.7	3.4	--	6.2	--	9.7	--	18.7	--
Vitamin A (µg RE/day)	63	92	16.1	83.3	53.5	70.0	30.2	75.0	46.2	85.7
Folate (µg/day)	22.7	27.6	27.8	50.0	47.9	20.0	23.7	43.8	42.4	21.4
Calcium (mg/day)	140	140	96.0	58.3	150.2	40.0	36.0	75.0	58.8	75.0
Iron (mg/day)	~9	~9	1.8	100.0	3.1	95.0	2.0	93.8	3.3	92.9
Zinc (mg/day)	3	3	1.3	91.7	2.3	80.0	0.9	93.8	1.4	100.0

[1]Percent of children whose nutrient intakes are below the estimated requirements from complementary food in children consuming an average intake of breast milk.

[2]No percentage is given for fat because estimates are based on a range of required energy as fat (0-34% for 6-8 months and 5-38% for 9-12 months of energy from fat) (12).

Fat. Children in Zimbabwe consumed less fat than children in Pemba. The estimated requirement for fat from complementary foods, assuming an average intake of breast milk, is a range from 0-34% and 5-38% of energy as lipid for 6-8 months and 9-12 months respectively (12). These median intakes are adequate for the lower end of that range, but not the higher end. The top sources of fat in Zimbabwe were maize porridge and cow's milk, while in Pemba they were coconut rice and wheat rolls made with coconut milk.

Vitamin A. Every age group in both settings had median vitamin A intakes that were much less than the estimated requirement, and the majority of children were not consuming that requirement. The top sources of vitamin A in Zimbabwe were cow's milk and soured cow's milk, which provide a moderate amount of vitamin A (43-55 µg RE/100 g), but the average number of feedings with cow's milk was ≤0.2 times a day for children in either country. Again, Pemban children differed by having 1 rich top source of vitamin A, mango (695 µg RE/100 g), but the other top source was cow's milk as well.

Folate. Median folate intakes were adequate for all groups, but there were still large proportions of children not consuming the estimated requirements. In Zimbabwe, the top sources of folate were the stiff maize porridge and its accompanying vegetable sauce. In Pemba, the top sources were rice and wheat rolls.

Calcium. Many infants were not consuming the estimated requirement of 140 mg/day. Cow's milk was a top source of calcium for both settings, but again the number of average feedings was small. In Zimbabwe, the other top source was the vegetable sauce; it contained a good amount of calcium (116 mg Ca/100 g) since it is essentially the cooking liquid from steamed kale, the most common vegetable during the study (38). Kale is a better source of bioavailable calcium than other green leafy

vegetables due to a lower level of oxalic acid (39). In Pemba, mangos were also a top source of calcium.

Iron and Zinc. Iron and zinc were limited in both diets—a common finding in infant feeding research. Nearly 100% of children were not getting the estimated requirements each day. Again the top sources of iron were plant-based, from rice and wheat in Pemba and maize in Zimbabwe. However, porridge made from millet, which contains higher levels of iron than other cereals, was a common food for children in Pemba (40). Although children in Pemba consumed fish stew on a daily basis, the white fish they consume has relatively low amounts of heme iron and zinc compared to other flesh foods.

Complementary feeding practices and their contextual determinants

Breastfeeding. All mothers in our studies were still breastfeeding their infants. In Zimbabwe, mothers often responded that they had exclusively breastfed until 6 months following the advice of local health workers. Their breastfeeding practices after six months were also optimal, reporting that they breastfed on demand and whenever they felt the baby had not fed for a long time.

Conversely, mothers in Pemba had several problematic breastfeeding practices. First, most mothers reported introducing complementary foods before 6 months, usually between 2-4 months. Mothers explained that they introduced the foods because "the baby was crying". A few mothers even reported ignoring health worker advice to breastfeed exclusively to 6 months. One mother said, "The nurses told me to stop (feeding solids) and breastfeed to 4 months but I continued." A second common practice was to stop breastfeeding altogether when the mother became pregnant with another child because "the breastmilk goes bad". This finding also highlights the short birth intervals associated with Pemba's high total fertility rate (7.3 children) and may

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be explained in part by an earlier return to menses from stopping exclusive breastfeeding (27). Lastly, although these mothers were still breastfeeding, mothers reported being away from their children 2-6 hours per day for work, preventing infants from breastfeeding on demand during those times.

Responsive feeding. Overall mothers in both Zimbabwe and Pemba were responsive and active when feeding their children. In Zimbabwe, one mother detailed how she decides to feed her infant, "I will be looking at the last time I gave solid food and also at the type of crying. Sometimes the baby cries and I give breastmilk and baby refuses, then I give food, baby keeps quiet." This comment highlights how the mother is actively keeping track of when the baby eats, and positively responds to the baby's hunger cues. Sometimes mothers reported force feeding the child because, "the baby needs the food," which is a negative form of active feeding (41).

Mothers in Pemba were active and responsive feeders in different ways. Several mothers mentioned that it is especially important to feed the baby first thing in the morning because the baby is "hungry in the morning." They described how they knew the infants were hungry by saying the babies only drink breastmilk during the night, and since breastmilk is "light" (liquid and thin) the baby "urinates a lot" which means the "stomach is empty". Despite the inaccuracy of the knowledge, it still demonstrates an active feeding style. During the rest of the day, mothers talked about responsive feeding behaviors such as knowing the baby may need to eat before the family meals in the evening as one mother described, "The baby may eat at her own special times. She cannot resist getting hungry before the family eats." Pemban mothers also talked about responding to the cue, "cries after breastfeeding." Force feeding infants was not a common practice in Pemba.

Meal frequency and energy density. Zimbabwean infants commonly received an adequate number of meals (3) with some snacks. Breakfast was usually

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maize porridge, lunch was stiff maize porridge (*sadza*) with vegetable sauce or another relish, and dinner was another meal of *sadza* or porridge. However, the porridge was typically thin because mothers worried the babies "could not swallow thick porridge" and would "choke". The porridges were   only enriched with sugar and salt and sometimes cooking oil. Additionally, the snacks were mostly of the thin fermented maize beverage (*mahewu*).

Pemban children received 3 meals per day. Usually, breakfast was tea and bread or leftovers from the day before, lunch was a fresh meal of rice and fish stew (sometimes with accompanying vegetables) or cassava and fish, and dinner was food leftover from lunch. Fruits were given as snacks "when others are eating." The energy density of most foods was adequate to high because high-fat coconut milk is a common ingredient in everything from rice, vegetables, cassava, and even porridge.

Dietary diversity. Zimbabwean infants consumed only a fraction of the foods available in the community. Mothers were hesitant to feed vegetables, meat, hard cereals, some beans, traditional insects, and hard fruits because of the worry that the baby "can't chew them; the baby may choke." Some foods were desired but mothers said they "can't afford" them or they were "not available" such as peanut butter, cooking oil, bananas, oranges, and eggs. Cow's milk was considered a special food for infants when it was available. Sour milk curd was a common relish for sadza on days when vegetables were not prepared.

In Pemba, children typically were fed any available foods. Limits were based on seasonality (for fruits) or family consumption patterns (for green leafy vegetables and nutritious breakfast foods). Another constraint was that some mothers in the inland rural site said they could not feed the seasonal mangoes to their children because "people sell them" in the larger markets or on the island of Unguja. Mothers reported that children ate vegetables "when the family eats" them. Families said they

were not eating many vegetables because of various reasons such as: 1) they could only eat vegetables with fish stew, 2) they did not have extra coconuts (which they perceived as an essential ingredient), 3) they did not have a garden to grow them, and 4) it was the dry season. We noted however that cassava greens were always available, even if other types of green leafy vegetables were not. The tradition in Pemba is to eat a light breakfast and dinner of tea and bread, and this meal is desired for infants as well. Fish was prepared daily for most people, to the point that it became monotonous. When one mother was asked what she would like to eat, she said, "We'd have beef with rice because we have fish every day." Interestingly, in the rural coastal village, infants were typically not given fish because of beliefs that fish will cause teeth decay or worms.

Sanitation and hygiene. Both sites had extensive problems with sanitation and hygiene practices. While both countries shared the practice of using poured water to wash hands at large gatherings, mothers in both countries only used still water when washing their hands at home with their children.

In Zimbabwe, soap was very scarce and reserved for washing the infants' nappies and visible dirt from hands when returning from the field. While families only consume leftovers occasionally, they store the leftovers improperly, kept in a closed pot and near the fireplace to "maintain temperature". Storing leftover porridges between 4-60°C may support the germination of spores from bacteria such as *Bacillus cereus* present prior to cooking (42) or the growth of microorganisms introduced by post-cooking contamination (43). One positive practice mentioned is the use of cups instead of bottles to feed liquids to infants, but it is mostly because mothers cannot afford bottles.

In Pemba additional problems exist. While soap is available daily, it is reserved for cleaning instead of washing hands. Leftovers are prepared intentionally

and consumed for dinner and sometimes the following breakfast because "it's more economical". This practice was even found in more affluent households in the semi-urban community. The likelihood that these leftovers are refrigerated is quite low because 97.5% of households in Micheweni and 88.1% of households in Wete do not have electricity (23). Lastly, mothers in Pemba frequently used bottles to feed liquids and thin porridges claiming that it's "easy to feed porridge with a bottle." In the focus group discussions, mothers talked about needing to make porridge thin enough to feed in a bottle because it was the only food mothers could leave to feed the young baby when they returned to work in the fields at around 2-4 months of age.

Summary of complementary feeding problems and their contextual determinants

　　　Zimbabwe. The major nutrient gaps were protein, vitamin A, folate, iron, and zinc because mothers were not feeding any animal source foods, legumes, fruits, or vegetables. While food insecurity (household and local) contributed to this behavior, the primary reason that mothers behave this way is an indigenous knowledge that children cannot consume those foods. The local community teaches mothers that children can only consume these foods when they develop teeth for chewing. There is a lack of knowledge around processing foods such that children can swallow them before they develop teeth. There was also an energy gap because children were consuming foods with a low energy density. The low energy density was due in part to the household and local food insecurity because cooking oil and peanut were not available and to the indigenous knowledge that babies cannot swallow thicker porridge.

　　　Children in Zimbabwe were at risk for disease due to poor maternal behaviors around sanitation and hygiene such as poor hand washing and improperly storing leftovers. Both of these behaviors stem from indigenous knowledge about sanitation

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and hygiene. To these mothers' knowledge, people are less at risk for germs and disease when they are at home alone so they do not have to wash their hands with running water. Also, they believe that keeping leftovers covered and warm will prevent contamination. Additionally, even though mothers used cups to feed liquids instead of bottles this does not stem from any knowledge regarding the health risk of using bottles.

Children were protected from some disease risk due to adequate maternal behaviors around breastfeeding. Several mothers were exclusively breastfeeding until 6 months. Mothers cited their formal health education about exclusive breastfeeding as the reason for this behavior.

Pemba. In Pemba the nutrient gaps were mostly in micronutrient (vitamin A, folate calcium, iron, and zinc), but many children were not consuming enough energy or protein. The micronutrient gaps were caused by mothers not feeding optimal amounts of fruits, vegetables, milk, and iron- and zinc-dense flesh foods. Mothers were also not preparing substantial, nutrient dense breakfasts and dinners which lowers the overall food intakes and produces the energy gap. The protein gaps were due to mothers not feeding the available fish to those children. These behaviors were due to several contextual factors. Indigenous knowledge prevented children from consuming more vegetables, fish, and nutrient dense meals. The larger agricultural and economic context determined when mothers could feed fruits to their children. The access to dairy and other iron- and zinc-dense flesh foods was limited due to local and household food insecurity as well as the larger agricultural and ecosystem context of being on a small island where fish are prevalent and extensive animal husbandry is not feasible.

Children in Pemba are at risk of disease due to poor sanitation and hygiene behaviors such as poor hand washing, feeding leftovers, and using bottles. Poor hand

washing is again related to indigenous knowledge, and so is feeding leftovers to some extent. The preparation of enough food at one time to last for two or three meals is a time-saver and a cultural adaptation to the larger context of food insecurity. Even the more affluent prepare leftovers. Bottle feeding is mostly due to a lack of time because mothers are returning to work (usually in the field or seaweed beds). Maternal livelihoods are directly related to the household and local contexts as well as indigenous knowledge regarding female labor.

Children in Pemba are not consuming enough breast milk because of maternal behaviors to stop exclusively breastfeeding before 6 months, stop breastfeeding during pregnancy, and not breastfeed on demand. The first two behaviors are caused by indigenous knowledge that does not support the formal health education mothers receive. The indigenous knowledge outweighs the formal education. The third behavior is mostly related to maternal livelihood and time allocation just as bottle feeding was.

Appropriate intervention options

    Zimbabwe. Since quality sources of iron and zinc, namely flesh foods, are regularly unavailable in this context, some type of supplement is needed to cover infants' requirements. A simple micronutrient supplement such as Sprinkles is inappropriate because there is a need to ensure intakes of quality protein as well. A LiNS would be more appropriate because it could supplement the diet with its small amount of milk powder and peanut protein. LiNS would also serve to increase energy density during the first introductions to solid foods.

    While the LiNS would provide adequate amounts of several other problem micronutrients such as vitamin A, nutrition education and behavior change is also important because mothers currently have inaccurate knowledge about infant feeding

and sanitation/hygiene. Educational messages should focus on the barriers to the ideal practices that are a result of mistaken indigenous knowledge. Educating mothers to process family foods would open up infants' access to several vitamin A-rich fruits and vegetables, vitamin C-rich fruits, and even protein rich legumes and seeds. Legumes are sometimes available and could be roasted, powdered, and reserved for infants' porridge. Additionally, protein and micronutrient rich-indigenous flesh foods such as insects and rodents could also be given to children when they are available.

Pemba. An appropriate intervention for Pemban infants would also include a micronutrient supplement and nutrition education. Since Pemban children have ready access to adequate calories (due to the energy density of most dishes) and protein (due to the abundance of fish), what is left is to address the gaps in micronutrient intakes. Although children have access to fish each day, fish is not a particularly good source of heme iron. Even though the fish can serve to enhance the bioavailability of nonheme iron (44), the total iron and zinc intakes are still well below recommended amounts. Thus, a micronutrient supplement that supplies iron and zinc, such as Sprinkles, would be required to achieve the estimated daily requirements. Promotion of absorption enhancers would still be crucial to get the most out of home-fortification with iron and zinc.

Education to promote behavior change is also imperative. Similar to Zimbabwe, mothers in Pemba are not maximizing the diets of their children with available foods and breast milk. However, the approach to education needs to focus on specific audiences as well as messages. A reason that these feeding problems persist was the disregard of health worker advice directed only at mothers. While maternal and child health clinics have been a preferred teaching venue in Pemba, other approaches should be considered, e.g. expanding the target audience to include female elders and mothers with older children who are disseminating the incorrect advice

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ultimately heeded by younger mothers. Another problem was not breastfeeding on demand and using bottles to feed thin porridge when the mother went back to work. Education and promotion of expressing and cup feeding breast milk would be beneficial, but it would only be successful if other family members were involved. A more community-based approach would help build the capacity of all women who are helping to rear the children of the village.

Secondly, the education should target family eating practices as well as infant feeding practices because family practices often trickle down to become infant feeding practices. If family preparation of vegetables or eating more nutritious breakfasts and dinners were targeted in educational messages and recommendations to improve family consumption, this might trickle down to infants as well as benefit all family members. Concurrently, education could also target household sanitation/hygiene behaviors which would only help to protect the infant from infection. Again, there are identifiable causes of infant feeding problems that ultimately account for poor consumption of a variety of foods. Behavior change communication should target these causes first to improve the capacity of mothers and other caretakers to provide the most nutritious diet available to their children.

DISCUSSION

Context played a large role in designing potential complementary feeding interventions in these regions of Zimbabwe and Pemba. On the surface these two sites would be considered food insecure as defined in The Lancet series and require food supplementation with fortification and nutrition counseling. However, we identified determinants at the local and household context levels that led to two different supplementation choices (one of which did not involve food) and an expanded view on nutrition education that targets the larger indigenous education system as well as

household eating behaviors. We developed a new framework for child undernutrition that collapses the well known immediate causes of undernutrition and delineates the underlying and basic causes within context (**Figure 2.4**). Understanding the context presents several opportunities to improve the efficacy of our interventions. Despite both sites being considered "food insecure," as defined by per capita income per day < US$1, only Zimbabwe appears to require a food-based supplement. In Zimbabwe, the income poverty definition of food insecurity matched the local agricultural and economic context of food insecurity, which made providing a food-based supplement vital to filling the nutrient gaps in the diet. A food-based supplement would not be necessary in Pemba because the local agricultural and ecosystem contexts provide coconuts (energy) and fish (protein).

We conclude that supplements should complement the local diet and fill in the gaps left by education and behavior change. Not doing this may result in replacement of nutritious local foods in the diet. An unfortunate example was our feasibility study in Pemba using a PCF. There was a significant decrease in the number of children consuming fish stew after the introduction of the PCF (30). On the other hand, in Zimbabwe, provision of LiNS would achieve nutrient goals (to increase complementary protein, iron, and zinc) and fill in for the peanut butter mothers would like to add to their traditional dishes. However, provision of LiNS alone would not be appropriate even in Zimbabwe. Although LiNS provides the daily recommended nutrient intake of micronutrients, mothers need education on feeding the valuable sources of them that are in the local diet. Improving maternal capacity will help sustain the program in case LiNS provision is prohibited by high costs and common
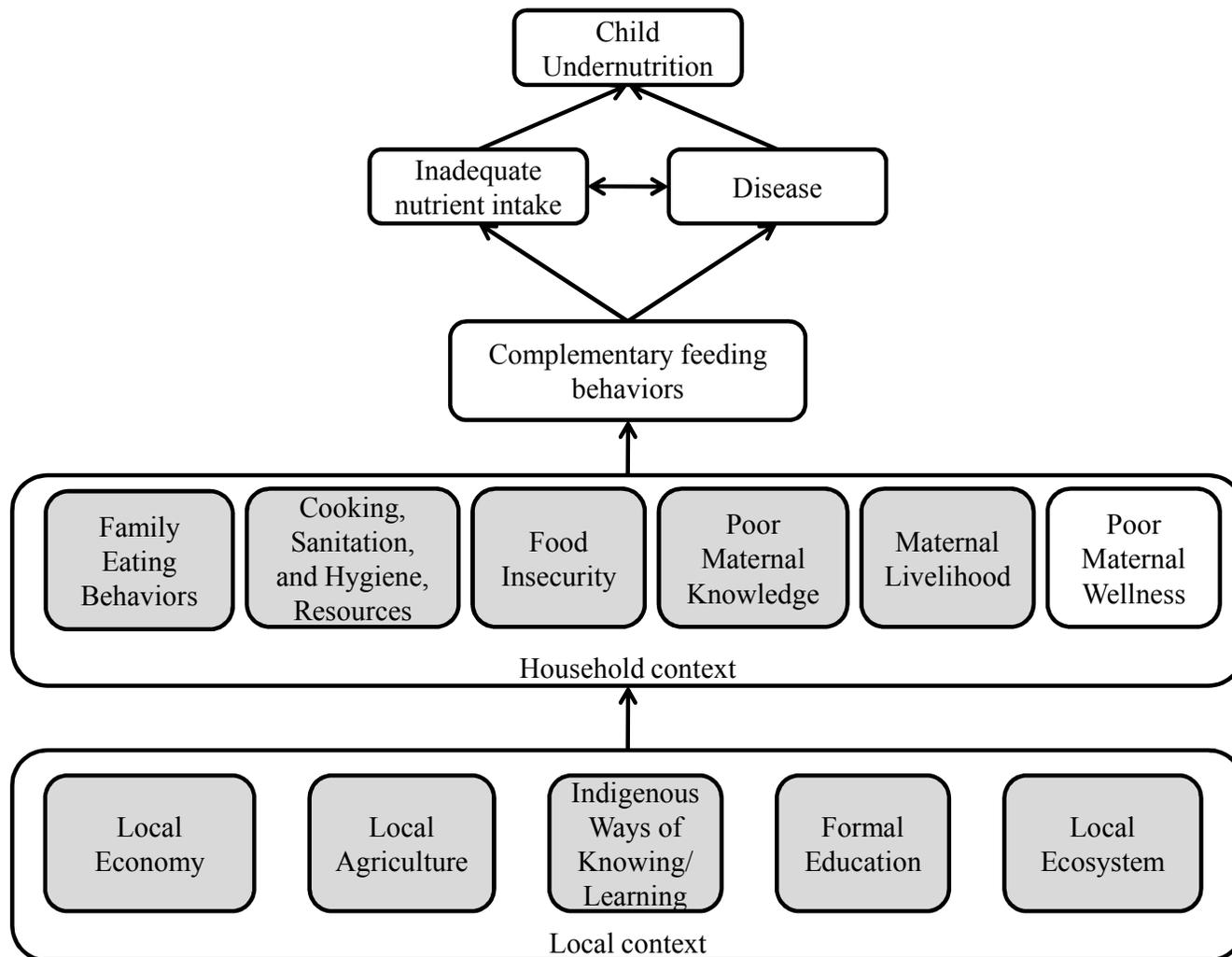
Figure 2.4 Expanded framework highlighting aspects of household and local context that helped determine the intervention strategies (in gray).

disruptions of the distribution system. This finding reiterates the emphasis on education presented in The Lancet series.

Furthermore, a careful examination of these two contexts revealed insights into the implementation of complementary feeding education. We know two things about complementary feeding education. First, some education is better than no education (45,46). Second, messages should be clear, specific, and targeted to the problematic feeding practices (45). Our research leads us to conclude in addition that educational messages should be grounded in the socio-cultural source of complementary feeding problems—the indigenous knowledge around food and child rearing. A basic principle of adult education is experiential learning (47-49). Adults already have a vast body of knowledge learned from their life experiences. They are not children with relatively open minds to fill. Therefore any presentation of new knowledge must be reconciled with their experience by critically reflecting on their past assumptions (50,51). Many nutrition education interventions do mention conducting formative research to understand the socio-cultural barriers to infant feeding when designing messages but this does not mean they were effectively mitigating them (10,18,45,46,52,53). Menon et al reported having developed culturally acceptable and feasible practices to promote but in the end only a third of the mothers adopted those practices often due to persistent, prohibitive cultural beliefs (53). The mothers in the two sites we studied have a complete and legitimate set of indigenous knowledge about infant feeding. If we disregard that knowledge, mothers may not have the chance to fully comprehend the new knowledge. For instance, if we simply told mothers in Zimbabwe that it is healthy to feed green vegetables to a child every day, we are not addressing their knowledge that green vegetables will choke the child. That is why we suggest giving recommendations that recognize and take into account that indigenous counter-knowledge.

Mothers not only have a culturally specific body of infant feeding knowledge, but they also have a culturally specific way of learning this knowledge (54,55). This was most evident in Pemba, where mothers followed the advice of their elders rather than the health workers. Utilizing that indigenous way of learning would be constructive. In the same study in Haiti, the original formative research identified messages that should be targeted to grandmothers and fathers as well as mothers, but in the end the education was directed only at the mothers during monthly mothers' clubs. This might have been a key to improving adoption of their promoted practices (53). Additionally, mothers would have immediate access to safe and accurate support. An educational intervention in India found that counseling mothers at multiple opportunities had a positive effect on feeding practices (56). Mothers would have extra sources of this information closer to their daily lives. Short of this, planners should at least be mindful of the legitimate position held by a community's indigenous way of learning. Projecting a western, formal way of learning on mothers may be the easiest to implement, but it may not be the most efficacious.

This study shows there may be room for innovation in intervention design. Typical complementary feeding interventions focus on caregiver behaviors to feed the infant, making special recipes, feeding times, feeding utensils, etc. However, if the infant feeding problem is really a family eating problem such as only eating vegetables with certain types of meals, why should the behavior change message only target the mother for the infant? If the mother has to perform two different behaviors when preparing food for the infant verses the family, this complexity may contribute to the unsustainability of behavior change interventions (19). Family-based interventions are considered a promising approach in childhood obesity prevention and treatment interventions, yet they have not been explored in childhood undernutrition prevention (57,58).

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Lastly, there is an inherent benefit in describing these contextual aspects in our research. Despite an extensive body of literature on complementary feeding, it lacks recognition and operationalization of the role context plays in the design and implementation of interventions. While we as researchers may privately acknowledge context, we have not publically valued it on par with discussions about the generalizability of our conclusions. However, describing contextual determinants of intervention design is necessary to translate research into practice. Translating research into effective practice includes thoroughly describing how complementary feeding trials were planned and implemented using case studies and/or more detailed methods sections in peer-reviewed manuscripts.

The comparison of these two sites is unique for two reasons. One, often comparisons are made between countries on different continents with the aim of generalizing to a global scale. (6,59). Both of our settings are in Sub-Saharan Africa. Two, even when comparisons are made within the same global region, rarely was the work conducted by the same researchers. Therefore the types of data collected could be very different (60). We had the opportunity to work in both of these settings and ensure that we collected the same type of data from each site. Moreover, comparing two similar food insecure settings in the same global region is the only way to see and understand how seemingly small differences in the underlying contexts may potentially affect the successful design of an intervention.

There are some limitations to this study that should be mentioned. The formative research protocols were not identical, but this discrepancy was due to dissimilar elements required for the different feasibility studies. The sample sizes are small and therefore not statistically representative of all children in the two settings. Small sample sizes are common for formative research methods because sampling is more purposive than random. Therefore, the quantification of nutrient intakes is

intended to identify potential nutrient gaps rather than to make any definitive estimate of actual intakes. Any discussion on the effect of the suggested interventions is speculative because these interventions have yet to be implemented.

The purpose of this paper was to present two case studies and compare the nuanced differences that can be found within the food insecure context described in The Lancet series, and we found these differences may significantly affect intervention design. Although Pembans might qualify as food insecure with regard to income poverty, it did not prove necessary to suggest a food-based supplement in Pemba. Additionally, understanding context highlighted new types of educational approaches that have not been utilized in complementary feeding interventions. We propose that our expanded framework on child undernutrition could be used to guide formative research designs for future interventions. A new focus on context may be the key to improving the efficacy of complementary feeding interventions.

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CHAPTER THREE

COUNSELING ON PROCESSING LOCALLY AVAILABLE FOODS ENHANCES
THE USE OF LIPID-BASED NUTRIENT SUPPLEMENTS TO IMPROVE INFANT
DIETS IN RURAL ZIMBABWE

ABSTRACT

Supplementation with lipid-based nutrient supplements (LiNS) is promoted as an approach to prevent child undernutrition and growth faltering. Previous LiNS studies have not tested the effects of improving the underlying diet prior to providing LiNS. Formative research was conducted in rural Zimbabwe to develop feeding messages for use in a later community-based trial using LiNS. Two rounds of Trials of Improved Practices were conducted with mothers of infants aged 6-12 months to assess the feasibility of improving infant diets using (1) only locally available resources (Non-NB) and (2) locally available resources plus 20 g of LiNS as Nutributter®/day (NB). Common feeding problems were poor dietary diversity and low energy density. Popular improved practices were to process locally available foods so that infants could swallow them and add processed local foods to enrich porridges. Consumption of beans, fruits, green leafy vegetables, and peanut/seed butters increased after counseling ($p<0.05$). Nutrient intakes of energy, protein, vitamin A, folate, calcium, iron, and zinc from complementary foods increased significantly after counseling with or without the provision of Nutributter ($p<0.05$). Intakes of fat, folate, iron, and zinc increased only (fat) or more so (folate, iron, and zinc) with the provision of Nutributter ($p<0.05$). While provision of LiNS was crucial to ensure adequate intakes of iron and zinc, educational messages that were barrier-specific and delivered directly to mothers were crucial to improving the underlying diet.

INTRODUCTION

The complementary feeding period, when solid foods are introduced to complement breastmilk, is associated with the onset of growth faltering in resource poor countries (1). While mothers may think they are providing more food for their children, this new diet may actually put the child at more risk for malnutrition for several common reasons: (1) foods lack sufficient energy and nutrient density; (2) foods displace breastmilk too quickly; and (3) foods when prepared, fed, and stored in unsanitary conditions increase exposure to food borne pathogens (2). Inappropriate care practices such as poor responsive feeding, low feeding frequency, and insufficient feeding when recovering from illness can compound the other effects to augment the risk of malnutrition (2). The mediating factors of these effects are variable social norms and lack of maternal knowledge, time, and resources.

The period of complementary feeding, usually from 6-24 months of age, also represents the optimal time for intervention (3). Previous frameworks favored recuperative approaches through the identification of faltering through growth monitoring (4). However, a preventive approach has recently been shown to be more effective than recuperative. In Haiti a cluster randomized trial showed that babies who received a preventative intervention of education and food assistance had 4-6 percentage points less stunting, underweight, and wasting than babies in communities given a recuperative intervention (5). If preventive interventions are more effective, various approaches are available, including processed complementary foods, education, and micronutrient supplementation.

Supplementation with lipid-based nutrient supplements (LiNS) is a promising new intervention that could overcome some of the limitations associated with other processed complementary foods (PCF) and provide benefits not found with micronutrient supplementation (6). Lipid-based nutrient supplements are usually

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peanut butter mixed with milk powder, sugar, and vegetable oil (7). Lipid-based

nutrient supplements can be manufactured locally using local ingredients, with the

exception of the fortificants, and do not require expensive extrusion technologies like

those used in cereal/legume PCF. The LiNS are also resistant to microbial growth

and oxidation due to a low water activity (6).

Lipid-based nutrient supplements evolved from ready-to-use therapeutic food

(RUTF) which has been successful in treating severe acute malnutrition (SAM) and

allows for home based treatment of SAM (8,9). However when used in a preventive

approach, LiNS has shown modest results. In a Ghanaian supplementation trial from

6-12 months of age, children receiving the LNS containing ~108 kcal/day gained ~200

g in weight and 5.5 cm in length more than children receiving only multiple

micronutrients (10). In Malawi, children of the same age given LiNS (127-256

kcal/day) experienced no advantage in weight or length gain compared to children

receiving ~282 g of a fortified, uncooked maize-soy flour per day (11). The only

significant effects of the LiNS was a lower incidence in severe stunting, and higher

length gains in children with baseline length-for-age z scores (LAZ) that were lower

than the trial median. In another study in Malawi, children from 6 to 12 months

consuming 200 kcal/day of LiNS showed a significant weight increase of only 100 g

compared to children consuming 200 kcal/day of a maize porridge fortified with fish

powder (12).

None of these studies attempted to improve the underlying complementary diet

of their infant subjects. Only the study in Ghana collected dietary intake data to

compare the diets of the different intervention groups and assess replacement of

complementary foods. While there was no replacement in the Ghana study, it should

be noted that they instructed mothers to feed only 20 g of LiNS per day mixed into

other complementary foods while the 2 other trials in Malawi suggested 25-50 g of

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LiNS/day without the recommendation to serve in other foods. How these instructions may have influenced intake of other complementary foods, and how much LiNS could improve growth combined with an improved local diet is unknown.

Our objective was to conduct two rounds of short home interventions known as Trials of Improved Practices (TIPs) to inform the design of a future intervention (13). The aim of the first round was to understand how local infant diets in rural Zimbabwe could be improved without the use of a new commodity. The aim of the second round was to introduce a LiNS, Nutributter®, within the context of an improved local diet.

METHODS

Study setting

The study took place between November 2007 and April 2008 during the hungry season in the Chirumanzu District of central Zimbabwe. Subsistence farming combined with market gardening is the main livelihood in this drought-prone, rural district. Maize, the staple crop, is prepared primarily as stiff porridge, *sadza*, with a relish of tomato and onions along with green leafy vegetables, beans, fish, or meat. During the study NGOs were active in the area giving various aid packages including items such as soap, beans, maize meal, barley, and corn-soy blend.

Enrollment

Two sites were picked, Chaka and Holy Cross, based on a 1-hour driving distance to and from research staff quarters. To obtain access to family homes, two existing village health workers (VHW) were employed from each site. The VHW identified all mothers with 6-12 month old children in their catchment area for potential eligibility. Eligible mothers had 6-12 month old infants and were actively breastfeeding. The list of children was divided into two age groups: 6-8 months and

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9-12 months. From the sorted list, children were randomly selected for enrollment (4 per age group per site, 16 total per round). The random selection was an attempt to avoid discrimination of children based on household location. Potential participants were divided among teams, each comprised of a district nutritionist and a VHW. Teams visited participants at home, and if written consent was obtained from the mother, the first interview was then conducted. The study was approved by the Medical Research Council of Zimbabwe, the Research Ethics Board of McGill University, and the Institutional Review Boards of Johns Hopkins University and Cornell University.

Preliminary work

A review of previously collected data was completed prior to deployment to the study site to identify general infant feeding behaviors and problems in rural Zimbabwe. The data included 24-hr dietary recalls, food frequency questionnaires, and focus group discussion summaries. Upon arrival in the study site, research supervisors met with a local VHW to learn about locally available foods. Two nutrition educators and the VHW worked with research supervisors to develop nutritious recipes based on the locally available foods. The nutrition educators then conducted recipe demonstrations for the rest of the research team and VHW. The preliminary work all went towards development of the initial set of improved practices.

Trial Protocol

TIPs round 1 without Nutributter (non-NB). Five household visits were conducted over 12 days. The first visit on Day 1 was the initial interview and the first 24-hr dietary recall to learn about current feeding behaviors. After the interview, the

research supervisors assisted nutritionists in assessing the problematic feeding behaviors and identifying appropriate improved practices. Two days later, on Day 3, the teams came back to the home for the counseling visit where they conducted a second pre-counseling 24 hour dietary recall and then discussed the identified feeding problems and the improved practices. Teams then negotiated with mothers to try 2-3 improved practices over 10 days. After another 2 days, on Day 5, teams conducted the first follow-up interview and a feeding observation to verify use of the improved practices. One week after the counseling visit, on Day 9, teams conducted the second follow-up interview and the first post-counseling 24-hr dietary recall. Three days later, on Day 12, teams conducted the final interview and 24-hr dietary recall.

TIPs round 2 with Nutributter (NB). A second group of mothers were enrolled for the second round of TIPs. The protocol for the second round of TIPs was similar to the first with a few exceptions. During the counseling visit, a demonstration and taste test of Nutributter followed the discussion of improved practices. At the end of the counseling visit, mothers were asked to (1) try feeding 4 teaspoons (~20g) of Nutributter per day, (2) choose 1 sanitation/hygiene improved practice from the options presented, and (3) choose 1-2 other infant feeding improved practices. Inclusion of a sanitation or hygiene practice was due to a strengthened focus on hygiene for the larger intervention. The third item was an attempt to reinforce the importance of continuing to improve feeding practices alongside the use of Nutributter. Other differences in protocol were that the feeding demonstration included Nutributter, and the follow-up and final interviews included questions that asked about Nutributter acceptance.

Data collection methods

Maternal acceptance and trial. Acceptance and trial of improved practices including Nutributter were assessed using semi-structured interviews with open-ended response. Interviews were conducted in Shona language, and bilingual interviewers (nutritionists) recorded mothers' responses in English if simultaneous translation was feasible, or maintained the Shona when necessary. The English competency of the nutritionists was high, and they were accustomed to working bilingually. Probes were used to obtain needed detail and clarity of responses.

Dietary intake. Two non-consecutive 24-hr dietary recalls assessed nutrient intake of children pre- and post-counseling. Intake of foods was measured two ways. For commonly consumed foods, teams brought samples to the house so mothers could show the amount of food the child consumed. The amount was weighed to the nearest gram using a digital kitchen scale (Philips, HR 2385). When samples were not available, mothers were asked to fill their personal dishes using water with the same volume of food as the child consumed. The water was then transferred to standard measuring cups. During days when no household visits were scheduled, the research team purchased the foods not brought as samples and prepared the foods in the manner described by the mothers in order to weigh the recorded volumes of food.

To calculate nutrient composition of mixed foods, recipes were entered into Nutrisurvey (WHO). A Nutrisurvey function was used to estimate nutrient retention of cooked foods. While the Nutrisurvey program draws from a collection of food composition tables, some indigenous foods (e.g. green leafy vegetables) needed to be added from a Zimbabwean composition table, a botanical reference book, and published articles (14-16).

Daily consumption. Consumption of Nutributter was measured three ways. One, containers were weighed at the end of the follow-up interviews. Two, 24-hr

dietary recalls post-counseling measured the number of Nutributter spoonfuls. Three, questions were asked about frequency of feeding at the beginning of all the follow-up interviews.

Trial food

Nutributter® was supplied by Nutriset (Malaunay, France). The primary ingredients were peanut butter, skimmed milk powder, sugar, and oil. The Nutributter was packaged in small plastic containers with 140 g product intended to last 1 week (i.e. 20 g/day). The package had a foil seal covered by a plastic lid. The package had Nutriset's standard label which listed ingredients, dosage, and storage conditions in English and French. The daily dose of 20 g/day provided ~1 day's requirement of micronutrients along with 108 kcal (**Table 3.1**).

Data analysis

Qualitative data. Interview responses were transcribed and labeled with codes related to acceptability and feasibility of improved practices or Nutributter. Coded data was tabulated and summarized for emergent themes (17). Pertinent quotes were selected to illustrate each theme.

Quantitative data. Data on daily nutrient intakes and daily nutrient densities were analyzed using a multi-level model with provision of Nutributter and time (pre- and post-counseling) as fixed effects and child as a random factor. Models were adjusted for daily intake of food (g). Additionally, significant interactions with time were included. The proportions of children not meeting estimated nutrient requirements from complementary foods were based on estimated requirements given an average intake of breast milk (6,18-22). Chi square (χ^2) tests were used to compare proportions. All children were included in the analysis (n=32). *P* values < 0.05 were

Table 3.1 Nutrient composition of Nutributter

Nutrient	Amount per 20 g
Energy, *kcal*	108
Protein, *g*	2.56
Fat, *g*	7.08
Calcium, *mg*	100
Phosphorus, *mg*	82.13
Potassium, *mg*	152
Magnesium, *mg*	16
Zinc, *mg*	4
Copper, *mg*	0.2
Iron, *mg*	9
Iodine, *µg*	90
Selenium, *µg*	10
Manganese, *mg*	0.08
Vitamin A, *mg RE*	0.4
Vitamin C, *mg*	30
Vitamin B1, *mg*	0.3
Vitamin B2, *mg*	0.4
Vitamin B6, *mg*	0.3
Vitamin B12, *µg*	0.5
Folic acid, *µg*	80
Pantothenic acid, *mg*	1.8
Niacin, *mg*	4

considered statistically significant. Analyses were done using JMP 7.0 (Cary, NC)

and Stata 8.0 (College Station, TX).

RESULTS

Participants

Demographic characteristics of mothers in the non-NB and NB TIPs were similar in most cases (**Table 3.2**). Most mothers were married with 4 single mothers in the non-NB round and 5 in the NB round. Mothers were relatively well educated, with 50% in the non-NB round and 62.5% in the NB round having completed secondary school. For mothers the major livelihood mentioned was subsistence farming and market gardening (75% in the non-NB round and 100% in the NB round). Fathers' common occupations were agriculture and business. The majority of households used some type of latrine and had a protected source of water. Fifty-six percent of children in the non-NB round and 81.3% in the NB round had experienced symptoms of illness in the previous 2 weeks such as cough (43.8% in both rounds) and diarrhea (43.8% in the non-NB round and 31.3% in the NB round).

Feeding and hygiene problems

The initial interviews identified 10 major feeding and hygiene problems for these mothers (**Tables 3.3 and 3.4**). The most common feeding problem was feeding a limited variety of foods (16 in non-NB/15 in NB). The three foods most frequently fed to the children were porridge, sadza, and sauce because the mothers believed children "could not chew and swallow" other foods like vegetables, fruits, and meat. Some foods were also believed to cause side effects like diarrhea, constipation, and vomiting of "bile." Low energy density of porridges was the second most common feeding problem (11/6) followed by low feeding frequency, low amount of food served at each meal (3/7), breastfeeds being reduced (4/2), and not assisting the child when eating (1/1).

Table 3.2 Demographics of study participants

	Non-NB	NB
N	16	16
Age group--6-8 mo., *n(%)*	7(43.8)	5(31.3)
Sex--male, *n(%)*	8(50.0)	12(75.0)
Marital status, *n(%)*		
Married	12(75.0)	11(68.8)
Separated/Divorced	1(6.3)	3(18.8)
Single/Never Married	3(18.8)	1(6.3)
Widowed	0	1(6.3)
Education level, *n(%)*		
Completed primary school	5(31.3)	2(12.5)
Some secondary school	3(18.8)	4(25.0)
Completed secondary school	8(50.0)	10(62.5)
No. of children caring for, *mean±SEM*	1.8±0.2	2.3±0.4
Type of toilet, *n(%)*		
Pit latrine	3(18.8)	4(25.0)
Ventilated Improved Pit Latrine	9(56.2)	5(31.3)
None, Bush	4(25.0)	6(37.5)
Other	0	1(6.3)
Water source, *n(%)*		
Protected source	9(56.3)	11(68.8)
Unprotected source	7(43.8)	5(31.3)
Morbidity in past 2 weeks, *n(%)*	9(56.3)	13(81.3)
Growth Faltering		
Children with ≥1 mo. of static weight gain, *n(%)*	4(25.0)	2(12.5)
Children with ≥1 mo. of negative weight gain, n(%)	2(12.5)	1(6.3)
Breastfeeding frequency, *mean±SEM*		
Day	7.1±0.5	7.2±0.6
Night	3.6±0.2	4.1±0.6
No. of meals/day, *mean±SEM*	2.8±0.3	3.0±0.2

Table 3.3 Identified feeding problems, suggested improved practices, and tried improved practices

	Non-NB			NB	
	Given	Tried		Given	Tried
1. Limited variety of foods given	16(100)			15(93.8)	
Mash fruit	14(87.5)	9(64.3)		13(86.7)	7(53.8)
Mash vegetables	15(93.8)	11(73.3)		12(75.0)	10(83.3)
Mash beans	13(81.3)	5(38.5)		10(62.5)	2(20.0)
Pound dried insects/fish	14(87.5)	5(35.7)		12(75.0)	0
Pound roasted seeds/beans	16(100)	10(62.5)		--	--
Pound roasted seeds	--	--		12(75.0)	0
Pound roasted beans	--	--		13(81.3)	3(23.1)
Mash other foods (e.g. meat)	--	1(6.3)		14(87.5)	4(28.6)
Give Fruit and/or Vegetables Daily	--	--		12(75.0)	1(8.3)
2. Low energy density	11(68.8)			6(37.5)	
Pound roasted seeds/beans (see Problem 1.)					
Thicken porridge	8(50.0)	5(62.5)		7(43.8)	3(42.9)
Ferment porridge	5(31.3)	5(100)		5(31.3)	2(40.0)
Add cow's milk to porridge	2(12.5)	1(50.0)		3(18.8)	1(33.3)
Feed 1 or 2 more meals (see Problem 3.)					
3. Low feeding frequency/amount of food served	3(18.8)			7(43.8)	
Feed 1 or 2 more meals	4(25.0)	2(50.0)		6(37.5)	2(33.3)
Feed 1 or 2 snacks	2(12.5)	2(100)		8(50.0)	5(62.5)
Feed 2 more spoonfuls	3(18.8)	0		4(25.0)	1(25.0)
Use different flavors to avoid monotony	2(12.5)	1(50.0)		2(12.5)	1(50.0)
Assist baby when eating (see Problem 4.)					

Table 3.3 (Continued)

4. Not assisting baby when eating	1(6.3)			1(6.3)		
Monitor quantity on special plate		1(6.3)	0		0	0
Let baby self-feed, then assist		0	0		1(6.3)	0
Assist baby when eating		0	0		1(6.3)	1(100)
Let grandmother feed baby		0	0		1(6.3)	0
5. Breastfeeding is being reduced	4(25.0)			2(12.5)		
Breastfeed before feeding CF		2(12.5)	1(50.)		0	0
Breastfeed on demand		0	0		1(6.3)	1(100)

[1] n mothers (% of 16 mothers in TIPs round) identified with feeding problem

[2] n mothers (%) with feeding problem who were given the improved practice recommendation

[3] n mothers (%) given improved practice recommendation and tried it

[3] —represents improved practices not given in that form during TIPs round due to modifications made for the subsequent TIPs, new problems, and a new focus on sanitation/hygiene.

Table 3.4 Identified sanitation/hygiene problems, suggested improved practices, and tried improved practice

	Non-NB		NB	
	Given	Tried	Given	Tried
1. Improper hand washing	6(37.5)[1]		15(93.8)	
Wash hands with soap or ashes at key points	3(18.8)[2]	1(33.3)[3]	--[4]	--
Wash hands with soap and running water	--	--	9(56.3)	7(77.8)
Wash hands with ashes and running water	--	--	14(87.5)	7(50.0)
Wash hands with running water	--	--	8(50.0)	5(62.5)
Wash hands with soap	--	--	0	1(6.3)
Wash hands after toilet	--	--	2(12.5)	1(50.0)
Wash hands after changing diapers	--	--	3(18.8)	2(66.7)
Wash baby's hands	--	--	0	1(6.3)
Wash hands before handling food	--	--	1(8.3)	0
Wash hands before feeding baby	--	--	1(8.3)	0
2. Feeding cold leftover food	6(37.5)		2(12.5)	
Make fresh meals for baby always	6(37.5)	1(16.7)	1(6.3)	0
Reheat food thoroughly	6(37.5)	1(16.7)	1(6.3)	0
Serve small portion and throw away leftovers	--	--	2(12.5)	0
3. Giving unsafe drinking water	5(31.3)		4(25.0)	
Use water from a protected source	--	--	3(18.8)	1(33.3)
Boil drinking water for child	4(25.0)	0	4(25.0)	1(25.0)
4. Using a sippy cup	2(12.5)		3(18.8)	
Use an open cup to feed liquids	1(6.3)	1(100)	0	0
5. Poor stool disposal	0		1(6.3)	
Throw stool in toilet or bury	--	--	1(6.3)	2(200)

Table 3.4 (Continued)

[1]n mothers (% of 16 mothers in TIPs round) identified with feeding problem
[2]n mothers (%) with feeding problem who were given the improved practice recommendation
[3]n mothers (%) given improved practice recommendation and tried it
[4]—represents improved practices not given in that form during TIPs round due to modifications made for the subsequent TIPs, new problems, and a new focus on sanitation/hygiene.

Issues around hand washing and stool disposal were probed further in the NB initial interviews, and improper hand washing (i.e. not washing after using the toilet, handling nappies, preparing food, and feeding the infant or not washing with soap and running water) was identified as the most common hygiene problem (6/15). Use of untreated drinking water was the next most common problem (5/4) followed by serving cold leftover food (6/2). Other hygiene problems were, using a cup with a spout (2/3), and poor infant stool disposal (0/1).

Improved practices suggested and tried

The improved practices given and tried most frequently corresponded with the frequency of feeding and hygiene problems (Tables 3.3 and 3.4). The lack of variety in the diet was due to mothers' beliefs about children's inability to chew, swallow, and digest non-cereal foods like vegetables, fruits, and meats. Thus improved practices focused on how to process these foods so infants could swallow them, along with motivational messages to mothers on their value for babies. In the non-NB TIPs, we did not know which types of foods mothers would want to feed their children, so each recommendation mentioned only one type of food. We subsequently found that all types of foods were acceptable to mothers. Therefore in the NB TIPs, we combined all the previous recommendations into a single recommendation to "mash and feed a variety of local foods" so mothers would not feel limited to trying only one type of food. Mashing fruits and vegetables were the most commonly tried recommendations for both the non-NB and NB TIPs.

Pounding roasted pumpkin seeds or beans and adding to porridge or relish was a single recommendation in the non-NB TIPs, but was subsequently split into two recommendations in the NB TIPs based on initial findings. Namely, mothers tended to serve only one relish per day along with sadza, and they preferred to alternate

relishes. Therefore the recommendation to pound roasted beans into a powder was modified to, "Make and store bean powder for the baby to add to porridge and/or relish every day." Thus the emphasis was less on finding a way to feed beans to the baby, and more on finding a way to feed beans every day to the baby. Similarly, another recommendation was to "give a fruit and vegetable to your baby every day" so that mothers would feed fruits and vegetables on a daily basis. The result was that more mothers actually made bean powder in the NB TIPs (3 in the NB TIPS vs. 1 in the non-NB TIPs), but only 1 mother tried the recommendation to give a fruit and vegetable every day. Pounding roasted pumpkin seeds or dried insects was only tried in the non-NB TIPs because none were available during the NB TIPs due to seasonality.

The most frequently suggested and tried hygiene recommendations were improved hand washing techniques (Table 3.4). Because of the greater focus on hygiene in the NB TIPs, more recommendations were given that were designed to improve the method or timing of hand washing. Most mothers used still, rather than running, water to wash their hands. Using running water was perceived as a necessary practice only when in a large group such as a funeral, etc. Mothers were given 3 levels of recommendations with the highest being "use soap and running water" when washing hands followed by "use ashes when soap is unavailable and running water," and finally, "use running water." At least fifty percent of the women who were given these recommendations attempted using them. The other hygiene recommendations were actually tried by only one or two women during either round of TIPs.

Acceptability of improved practices

The motivations and barriers for practicing the recommendations in both rounds of TIPs centered on 4 major themes: transformative learning, maternal values, resources, and cultural traditions.

Gaining new knowledge through transformative learning was the most critical factor for overall acceptability. Transformative learning is characterized by reflection of previous experience in order to "foster learning at a deeper level by developing an understanding of assumptions that may frame the actions of individuals or groups…identifying assumptions may then permit a new perspective on actions to be taken" (23,24). Mothers were surprised because they believed children could not chew and therefore could not be fed many foods as one mother said, "I was not feeding fruits such as mangoes because the baby can't chew…I used to caution other children not to give the baby fruits." Mothers were also unaware that foods could be processed via mashing, chopping, or sieving and said they had not thought about doing that. One grandmother asked, "How did you know that these foods such as termites can be fed to babies?" Mothers were impressed that children were now able to eat, meaning chew, swallow, and digest foods like fruits, vegetables, insects, fish, etc. One mother said, "When I grated cabbage or chopped vegetables, they did not come out like that. The baby managed to digest them." Further, mothers recognized that their lack of knowledge had prevented them from feeding their children a diverse diet saying things like "I saw that I had been depriving my baby of them," and "I mashed vegetables since I have now learned that it's easy for the baby to have them—when mashed they are easy to swallow."

Furthermore, mothers were motivated to transfer that knowledge to other mothers who did not know about processing foods, without any encouragement from the study team. One mother said, "Yes, I will recommend to others because many

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mothers don't know about these recipes and because the recipes are also cheap and easy to prepare." Some mothers were already teaching others as one mother explains, "I have already taught one mother on how to prepare these foods particularly preparation of *mowa* (amaranth) and pounding of *mapudzi* (pumpkin) seeds, and she liked it." This common experience embodies qualities of transformative learning in that mothers critically reflected on their previous assumptions about what children could eat and were so transformed by their new understanding of food processing that they were compelled to transform others in their community.

The one barrier to this new knowledge that affected *initial* acceptability was the persistent assumption that certain foods cause side effects, such as sweet fruits causing diarrhea and/or constipation. Only two mothers expressed this concern in the first round of TIPs, but by the second and final follow-up, they too learned this was not true because their children were happily eating them without any side effects. Two mothers mentioned that other family members still believed that vegetables and fruit were harmful, but in one case the grandmother was contradicted by the grandfather who had learned the vegetables were healthy.

Maternal values included concepts around being healthy, the baby liking the improved practices and not having any reactions to the improved practices. Being healthy or preventing illness and the baby liking the new food were the most common motivations mentioned by mothers for all improved practices, including the hand washing recommendations. However, there were a few women who commented positively that the improved practice caused no reactions in their children. This was particularly the case for questions around Nutributter itself, but was also mentioned with regard to mashed fruits and vegetables.

Concepts around resources included everything from food availability, time, and ease of preparation. Availability was simultaneously one of the greatest

motivators and barriers for mothers' acceptability of all the improved practices. Availability encompasses cost and supply because items such as cooking oil and sugar were often scarce in these rural villages, and when they were available in shops, the cost was prohibitive for many families. Mothers' said they liked these improved practices because, "no money is required," and "This substitute (meaning pounded pumpkin seeds) for peanut butter is cheap and locally available." One mother who came up with the idea of adding mashed custard fruit to porridge along with pounded pumpkin seeds said, "Adding custard fruit makes the porridge sweet as if I added sugar." When asked why mothers chose the recommendations that they did, the second most common response after availability was that it was "easy," meaning that the practice did not require lots of skills and was time efficient.

Mothers responded similarly regarding hand washing with ashes. One mother said, "I can try that since you can never be without ashes." The reason fewer mothers tried washing their hands with ashes than with soap was that mothers were using soap that was available (from NGOs) during the study. Only one mother rejected using ashes because it was harder than using soap; she perceived that it made her hands dirtier.

Conversely, when foods or other resources were unavailable, this prohibited mothers from trying the recommendation or being willing to continue the recommendation on a daily basis. For instance, even though a lot of the mothers in the non-NB TIPs had a supply of dried beans given to them by an NGO, they were hesitant to cook them because of a lack of firewood. One mother said, "The problem is that there is no readily available firewood to use for preparation of beans which takes time." Another example is that no mothers in the NB TIPs could try the pounded seeds or pounded insects because the pumpkin harvest was poor and the insects were out of season.

Finally, cultural traditions played a role in determining these mothers' motivations and barriers for trying and continuing these improved practices. Several mothers in the first round of TIPs liked that the recipes were all based on family foods that were eaten every day and appealed to more than just the infant. One mother said, "These foods actually taste good and can be eaten by adults." The fact that several of the foods such as the pounded seeds were once highly valued indigenous foods appealed to mothers and other family members. One grandmother said, "It's good you talked about *mashamba* (a pumpkin variety) seeds because it was also used by our forefathers." Some of the preliminary research uncovered the notion that during times of better economic prosperity commercial products gained favor among younger women who started to stigmatize indigenous foods and feeding practices as primitive and antiquated (unpublished focus group data).

As mentioned previously, the concept of alternating relishes each day was a barrier towards consuming a variety of foods on a daily basis. One mother who had actually previously been giving vegetables to her 11-month old said at the end of the study, "She is eating less of the vegetables because I'm alternating them with other relish (*meaning any type of accompaniment with sadza).*" The prevalent practice of serving only one relish per day may stem partly from the limited resources available to the families, but it is also a cultural tradition inasmuch as green leafy vegetables and beans are continuously available.

Nutributter acceptability

Overall Nutributter was highly acceptable to mothers and children. During the Nutributter demonstration, most mothers thought it tasted good, and children had positive reactions such as continual licking of the spoon. Mothers noted that the Nutributter was not like regular peanut butter because it was lighter in color and

sweeter. During the TIPs follow-ups, several mothers noticed that their children were eating more of their food because of the added Nutributter. One mother reported, "I like the taste and that my baby likes it so much. This makes him eat more." Other mothers commented that it was like a substitute for cooking oil and sugar, which are common additives to porridge. Only one infant disliked the Nutributter because the child disliked sweet foods according to the mother.

Impact on diet

    Nutrient intakes from complementary foods. Based on the 24-hr dietary recalls, intakes of energy, protein, vitamin A, folate, calcium, iron, and zinc were significantly higher after TIPs counseling with or without the provision of Nutributter (**Table 3.5**). With the provision of Nutributter, intakes of fat, folate, iron, and zinc after counseling were significantly greater than post-intakes in the non-NB TIPs. After counseling, the proportion of children not meeting the estimated requirements of fat (based on 45% energy from fat estimates), Vitamin A and calcium were significantly lower with or without the provision of Nutributter (**Table 3.6**). The proportion of children not meeting the estimated requirements for iron and zinc were only significantly decreased with the provision of Nutributter.

    While quantities of food consumed were a significant factor of nutrient intakes, nutrient density was also higher after TIPs counseling. Energy, protein, Vitamin A, and folate densities were increased significantly with or without provision of Nutributter (Table 6). Not surprisingly, the increase in energy density was even greater with the provision of Nutributter. Densities of fat, iron, and zinc were only increased when Nutributter was provided.

    Diet characteristics. Although breastmilk intake was not directly measured, the final interview and all 24-hr dietary recalls asked questions about breastfeeding

Table 3.5 Daily nutrient intakes and densities from complementary foods

Nutrient	Factor[1]	Group	Pre	Post	*p*	Adjusted R[2]
Energy						
kcal/day			360±19.7	460±19.7	<0.001	0.9
kcal/100 g	NB	No	62.9±4.9[a2]	72.9±4.8[b]	0.04	0.6
		Yes	64.5±4.8[ab]	88.0±4.8[c]	<0.01	
Protein						
g/day			8.7±0.7	11.9±0.7	<0.001	0.8
g/100 kcal			2.4±0.1	2.5±0.01	N.S.	0.4
Fat						
g/day	NB	No	4.7±0.8[a]	5.7±0.8[a]	0.109	0.8
		Yes	5.5±0.8[a]	11.3±0.8[b]	<0.001	
g/100 kcal	NB	No	1.5±0.2[a]	1.3±0.2[a]	0.84	0.8
		Yes	1.8±0.02[a]	2.4±0.2[b]	<0.01	
Vitamin A						
µg RE/day			29.0±1.3	208±1.3	<0.001	0.7
µg RE/100 kcal			10.0±1.3	54.6±1.3	<0.01	0.5
Folate						
µg/day	NB	No	44.4±7.0[a]	74.2±7.0[b]	0.001	0.7
		Yes	48.8±7.0[a]	106.0±7.0[c]	<0.001	
µg/100 kcal			15.4±1.8	21.0±1.8	0.02	0.3
Calcium						
mg/day			159±11.4	209±11.4	<0.001	0.8
mg/100 kcal			47.6±3.0	49.5±2.9	N.S.	0.6
Iron						
mg/day	NB	No	3.2±0.5[a]	4.6±0.5[b]	0.041	0.8
		Yes	3.3±0.5[a]	10.6±0.5[c]	<0.001	
mg/100 kcal	NB	No	0.9±0.1[a]	1.0±0.1[a]	N.S.	0.6
		Yes	0.9±0.1[a]	2.3±0.1[b]	<0.01	
Zinc						
mg/day	NB	No	2.1±0.2[a]	2.6±0.2[b]	0.031	0.9
		Yes	2.2±0.2[ab]	5.1±0.2[c]	<0.001	
mg/100 kcal	NB	No	0.6±0.05[a]	0.6±0.04[a]	N.S.	0.6
		Yes	0.6±0.4[a]	1.1±0.04[b]	<0.01	

[1]Model factors which had a significant interaction with the time factor, p<0.05. If no factor is shown, time is the only factor shown.
[2]Means within factors with different letters are significantly different, p<0.05.
Means are least square mean ± standard error, n=32.

Table 3.6 Children not meeting estimated nutrient requirements from complementary foods

	Non-NB (n=16)		NB (n=16)		Time[1]	Time*Nutributter[2]
	Pre	Post	Pre	Post	*p-value*	*p-value*
Energy	5(31.3)[3]	5(31.3)	7(43.8)	2(12.5)	0.055	N.S.
Protein	4(25.0)	3(18.8)	2(6.3)	1(6.3)	N.S.	N.S.
Fat	15(93.8)	12(75.0)	15(93.8)	6(37.5)	0.002	N.S.
Vitamin A	14(87.5)	5(31.3)	10(62.5)	1(6.3)	0.001	N.S.
Folate	3(18.8)	3(18.8)	4(25.0)	1(6.3)	N.S.	N.S.
Calcium	8(50.0)	5(31.3)	7(43.8)	2(12.5)	0.019	N.S.
Iron	15(93.8)	13(81.3)	15(93.8)	3(18.8)	0.009	0.046
Zinc	13(81.3)	10(62.5)	15(93.8)	1(6.3)	0.143	0.035

[1]Effect of time (pre- to post-counseling)
[2]Effect of interaction between time and Nutributter provision
[3]n(%)

frequency. Eight women in the non-NB round and six women in the NB round reported they were breastfeeding less by the end of the study. The rest said they were breastfeeding about the same or more. At the beginning of the 24 hour dietary recalls, mothers were asked to report the number of breastfeeds during the previous day and night. For mothers in the non-NB round, the point estimate of the mean breastfeeding frequency declined slightly from 10.4±0.7 to 9.9±0.7 breastfeeds/24-hr period.

However, mothers in the NB round had a significant increase in breastfeeding frequency going from 9.9±0.7 breastfeeds/24-hr period to 10.8±0.7, p=0.034. Provision of Nutributter was nearly a significant factor in the individual change in breastfeeding frequency, p=0.056.

Mothers were also asked about changes in feeding frequency in the final interview. Six mothers in the non-NB round and seven in the NB round said that

feeding frequency was the same as the beginning of the study. Seven mothers in the non-NB round mentioned that frequency had gone up, but no mothers in the NB round mentioned this. According to the 24-hr dietary recalls, feeding frequency significantly increased in both rounds but more so in the NB round (3.0±0.2 to 3.5±0.2 feeds/day in the non-NB round, p=0.023 and 3.1±0.2 to 4.5±0.2 feeds/day in the NB round, p=<0.001). Provision of Nutributter was also a significant factor in the increase in individual feeding frequencies, p=0.024.

The main feeding problem, lack of dietary diversity, was reflected in the two 24-hr dietary recalls conducted prior to TIPs counseling (**Figure 3.1**). Only 3 and 5 mothers in the non-NB and NB TIPs respectively had fed a green leafy vegetable (GLV) to their child, and only 2 and 4 mothers had fed a fruit to their child. Fewer mothers had fed any, beans, or meat to their children. This is in contrast to staple foods like maize porridge, sadza and its accompanying sauce (cooking liquid from steamed GLV or meat with or without a tomato and onion sauce). After counseling, the proportion of mothers feeding beans (18.8% to 43.8%, p=0.046), fruits (18.8% to 62.5%, p=0.009), GLV (25.0% to 84.4%, 0.038) and peanut/seed butters (18.8% to 46.9%, p=0.009) increased, and there was also a modest increase in the number of mothers who had fed meat (9.4% to 21.9%) on the previous day. There were no real changes to the numbers of women who fed maize porridge (71.9% to 81.3%), sadza (93.8% to 96.9%), or sauce (87.5% to 87.5%) to their children after counseling.

From the final interview, when asked how the child's diet had changed and what foods the child was eating more or less of, mothers responded that the diet was now more varied (7 Non-NB mothers), the child was now eating or eating more vegetables than before (7 non-NB mothers and 5 NB mothers), the child was eating more sadza and porridge (8 non-NB mothers and 5 NB mothers), or the children was now eating or eating more fruits (6 non-NB mothers).

The second most common feeding problem from the initial interviews, poor energy density, was also evident in the 24-hr dietary recalls before counseling. The majority of mothers in the non-NB round were feeding a thin maize porridge without any type of enrichment with the exception of a little cooking oil (**Figure 3.2**). In the NB round, fewer mothers had this problem and this is seen in the pre-counseling 24-hr dietary recalls because mothers were more likely to make thick porridges than thin (48.6% vs. 11.4%, p=0.049) and fewer porridges contained no enrichments (51.4% vs. 68.6%). After counseling in both rounds, the majority of reported porridges was thick and contained some type of enrichment such as bean powder, cream, custard fruit, juice, milk, Nutributter, peanut butter, pounded termites, or pounded seeds. However some enrichments were found in only one of the rounds. Custard fruit, juice, milk, pounded termites, and pounded seeds were only in the non-NB round. Cream and Nutributter were only found in the NB round.

Nutributter consumption

Based on the disappearance rate of Nutributter, infants consumed on average 21.0±1.3g Nutributter/day, which is consistent with the recommended dose of 20 g Nutributter/day. However the feeding frequency of Nutributter based on the 24 hour dietary recalls was only 2.8±0.3 spoons Nutributter/day, less than the instructed 4 spoons. In the interviews zero mothers reported feeding less than 4 spoons a day, and only a few mothers reported anyone other than the baby having consumed any of the Nutributter.

Out of 77 food entries in the 24-hr dietary recalls that included Nutributter, 40% were some type of porridge, 20% were some type of green leafy vegetable, 20% were plain Nutributter, and the rest were beans, pumpkin, sauces, mango, meat, potatoes, rice, and sour milk. This corresponds to how mothers responded in the

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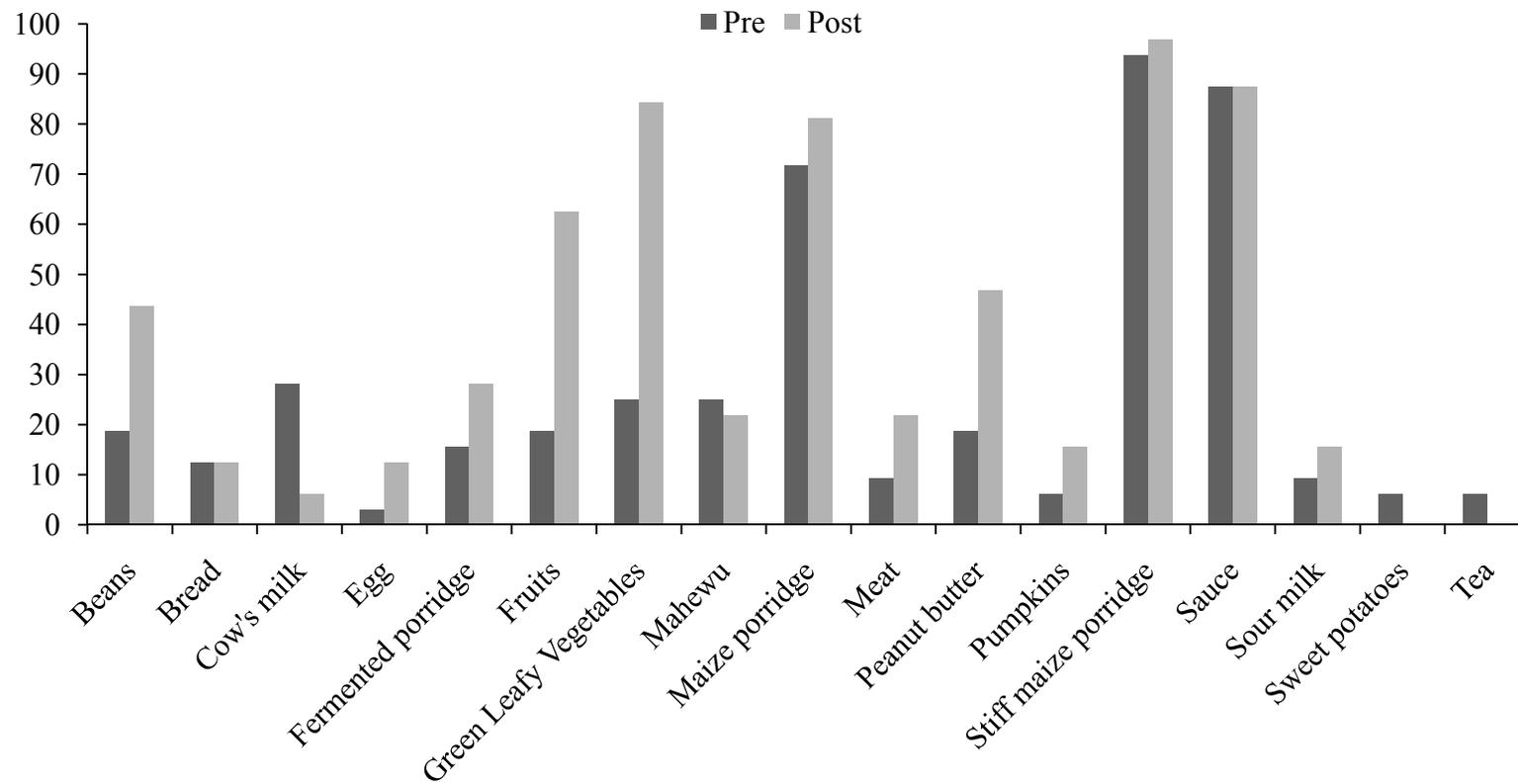
Figure 3.1 Percentage of children receiving foods pre- and post-counseling based on 24 hour dietary recalls. Foods fed by more than 1 mother are included. Foods denoted with an asterisk are significantly different pre-post. *p<0.05; **p<0.01
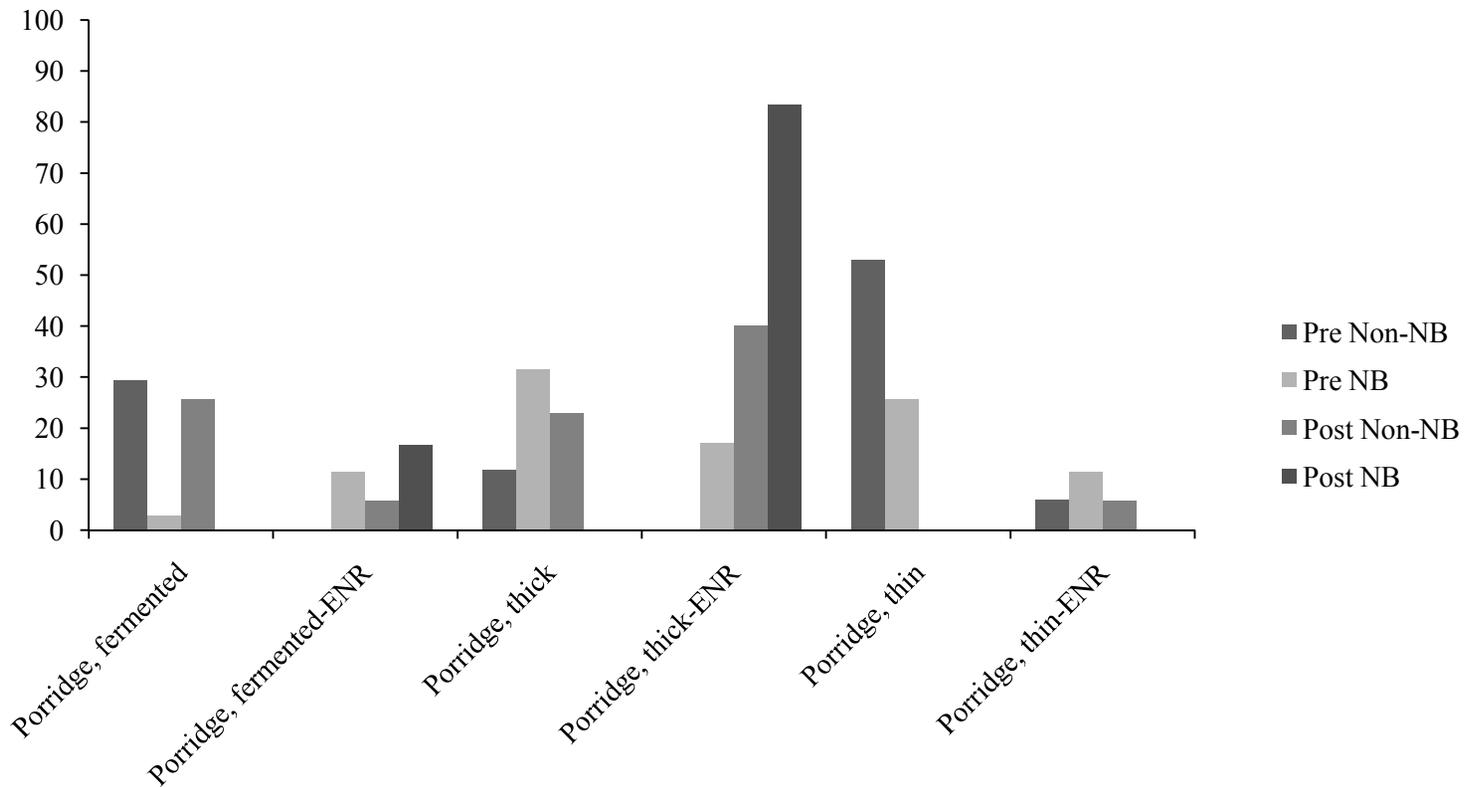
Figure 3.2 Percentage of reported types of porridge in each round of TIPs pre- and post-counseling in the 24 hour dietary recalls. ENR=some type of enrichment added such as Nutributter, peanut butter, pounded pumpkin seed, pounded insects, cow's milk, cream, bean powder, juice, or custard fruit. Cooking oil was not regarded as an added enrichment.

interviews. The majority of mothers said they had tried the Nutributter in porridge and green leafy vegetables followed by feeding it plain and with pumpkin. Only a few of the foods mentioned in the interviews were not in the 24-hr dietary recalls.

DISCUSSION

Mothers were able to increase nutrient intakes from complementary foods and feeding practices of their infants with and without the provision of Nutributter. This indicates that significant and meaningful improvements in infant diets were achieved through focused infant feeding messages based on local foods. However, Nutributter as a micronutrient supplement was crucial for adequate intakes of iron and zinc due to a lack of animal-source foods in the diets.

Previous studies with LiNS conclude that in order to see even greater growth effects future studies need to use a multi-faceted approach (i.e. provision of LiNS along with some type of disease prevention) (11,12). While this is likely true, these comments maintain the notion that providing LiNS circumvents the need to change the underlying dietary practices in a community (6,25). In this acceptability study with in-depth dietary assessment, we found limited compliance, according to the 24-hr dietary recalls, and no extra effect of Nutributter on energy, protein, vitamin A, or calcium intakes. However we found improvements in energy, protein, vitamin A, folate, calcium, iron, and zinc with or without the provision of Nutributter indicating meaningful behavior changes were brought about by the TIPs counseling. Vitamin A intake is the best example since reporting of green leafy vegetables increased by a factor of 3.4 after counseling. In this context there was a need for these dietary changes prior to introducing Nutributter. While some have promoted the use of LiNS on the basis that mothers are unwilling to change dietary practices and sustain new ones, there is evidence for the opposite when new feeding messages are adapted from

local foods and customs and mothers are given the information directly to learn and apply for themselves (26-28). Improving feeding practices can complement the provision of Nutributter or other at-home fortificants by optimizing the diets to which these supplements are added. Mothers will also be less reliant on the supplements and may be able to carry on if distribution of supplements is disrupted, a common worry for any program. When there is nutritious food to be consumed such as fruits, pumpkin, green leafy vegetables, and insects, there is little justification for ignoring any dietary practice that prevents children from consuming them.

A major lesson learned through this formative research was that specific feeding messages must be crafted to address the specific feeding barriers and target audience. Culturally-specific messages about processing locally available foods may be more effective in promoting behavior change than the general messages outlined in the WHO training curriculum on Infant and Young Child Feeding (IYCF) (e.g.: "mash mango," "grind termites," and "prepare bean powder" compared to "feed a variety of foods including legumes, green leafy vegetables, and fruits"). We developed 3 key messages after the study for the later intervention: (1) An infant can eat any food an adult eats; (2) Grind food so that infants can swallow and digest it; and (3) Food which is locally available in your area is important for your baby. These messages do not have direct parallels in the WHO IYCF curriculum (although they do not contradict any messages), but were the most impactful messages from our study. A cluster-based randomized controlled nutrition education trial in Peru found significantly reduced rates of stunting, improved feeding practices and increased nutrient intakes using different key messages developed from their own formative research (26). The important conclusion is that general key messages, although

inherently correct and comprehensive, may not impact feeding practices as much as context specific messages that are generated from formative research.

Secondly, mothers personally received these messages from Village Health Workers, as opposed to nurses or other facility-based workers (29). A more community based effort such as training of Village Health Workers or coordination of mothers' groups to educate mothers may be the most effective way to deliver of messages in this type of setting. In our study, we saw a reinvigoration of VHW and a transformation among mothers as they first recognized their community's inaccurate knowledge on infant feeding, and then as they eagerly transferred their new knowledge to other community members. This multiplication of the messages by the mothers themselves was a key observation in the non-NB tips that was not seen during the NB TIPs. We speculate that this was because amongst mothers who received the Nutributter, more attention was being paid to the product than anything else, and instead of neighbors sharing in the intervention they were mostly upset at not receiving the product themselves. In Mozambique many community health volunteers for Save the Children US, who were all mothers, maintained their involvement beyond the end of their 3-year program because of strong community based motivations, not any type of material incentive (30). On a day to day basis, the motivation for maintaining good health resides at the household and community level, not in the health clinic.

A benefit of counseling in addition to the provision of Nutributter was the variety of foods to which mothers were able to add Nutributter. Since peanut butter is a common food in Zimbabwe, mothers already desire adding it to foods like porridge and vegetables. Indeed enrichment of foods is also a desirable concept so mothers found it quite acceptable to use Nutributter to enrich their children's foods in addition to the other processed locally available foods we suggested. That we constructed all

of our recipes around local foods was a major motivator for mothers, some of whom said these recipes were tasty for all the members in their families. Because commodities such as cooking oil and sugar are often scarce and or expensive, using Nutributter and other locally available foods like pumpkin seeds or mashed fruits to substitute for cooking oil and sugar was a popular idea. The response of these Zimbabwean mothers to learning how to prepare locally available and usual family foods for their children echoes a similar response to mothers in rural Bangladesh, who criticized a nutrition education program for not providing recipes that incorporated wholesome traditional family foods (31). Mothers here reported that when enrichments were added to their children's food, the children were inclined to eat more of that food. This statement was particularly common in the NB tips. While increased portion sizes were not evident in the 24-hr dietary recall data, a longer study may detect this effect. Nutributter may improve palatability of a variety of foods leading to an increase in consumption of those foods.

Several limitations to this study are worthy of mention. There were different protocols and improved practices for the two rounds of TIPs. This was due to the added emphasis on hygiene in the planning of the larger trial that these studies were meant to inform, as well as information learned during the course of the first round. Such evolutions are the nature of TIPs and other formative research methods. The sample size was small, but children were randomly selected from the communities and feeding observations verified the use of improved practices. An unintentional limitation was a gap in time between the first round of TIPs and the second round making the Nutributter factor representative of a seasonal difference. Possible consequences were a different set of seasonal foods and leakage of nutritional messages, which may have caused some changes in initial dietary diversity in the second round. However, the pre-counseling nutrient intakes did not differ greatly

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between the two rounds of TIPs, and in both rounds the predominate problem was lack of diversity in children's diets.

Breastfeeding displacement is always a concern when studies encourage increasing intake of complementary food. Drewett calculated a decrease of 57 kcal from breastmilk for every increase in 100 kcal from complementary food (32) which was the increase seen in our study. This represents a decrease of 85 g of breastmilk/day, which is within the standard deviation of breastmilk intakes in other studies (32,33). Encouragingly, mothers in the NB TIPs actually increased their breastfeeding frequency perhaps due to increased thirst from the Nutributter, and non-NB mothers did not report significantly fewer breastfeeds. Because breast milk is normally displaced in programs and studies meant to improve complementary feeding, future work should investigate what appropriate levels of breastmilk should be in these situations which may help to assess what inappropriate levels of displacement look like (6).

We conclude that context-specific counseling to improve complementary diets of infants aged 6-12 months in rural Zimbabwe can bring about substantial improvements in infant diets. However, improvements in iron and zinc intake were observed only after the provision on Nutributter, a fortified food. Provision of barrier specific feeding messages directed at the household and community level were important to achieving the transformative impact on infant feeding practices. While Nutributter has many advantages over other technological approaches, in contexts such as Zimbabwe where local situations may change daily, over-reliance on this or any product is worthy of caution. Just as prevention of childhood undernutrition will require a multi-faceted approach including nutrition and infection-prevention strategies, nutrition interventions themselves may require a multi-faceted approach

that incorporates both technological approaches such as Nutributter and contextually appropriate educational strategies.

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CHAPTER FOUR

SOY-RICE BASED PROCESSED COMPLEMENTARY FOOD INCREASES
NUTRIENT INTAKES IN INFANTS AND IS EQUALLY ACCEPTABLE WITH
OR WITHOUT ADDED MILK POWDER[1]

ABSTRACT

Processed complementary foods (PCF) might mitigate several complementary feeding barriers in developing countries. Efficacy trials, however, have not shown substantial improvements in child growth, possibly due to inadequate formative research to assess acceptability and identify pitfalls. Milk powder might improve palatability of PCF but incurs a higher cost. We compared the acceptability of an instant soy-rice PCF without (SR) and with (SRM) milk powder. Best practices for formative evaluation of PCF are not established. We therefore compared findings from randomized trials of SR vs. SRM in 1-day sensory tests (n=71 mother-infant dyads) vs. Trials of Improved Practices (TIPs), a 2-wk in-home mixed methods evaluation (n=54 dyads). TIPs included interviews, disappearance rates, observations, and 24-h dietary recalls to assess acceptance, consumption of the 50g/day ration, and impact on diet. Although mothers preferred SRM to SR in the sensory tests, in the TIPs children consumed >50 g/d of SR (87±9 g/d) and SRM (89±8 g/d) with no difference between the foods (P=0.55). Despite some replacement of family food, increases in energy (137 kcal/d, P<0.001) and protein (19 g protein/d, P<0.001) were seen in both groups. Mothers' preferences for milk, more sugar in SR, and preparation with hot water were concerns raised in the sensory tests that proved insignificant in TIPs. However, TIPs uncovered new concerns of over-consumption and food safety.

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We found milk did not improve the acceptability of the soy-rice PCF and recommend TIPs as a useful tool for formative research of PCF interventions.

INTRODUCTION

Processed complementary foods (PCF) have long been proposed as a component of infant and young child feeding interventions because of their potential to mitigate several common barriers to optimal complementary feeding in resource-poor areas. PCF can supply appropriate levels of nutrients via a fortified cereal/legume mixture, and provide a precooked, instant product which may be easily prepared one serving at a time, thus avoiding storage of leftovers (1). Use of PCF has been widespread and successful in improving growth and micronutrient status in many Latin American countries (1-3).

In contrast to evidence from Latin America, efficacy trials with PCF in sub-Saharan Africa and South Asia have had inconclusive effects on growth and micronutrient status (4-6). In addition to problems with trial design and fortificant bioavailability, researchers cite problems with contextual and behavioral issues. In Ghana, study children may have been less zinc-deficient than anticipated, limiting their potential to benefit from the provision of the fortified PCF (4). In India, replacement of breastmilk was an unanticipated obstacle to improving diets and therefore growth (6). In Tanzania and India, mothers did not feed adequate amounts of the PCF (5,6).

The use of milk powder in PCF might improve palatability therefore increasing intakes and positive health effects. Milk powder is a high quality source of protein and calcium, and there is evidence that other milk constituents have specific benefits for child growth (1). However, milk powder is an expensive and usually imported commodity, with implications for economic feasibility.

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To predict compliance with PCF interventions, previous research included very short-term acceptability studies that did not identify the problems eventually encountered (4,5). Acceptability studies have typically been 1-day sensory panels of mothers, with or without their children, or assessment of infant consumption of the PCF during very structured feeding observations (7-10).

Trials of Improved Practices (TIPs) are a formative research approach for identifying practices to promote in health behavior change interventions. Originally designed to identify acceptable and feasible practices to improve child feeding (11), TIPs have also been used in programs on family planning, malaria prevention, and indoor air pollution (12). TIPs involve assessment of household conditions by program or research staff, followed by negotiation with families to try 1-3 improved practices for a short period. Follow-up interviews assess responses to the new behaviors, elucidating which practices are most acceptable and feasible in a population, and the factors that influence household responses (11). The use of TIPs has been recommended prior to implementation of infant feeding interventions (13); but requires more resources and time than simple sensory tests.

We present results from an acceptability study of two PCF, studied in preparation for a planned efficacy trial in Zanzibar. Because efficacy trials are expensive and time-consuming, we conducted an in-depth acceptability trial to gain insight into the potential impact and pitfalls of introducing a PCF in this low-income African setting. We had two objectives: 1) to compare the acceptability of a soy-rice PCF with or without milk powder, and 2) to compare the knowledge gained using 1-day sensory tests vs. 2-week at-home Trials of Improved Practices.

METHODS

Study setting

We conducted the study in Pemba Island, Zanzibar, Tanzania from January, 2006 to March, 2006. Three study sites were selected purposively to maximize sample diversity: one semi-urban (Urban), one inland rural (Inland), and one coastal rural (Coastal) site.

Trial foods

Two soy and rice-based extruded products were used in this study (InstaLIFE International, Weiser, ID and InstaPRO International, Des Moines, IA). The soy and rice (SR) only product contained a mixture of 50% full fat soybean, a common PCF legume (14,15), and 50% rice extruded together, dried and milled. The extrusion process made SR fully digestible and instant, needing only reconstitution with water. The soy and rice with milk (SRM) product was 50% SR mixed with 50% non-fat dry milk powder after milling. Because the lactose in SRM made it sweeter than SR, 7.5% w/w powdered sugar was added to SR to provide similar sweetness.

Trial food formulations and macronutrient composition are in **Table 4.1**. This formative study was not designed to assess impact on micronutrient status, and the fortificant premix was not yet optimized for infants, with final decisions pending findings on infant consumption. The products used in the studies were fortified with B vitamins, vitamins C and D, and iodine, but not with iron, zinc or vitamin A, all key nutrients for infants. Among these, iron is of greatest concern for organoleptic changes. Following this fieldwork we conducted sensory trials in US adults with iron-fortified SR and SRM, and found no negative taste differences between the iron-fortified and unfortified product (data not shown). Thus the lack of iron fortificant in the trial products is unlikely to have affected our findings.

Table 4.1 Trial product formulation[1] and macronutrient content

	SR	SRM
50:50 Soy Rice	92.5%	50.0%
Sugar	7.5%	0%
Dry Skim Milk	0%	50.0%
Energy, *kcal/100* g	410.3	384.2
Protein	21.3%	29.0%
Fat	8.1%	3.2%

[1]A fortificant premix was added to the final formulation at 0.32% w/w. The premix contained recommended target levels (1) of B vitamins, vitamins C and D, and iodine, given that there were only trace amounts of these micronutrients in the unfortified product . Vitamin A, iron, and zinc were not added pending results on daily consumption during the TIPs.

Enrollment

Mothers with infants aged 10-15 months (n=125 dyads) participated in the trial. This is the age range at which the prevalence of stunting and wasting is greatest in this population (16), and a previous trial in Ghana found greatest benefit from a complementary food intervention after 9 mo of age (4). From a representative list of women who attended antenatal care (17) we randomly selected infants evenly distributed across the age range in each site.

Trial protocol

We conducted the study in two parts: 1) 1-day sensory tests (n=71 dyads) and 2) 2-wk home trials (n=54 dyads). Four 1-day sensory tests were conducted in each site to compare the acceptability of SR and SRM. Mothers prepared 25 g samples of the two porridges, preparing one at a time so that an observer could ask the mother

about each porridge individually. The order of the porridges was randomly assigned to dyads.

The 2-wk home trials were based on TIPs but modified to allow detailed dietary assessment and to evaluate longer-term acceptability and ability of children to consume the minimum targeted ration of 50 g/d (1) of SR and SRM.   In each site, we enrolled 18 mother/infant dyads who had not participated in the sensory tests. Within each site age-matched pairs of infants were randomly assigned SR or SRM by the flip of a coin.

During the enrollment visit, fieldworkers conducted a 24-h recall. During the second visit we delivered the assigned trial food, demonstrated how to measure and prepare a 50 g serving, and asked the mother to: 1) feed at least 50 g/d dry SR or SRM; 2) continue breastfeeding and feeding nutritious family foods as usual; 3) not share the infant's food; and 4) feed as much SR or SRM as the child wanted. Teams of two fieldworkers visited the mother and child 3 more times, for a total of 5 visits, to monitor changes in dietary intake, acceptance and consumption of trial food. To discourage sharing of the infant's food, fieldworkers provided family rations ad libitum for the duration of the 2-wk trial. On day 14, mothers responded to questions about food sharing. All protocols and consent forms were approved by Institutional Review Boards of Cornell University and the Zanzibar Ministry of Health. Informed consent was obtained from all participating families.

Data collection methods

Reactions to SR and SRM. During the sensory tests, mothers rated product characteristics on a 5-point hedonic scale. Characteristics included appearance, ease of preparation, mother's and child's reactions to tasting, and mother's willingness to

feed the porridges. Observers recorded verbatim any comments the mothers made in regard to each question. Finally, mothers were asked which porridge they preferred.

During the TIPs, semi-structured interviews were conducted using a prepared set of open-ended questions. Follow-up interviews focused on how often the mother tried feeding the porridge, reactions of mother, baby, and other family members to the new porridge, and mother's willingness to continue feeding it. Feeding observations were conducted during the third visit on Day 5.

Energy density and daily consumption. We calculated energy densities of the porridge as prepared by the mothers during sensory tests, food demonstrations, and feeding observations. The primary measurement of daily consumption was the household disappearance rate of SR or SRM. Consumption based on the disappearance rate was positively correlated with intakes based on the 24-h recalls (r=0.64, P<0.001).

Dietary intake. Fieldworkers conducted four 24-h dietary recalls for each child: on Visits 1 and 2 to determine baseline dietary intakes, and on Visits 4 and 5 (days 10 and 14) to determine dietary intakes after the introduction of SR or SRM. Sample amounts of food that the child consumed were weighed by staff. If weighed samples were not feasible, staff recorded qualitative descriptions of amounts which were then reproduced and weighed in the laboratory. If no amount was reported (8% of food items), median portion sizes of that food from the same child were used, or if not available, from other children. Interviewers asked mothers for all the ingredients in a mixed dish and probed as to whether the child ate some of all the ingredients.

Reported food intakes were converted to daily intakes of energy, fat, and protein. Nutrient composition of raw foods and non-mixed foods were taken from an East African foods database if available, or if not, from a general African food database or the USDA database (18-20). To estimate nutrient composition of local

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mixed dishes, research staff prepared the recipes, weighing the raw ingredients and the final cooked product. Standard algorithms for estimating nutrient composition of recipes were used (21,22). Frequencies of all foods mentioned for all children at each 24-h dietary recall were also compared pre- and post-intervention.

Data analysis

Quantitative data. Data on dietary intake, energy density, and consumption of SR and SRM were analyzed using a multi-level model with age, gender, site, time (pre- and post-intervention), and type of food as fixed effects and child as a random factor. Significant effects were followed with multiple comparisons with Bonferroni correction. Non-breastfeeding children (n=5) and children who were ill on both days (pre- or post-intervention, n=4) were excluded from the dietary intake analyses. Chi-square (χ^2) tests were used to compare proportions. *P* values <0.05 were considered statistically significant. Analyses were done using JMP 6.0 (Cary, NC) or STATA 8.0 (College Station, TX).

Qualitative data. Fieldworkers' detailed notes on interview responses and observations were translated from Swahili into English. Using software for qualitative data analysis, Atlas.ti (Berlin, Germany), text segments were labeled with codes identifying content related to specific aspects of acceptability of the new foods and related themes. The coded data were then tabulated and summarized according to themes that emerged from the data (23).

RESULTS

Participants

Mothers' median level of education was primary school (**Table 4.2**). Most fathers were fishermen in the Coastal site, farmers in the Inland site, and civil servants

Table 4.2 Demographic characteristics of study participants

	Sensory Tests			TIPs		
	Coastal n=24	Inland n=24	Urban n=23	Coastal n=18	Inland n=18	Urban n=18
Age of Child, (mo.), *%(n)*						
10-11	20.8(5)	29.2(7)	34.8(8)	38.9(7)	33.3(6)	33.3(6)
12-13	50.0(12)	41.7(10)	47.8(11)	38.9(7)	38.9(7)	50.0(9)
14-15	29.2(7)	29.2(7)	17.4(4)	22.2(4)	27.8(5)	0.17(3)
% of males	42	50	43	39	33	56
Age of Mother, (yr.), *%(n)*						
≤20	12.5(3)	16.7(4)	13.0(3)	27.8(5)	11.1(2)	16.7(3)
21-30	75.0(18)	45.8(11)	52.2(12)	61.1(11)	16.7(3)	44.4(8)
31-40	12.5(3)	37.5(9)	30.4(7)	0	66.7(12)	27.8(5)
≥40	0	0	4.3(1)	11.1(2)	5.6(1)	11.1(2)
Educational Level, *%(n)*						
No primary school	75.0(18)	41.7(10)	13.0(3)	66.7(12)	77.8(14)	27.8(5)
Some primary school	20.8(5)	25.0(6)	8.7(2)	16.7(3)	11.1(2)	11.1(2)
Completed primary school	4.2(1)	16.7(4)	39.1(9)	16.7(3)	5.6(1)	16.7(3)
Secondary school	0	16.7(4)	39.1(9)	0	22.2(4)	44.4(8)
%(n) 1st child	4.2(1)	25.0(6)	13.0(3)	5.6(1)	5.6(1)	22.2(4)

or teachers in the Urban site. Most mothers identified themselves as housewives or farmers, and were 20-30 y old.   Most were experienced mothers, with only 16 of the 125 dyads including first children.

Milk verses no milk

The majority of mothers in the sensory tests rated both SR and SRM highly for taste, infant's reaction, ease of preparation, and their willingness to feed the porridge. According to fieldworkers' ratings, the majority of infants reacted well to both of the porridges with 76.3% of infants "liking" SRM and 64.9% "liking" SR; the reactions of the 2 groups did not differ (P=0.30).   When asked directly which product they preferred, 74% of mothers preferred SRM. Their reasons were: 1) mothers liked the milk (51%), 2) mothers liked the sweetness of SRM (34%), and 3) mothers perceived that the baby ate more of the SRM (17%). However, in the 2-wk TIPs, infants' consumption of SR (87±9.4 g dry product/d) and SRM (89±8.7 g dry product/d) did not differ (P=0.55).

Comparison of 1-d test verses 2-wk TIPs

Interviews with mothers. Mothers' views on preparation, taste, and motivation to feed the porridges did not differ between sensory tests vs. TIPs.   Most felt that preparation was convenient, noting that it's "quick to prepare," and "you don't have to boil water". The mothers generally liked the milk and sweetness of SRM, and often commented in sensory tests and TIPs that SR had too little sugar. Mothers assumed that the porridges were made of common foods such as groundnuts, maize, biscuits, and other cereals, and they regarded mixtures of these types of ingredients as healthy. Around 10-20% of mothers in both sensory tests and TIPs commented that the porridges tasted "cold" and needed to be made with hot water. The motivation most frequently mentioned by mothers (in sensory trials and TIPs) for feeding either

product was that these were healthy and nutritious foods that would be good for their children. The second most common motivation was that the child liked the foods.

There were, however, some differences between sensory test and TIPs results. First, ease of preparation and familiarity of ingredients were mentioned frequently during the TIPs, but rarely during sensory tests. Second, during TIPs, mothers became less concerned that the prepared food was cold—a concern they had raised in the sensory tests. Although 16.7% of mothers in the sensory tests and 14.8% of mothers in TIPs initially said the porridges needed to be made with warm or hot water, only 5.6% of mothers in TIPs actually did so. Finally, only TIPs allowed in-home assessment of consumption and potential impact on diet, as reported below.

Energy density and daily consumption.   Over-dilution of the porridges was not a problem. On average, mothers mixed SR with water in a 2:1 proportion, compared to 1.5:1 for SRM--likely due to the higher starch content in SR making it more viscous. As a result, the energy density of prepared SRM (1.9±0.03 kcal/g) was significantly higher during sensory tests and TIPs than SR (1.4±0.03 kcal/g) ($P<0.001$). During feeding observations, almost half of all mothers added extra ingredients to the porridges. Most commonly, they added sugar to SR, although 6 mothers added sugar to SRM. Three mothers added milk to SR.

Children in all age groups ate on average >50 g dry product/d for both SR and SRM (**Figure 4.1**). Children aged 10-11 months consumed significantly less food per day than children aged 12-15 months ($P<0.001$). Unexpectedly, TIPs data revealed a potential problem of over-consumption. Children in the Inland site consumed significantly more food per day than children in the Coastal and Urban sites ($P<0.001$). In the Inland site, children 10-11 months old ate on average double our target daily intake, and those 12-15 months old ate three times our target intake. There were no significant interactions.
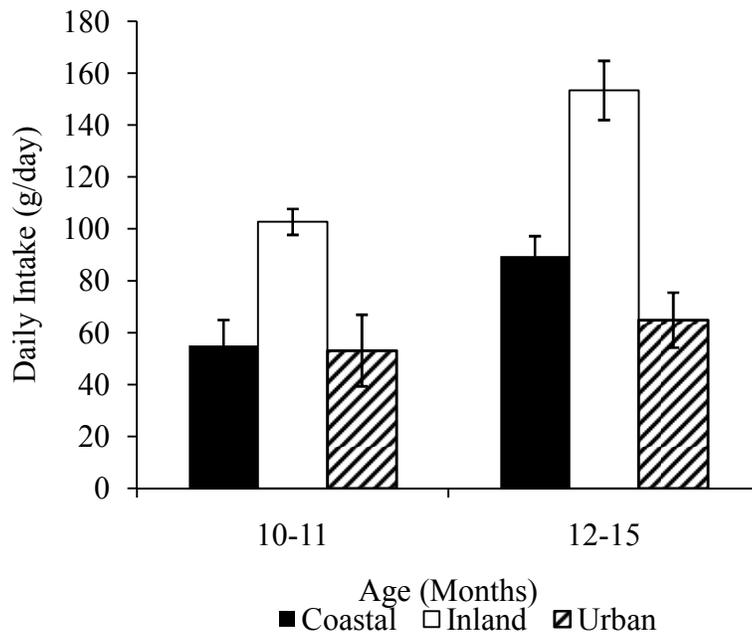
Figure 4.1 Daily consumption of SR and SRM combined by age and site. Values are mean ± SEM, *n*=47

Impact on diet. During the final TIPs interview mothers were asked about any changes in feeding. The majority (67%) reported no changes in breastfeeding frequency, and most who did report a change reported decreased breastfeeding. Thirty-three of 54 mothers reported that the baby had begun to refuse some other foods during the intervention, but 35 mothers also reported that the baby was eating more frequently after the intervention. The 24-h recalls showed an average increase of 1 feed per day over the 2-week period, from 3.35 to 4.34 feeds (P <0.001). The reported frequency of some family foods changed during the intervention (**Figure 4.2**). The most commonly reported family foods in the 24-h dietary recalls before the intervention were rice, tea, bread rolls, fish stew, boiled cassava, and mango. After the introduction of SR and SRM, frequency of reporting these foods decreased, suggesting some replacement by the PCF.
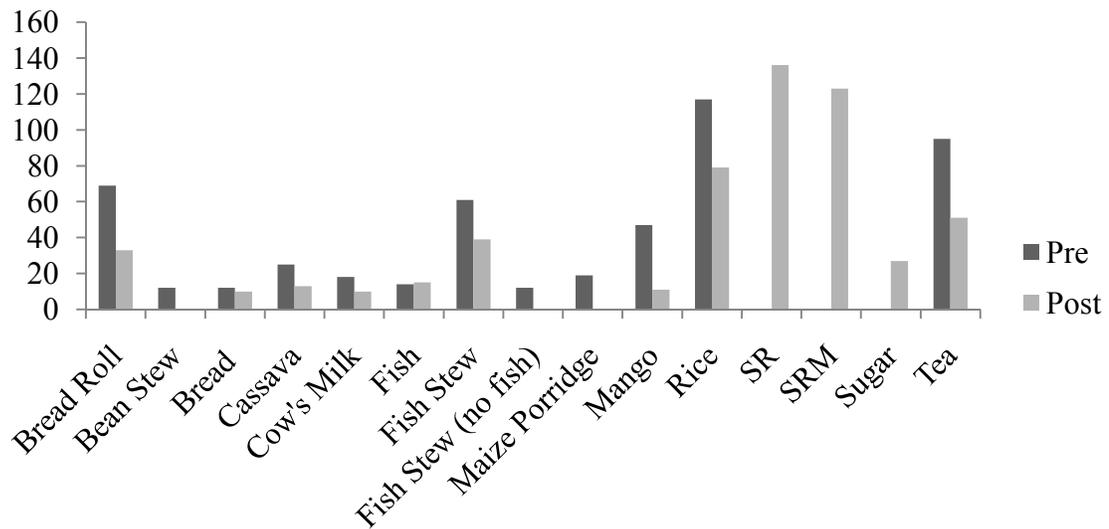
Figure 4.2 Changes in frequency of reported foods from pre- to post-intervention. Figure includes only foods mentioned at least 10 times in the sample of all recalls.

Dietary recall data indicated that energy and protein intakes from complementary foods increased significantly in all sites with the introduction of SR and SRM (**Table 4.3**). Assuming an average intake of breast milk, in all age groups, 35% of children were below estimated energy requirements at baseline (13), compared to 11% by the end of the intervention (P=0.015). Protein intakes were generally adequate pre-intervention as well as post-intervention. Children consuming SRM experienced a significant decrease in fat intake while children consuming SR did not. This was expected given that the non-fat milk powder displaced 25% of the full-fat soy in SRM. It is worth noting that the percentages of energy from fat in these products (18% for SR and 7.5% for SRM) are lower than the recommended 24-28% for PCF (1). These were levels set by the manufacturers' base formulation and could not be altered for the study. Other significant determinants of energy and protein intakes included site, age, and sex (for energy only).

Table 4.3 Daily nutrient intakes from complementary foods using dietary recalls[1]

	n^2	Energy Kcal	P	Protein g	P	Fat g	P
Site							
Coastal	33	544±39.0		18.7±1.5		19.1±1.8	
Inland	28	728±41.1[3]	0.0049	26.8±1.6	0.0003	23.2±1.9	0.278
Urban	32	570±39.0		18.8±1.5		20.3±1.8	
Age							
10-11 mo	39	553±35.1	0.0124	18.2±1.4	0.0004	20.1±1.6	0.4388
12-15 mo	54	675±30.1		24.8±1.1		21.7±1.4	
Time							
Pre	49	566±28.9	0.0004	11.8±1.2	<0.0001	22.1±1.4	0.22
Post	44	686±30.1		31.2±1.3		19.7±1.4	
Sex							
Male	43	664±33.9	0.0381	23.1±1.3	0.0724	22.7±1.6	0.1015
Female	50	564±31.1		19.9±1.2		19.1±1.4	
Food							
SR	46	616±32.0	0.9462	19.8±1.2	0.0581	21.3±1.5	0.7887
SRM	47	614±32.0		23.1±1.2		20.5±1.5	
Food x Time[4]							
SR Pre	24	--[5]		--		20.5±1.9	1.054
Post	22	--		--		22.2±2.0	
SRM Pre	25	--		--		23.6±1.9	0.031
Post	22	--		--		17.3±2.0	

Table 4.3 (Continued)

[1]Values are least squares means ± SEM.
[2]Number of observations used in model, excludes observations of sick and non-breastfeeding children.
[3] Different from Coastal and Urban, $P<0.05$.
[4]There were no differences between fat intakes pre- and post-intervention.
[5]--, Variable was not included in the models.

The only reported leakage of the infant food to other family members occurred when siblings or the mother occasionally ate the leftovers of porridge prepared for the infant. Mothers stated that provision of the family food was crucial to deter sharing of the infant food amongst family members.

DISCUSSION

Milk verses no milk

Milk powder was not necessary for the acceptability of the soy-rice PCF, nor did it improve the acceptability. Despite mothers' preference for SRM during the sensory tests, children ate the same amount of SRM and SR during the TIPs. This was in contrast to our expectation that children would find the milk product more palatable and eat more of it. Milk is high in lactose, and children have a preference for sweet foods even as early as birth (24). However, a study in Burkina Faso found that while children did like sweetened porridges, more sugar did not lead to higher intakes (25). The lack of a milk effect in our study might be explained by our addition of 7.5% sugar to SR, making both products mildly sweet. In this context at least, there is little need to include a high-cost ingredient (milk) to ensure palatability.

Comparison of findings from 1-d verses 2-wk acceptability methods

Several concerns raised by sensory tests proved insubstantial during TIPs. One was the preference for the milk product expressed by the mothers in the sensory tests, as noted above. Similarly in Peru, an acceptability study of porridges containing lyophilized liver or thigh meat found that, despite a negative reaction by mothers, infants readily consumed the meat porridges (7).

Based on the sensory tests, we were unsure whether or not children would consume the recommended 50 g/d of SR, given that some mothers preferred SRM, felt

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sugar needed to be added to SR, and expressed desire to use hot water to prepare the porridges, all of which might limit feeding frequency and, ultimately, intake. However, TIPs showed that neither milk nor preparation with hot water was necessary for acceptability, and mothers easily added sugar if desired.

The TIPs raised two major concerns that could not be detected in the sensory tests. Although consuming the targeted amount of at least 50 g/d was not a problem for the majority of children in the TIPs, over-consumption of the porridges emerged as a concern. There are very limited data on PCF intakes by children, and the fact that some children in our study ate much more than the recommended amount of 50 g/day highlights the need to conduct formative research in intervention settings prior to finalizing fortification levels. If this PCF had been fortified to recommended levels (1), 12-15 mo old children in the inland site would have consumed 38.2 ± 6.5 mg/d (mean $\pm$ SEM) iron and 20.5 ± 3.3 mg/d zinc, compared to RDA's of 7 mg/d for iron and 3 mg/d for zinc (Upper Limits: 40 mg/d for iron, 7 mg/d for zinc). On the other hand, children in the Urban site would have consumed the appropriate levels of iron and zinc because their daily intakes of PCF were within ~10 g of the target ration. Other acceptability studies have looked at ad libitum consumption but usually on a single serving, one-time basis (7,10), while the intakes we measured are 2-week averages in the home setting. We chose not to limit the amount of food and to encourage the mothers to feed as much as the infant wanted, but counseled not to reduce breastfeeding or other nutritious family foods. Our study illustrates the difficulties of setting fortification levels over various age ranges as discussed by Lutter and Dewey (1), and site-level differences in intake emerged as an additional context-specific influence (Figure 1). The high levels of consumption we observed were certainly influenced by the unlimited availability of free food during this trial, an unlikely circumstance under most program contexts. Nonetheless, potential over-

consumption of PCF should be considered when developing interventions to ensure that consumption of fortified foods is kept within safe limits. We concur with WHO recommendations that fortification levels of PCF should be determined from formative research on current dietary intakes and consumption ranges of the PCF in the target population (26). In-depth TIPs proved to be an appropriate formative methodology to gather such information.

A second concern that emerged in the TIPs was food safety. The field staff discovered that most mothers did not comply with instructions to use cool, boiled water to prepare the porridges but instead used untreated water from local taps. Preparing PCF using untreated water in unsanitary household conditions contributed to high levels of microbial contamination. We subsequently carried out a microbiological study of complementary foods in this population, including the soy-rice PCF studied here. When the instant PCF was mixed with unboiled water, coliform contamination above international guidelines was found in 75% of households (27). Mothers customarily give this water to infants to drink and said that boiling water was not feasible. However, we found that mothers complied with the instruction to avoid storage of the prepared product, thereby preventing further microbial growth, and our limited monitoring of morbidity did not indicate any increase in diarrhea. Ideally, educational or material interventions to improve hygiene and sanitation would be offered alongside the promotion of instant products and, in efficacy trials, data on diarrhea would be collected to identify functional consequences associated with preparing such foods using untreated water.

The TIPs (including 24-h recalls) also helped gauge the potential impact of this intervention in an efficacy trial by assessing actual intake of PCF over time, risk of replacement of other foods in infants' diets and leakage of the food supplement to other family members. From the dietary intake data over 2 weeks, we conclude that

there would be potential to benefit from this intervention. While there was some replacement, feeding frequency and overall energy and protein intakes from complementary foods increased significantly. More specific and persuasive educational messages would likely help prevent the replacement of nutritious foods such as fish stew and breastmilk. Sharing of the infants' food was deterred by providing food for the family. These findings have important implications for the design of efficacy trials, but do not mean that food sharing would not occur if the new foods were purchased by families or provided in smaller amounts by a social program.

Implementation and analysis of TIPs with repeated 24-h dietary recalls required considerably more time and expertise than did the sensory tests, and training required 10 days verses 3 days for the sensory tests. The sensory tests for all three sites were conducted simultaneously in 1 week, but the 2-week TIPs, with the same staff, could only be conducted in 2 sites simultaneously, and required 4 weeks total to complete. However, considering the depth of information gained and the documented pitfalls in previous efficacy trials not guided by in-depth formative work, the extra investment in a TIPs-based acceptability trial seems justified. In conclusion, we found milk did not improve the acceptability of the soy-rice PCF, and we recommend TIPs as a useful tool for formative research on PCF interventions.

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CHAPTER FIVE

CONCLUSIONS AND RECOMMENDATIONS

There are four sections in this chapter. In Section 1, I will review the formative research models that I described in CHAPTER ONE. I saved this discussion for the final chapter because I am reflecting on my research experience to evaluate these models and recommend changes to an IYCF formative research framework. In Sections 2-4, I will conclude my original dissertation research. I will discuss my contribution to the literature in Section 2, summarize my research conclusions in Section 3, and make recommendations for future research in Section 4.

REVIEW OF FORMATIVE RESEARCH MODELS

In CHAPTER ONE, I described four formative research models: the Hearth Model using the Positive Deviance Approach[1], Designing by Dialogue, *Pro*PAN, and the Program Theory Approach. These models and their accompanying manuals are useful tools for institutions and organizations who would like to design and implement an infant and young child feeding program. However, the presence of so many models may create confusion for those trying to decide which model to use. Therefore, it is imperative to thoroughly review 1) the degree of discontinuity among these research models and 2) the feasibility and efficiency of implementing these models.

I want to begin this review by explaining the basis for which I am assessing these formative research models. One, I have experience conducting formative research in two different African contexts. This experience is primarily based on a

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[1] Henceforth, the Hearth Model using the Positive Deviance Approach will be referred as the Positive Deviance Approach because that is the formative research portion of the model.

Designing by Dialogue approach. Two, I have discussed the informal, off-the-record comments about these models with people familiar to them. Three, I have interviewed someone who has experience implementing the Positive Deviance Approach.

Degree of discontinuity

Among these four formative research models, discontinuity exists on multiple levels: the core elements included, the methodologies used, the contextual aspects studied, and the research tools provided in the manuals. My observation about this discontinuity is that it ultimately stems from the underlying philosophy of the research model. I have listed below the explicit and implicit philosophies based on the frameworks of each model:

1. **The Hearth Model using Positive Deviance Approach**: The solutions to undernutrition already exist in the community, and those solutions need to be found among community members.

2. **Designing by Dialogue**: Acceptable and feasible recommendations to improve infant and young child feeding can be identified within the community by the research team and local families working together.

3. ***Pro*PAN**: Acceptable and feasible recommendations to improve infant and young child feeding can be identified within the community by the research team.

4. **Program Theory Approach**: Gaps can be identified within current IYCF program theories and filled in appropriately by program staff.

Key differences appear to come from the place where solutions are identified and the people who identify them. These types of differences subsequently affect the levels of discontinuity.

The first level of discontinuity is the core elements of formative research: 1) assessment of current infant feeding practices and other contextual aspects, 2) development of potential solutions, and 3) testing of the potential solutions. Designing by Dialogue, *Pro*PAN, and the Program Theory Approach include all three core elements. The Positive Deviance Approach is the only model that does not include the third element, testing of the potential solutions. The idea from the underlying philosophy would be that if we find positive deviance it is already feasible in that context.

The methodologies used within the core elements are the second level of discontinuity. The methodologies are summarized according to core elements in **Table 5.1**. The first observation to make about these methodologies is that *Pro*PAN includes more methodologies than any of the other formative research models. The assessment includes not only literature review and interviews, but also a large representative survey and dietary assessment using a 24 hour dietary recall, a food attributes exercise, and a market survey. The large quantitative survey and dietary assessment illustrates the authors' attempt to provide a comprehensive set of tools to users from Ministries of Health who would desire a more in-depth assessment prior to program development. Even though other models use 24 hour dietary recalls, only *Pro*PAN suggests the representative sampling. *Pro*PAN includes a market survey to help devise lists of cost-effective foods to promote in recipe trials and the later intervention. The Positive Deviance Approach does mention an informal market survey, but only in the context of assessing how appropriate the community is for the model.

The methodologies used for the testing of potential solutions are another noticeable contrast among the formative research models. As mentioned above, the Positive Deviance Approach does not include this core element. The targeting of

Table 5.1 Comparison of methodologies used in IYCF formative research models

Core Element	Methodology	The Positive Deviance Approach	Designing by Dialogue	*Pro*PAN	Program Theory Approach
Assessment of infant feeding practices	Literature review	X	X	X	X
	Interviews w/ mothers		X	X	X
	Interviews w/community members	X	X		X
	Feeding observations		X	X	
	Surveys			X	
	Dietary assessment		X	X	X
	Food attribute exercise			X	
Development of potential solutions	Recipe trials		X	X	X
	Interviews	X	X	X	X
	Household observations	X	X		
	Literature review		X		
	Market survey			X	
	Observation of program operations				X
Testing of potential solutions	Household trials		X	X	
	Interviews				X
	Focus group to modify recommendations		X	X	

households with well-nourished children in the development of potential solutions eliminates the need to further test the feasibility of those behaviors. The assumption is that if these mothers can do it, then everyone can. The other big difference among the remaining three models is the degree to which these potential solutions are tested. The interviews to pre-test messages in the Program Theory Approach only provide an estimate of potential acceptability and/or feasibility for the recommendations mentioned. These interviews would not test compliance and issues related to longer-term feasibility in the home. The household trials in *Pro*PAN only test the feasibility and compliance of one recommendation at a time, not the acceptability of several recommendations. The research team initially determines the acceptability and potential feasibility of proposed solutions and chooses which recommendation will be given to mothers using one of the pre-developed decision matrices. On the other hand, the household trials in Designing by Dialogue, TIPs, test the acceptability, compliance, and feasibility of multiple recommendations. The negotiation between mothers and interviewers establishes the acceptability of several recommendations by seeing how mothers react to them and choose the ones they want to try for two weeks.

The last difference in methodologies is the use of dietary assessment, particularly 24 hour dietary recalls. Only Designing by Dialogue and *Pro*PAN describe the protocol. The Program Theory Approach model is not packaged as a research manual and therefore does not include explanations of protocols. Designing by Dialogue provides very basic guidance on conducting 24 hour dietary recalls and suggests leaving most of the planning to the nutrition expert attached to the user's research team. The 24 hour dietary recalls in Designing by Dialogue are supposed to provide a more qualitative understanding of the local infant diet with a particular focus on energy. However, the *Pro*PAN manual describes a more quantitative and in-depth protocol to quantify the nutrient intakes of the population.

A third level of discontinuity is the contextual aspects studied in the formative research models. First, only the Positive Deviance Approach and *Pro*PAN describe methods to assess the population by sampling either the whole population or a large random sample. Second, these are also the only two models to distinctly suggest a market survey. However, the other models allude to gathering similar information through interviews with people in the community. Third, the Positive Deviance Approach and Designing by Dialogue both sample well-nourished children to understand the range of feeding practices in the community.   Fourth, the Program Theory Approach is the only model to specifically study existing program structures and relate them to the needs of the population. The other models only include the study of current programs in the context of familiarizing the research team with the general nutrition situation. Overall, through the qualitative research methods and reviewing available literature, all of the models may collect data on the same contextual aspects, but the degree of operationalization for data collection varies. The research tools that are available with each model, discussed below, indicate such operationalization.

The fourth level of discontinuity is the differences in the research tools available with each model. All of the models provide matrices to help organize and analyze collected data. Additionally, all of the models provide at least one example to illustrate the purpose of the matrix. However, Designing by Dialogue is different because it provides multiple examples (i.e. examples of multiple feeding practices, recommendations, motivations, settings, etc.). Second, the *Pro*PAN manual includes software that provides data entry and data analysis mechanisms for the General Survey and the 24 hour dietary recall. Third, the *Pro*PAN manual also gives very detailed instructions on how to sample populations as well as conduct and analyze 24 hour dietary recalls compared to the other models. Lastly, Designing by Dialogue has some

training materials included, but there is also a separate training manual available. Again, the Program Theory Approach model does not have any other tools besides their matrices because it was not packaged as a manual.

In summary, three areas stand out as the major sources of discontinuity among the four formative research models. One, the Positive Deviance Approach is fundamentally different from the other models with its narrowed focus on identifying positive deviance in the community. This focus eliminates the core element of testing the acceptability and feasibility of potential solutions. Two, there are stark differences in the methods used to test the potential solutions. Having different ways of evaluating these potential solutions could produce different recommendations to promote in a final program design. Three, this review of the methodologies, the contextual aspects studied, and the research tools highlights the differences in the level of operationalization of formative research. *Pro*PAN operationalizes more methods and contextual aspects to be studied so that users may have a set of tools to conduct the necessary research without having to second guess the amount or types of data being collected. Designing by Dialogue on the other hand is more open-ended in its suggestions on what and how much data to collect. The Program Theory Approach was developed within an existing program which provided structure to the type of data needing to be collected. Now that these differences are highlighted, we can evaluate how they may affect the feasibility and efficiency of these formative research models

The feasibility and efficiency of the formative research model

A lot of the criticism of these formative research models, particularly *Pro*PAN, is that its comprehensiveness is infeasible because it takes too much time. Therefore it is reasonable to look at the estimated time necessary to carry-out these models. The Hearth Model using the Positive Deviance Approach can take up to one year, but that

includes the implementation of the Nutrition and Education Rehabilitation Sessions, which are not part of the formative research phase. Designing by Dialogue lists a time period of five to six months to complete the 3 phases of formative research (exploratory, testing, and checking). Yet, the authors stress the model's flexibility such that you can skip components that are unnecessary. The first two modules of *Pro*PAN have an estimated time of 3-3.5 months, and again the authors stress only conducting the necessary methodologies from those modules that you need. The formative research phase for the Program Theory Approach was completed in 5 months according to the project report and that does not include the development phase where recommendations were pre-tested. Thus, despite its reputation, *Pro*PAN has the shortest estimated timeline. In my experience though, the reality of fieldwork would make these estimated timelines more equal than not, so it is important to look beyond time at the actual outputs for each model.

Feasibility simply means that these models are capable of being completed in a variety of contexts. However, adding efficiency to the requirement means that these models must also produce the maximum output without wasting time and effort. Based on the philosophies underlying these formative research models, the goal is to find reasonable solutions to improve infant and young child feeding within the community and/or existing program. Thus, the major question is—*for the effort we are exerting, are we getting the same results?* With that goal in mind, I will critique each model in turn.

The Positive Deviance Approach was a radical idea in international development for its asset-based approach; however its use is ultimately limited. Time is spent evaluating the feasibility of the community to determine whether you can even find Positive Deviant behaviors. This means that no matter the effort put into some settings, there may be no useful outcomes. The field guide also lists five potential

pitfalls of the Positive Deviance Inquiry such as finding no Positive Deviant behaviors or foods in a Positive Deviant household. An example of this pitfall occurred in a slum area of Brazil. Well-nourished children were identified by a nutritional survey as described in the model. However, upon visiting the households, the research team found no examples of Positive Deviance. The project leader said:

> *So these positive families had a couple of children that were not undernourished. So we went, and we wanted to see what their practices were at home in terms of hygiene, nutrition, etc. And we kind of knew what we were going to see, but not entirely… One thing we didn't expect, we were arriving just before a meal and it was about 11:00, was that there was no food in the house where we went. None. I could not look at the meal because there was nothing.* (1).

Again, these pitfalls stem from the narrow philosophy, meaning that the researchers only look at one type of data to come up with the appropriate solution, guiding the Positive Deviance Approach, but at least the field guide does warn users about this.

The uniqueness of this limited philosophy is also in question. In one validity study, researchers compared using the Positive Deviance Approach to a case-controlled, close-ended survey to identify nutrition promoting behaviors in Pakistan. The Positive Deviance Approach identified twelve behaviors while the case-controlled survey found six (2). The authors state that it was the semi-structured nature of the interviews and observations that allowed them to identify these extra, more complex behaviors such as responsive feeding. While this shows an advantage over close-ended surveys, this does not make the Positive Deviance Approach stand out among the other formative research models reviewed here. Designing by Dialogue also mentions conducting in-depth interviews and observations with well-nourished children, and therefore does not preclude identifying Positive Deviant foods and

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behaviors. By not moving beyond Positive Deviance foods and behaviors, this model precludes other solutions that could be found in the community, a major limitation for efficiency.

Overall, Designing by Dialogue is a comprehensive formative research model. It may not be comprehensive in terms of guiding program implementation and monitoring and evaluation, but it is not designed to be such. The phases of formative research described in this model seek to thoroughly describe the infant and young child feeding context by guiding users in how to conduct qualitative research. This manual does not have a distinct protocol and set of tools targeted to as many contextual aspects as *Pro*PAN (e.g. no market survey, no food attribute exercise, and no quantitative dietary assessment), but it does not preclude the users from understanding those contextual aspects. Designing by Dialogue instructs users on the basic tools of interviews, observations, and 24 hour dietary recalls so that they can collect a lot of different types of data. This inductive process requires a high tolerance for ambiguity which may deter some users, however the multiple examples that are provided helps mitigate this apprehension. The TIPs methodology is the most efficient way to test potential recommendations compared to the other models. One gets more information for the same amount of time and only a little more effort. Thus, although the open-ended nature of the exploratory research may seem intimidating, the use of examples and the entire TIPs methodology make Designing by Dialogue a workable model for programmers in many contexts.

The comprehensive nature of *Pro*PAN ensures that users collect an abundance of data, but it ultimately limits the types of results that come out of the research. For users with a lot of demands on their time, having the research plan and research tools readily available is quite useful. The detailed protocol of the 24 hour dietary recalls and provision of a food composition table helps users conduct more accurate dietary

assessments and collect more meaningful data than the qualitative 24 hour recall in Designing by Dialogue. However, having the research tools laid out disables the model by taking some of the creativity out of the process. The biggest example is household trials, where the research team assigns a recommendation to a family that was pre-determined by the recipe trial or feasibility matrix. There is less collaboration with families and less freedom to try things out because of this pre-determination of recommendations. A second illustration is the example recommendation given in for the household trials, "Increase meal frequency." That does not sound like a recommendation; that sounds like the ideal practice. These solutions given in the middle session of the household trial to overcome barriers to this recommendation include such things as "Feed the child an extra fruit" or "When his siblings are eating bread or fruit, ask them to share it with the baby." The solutions would be the recommendations given in a TIPs trial. By not testing these more specific recommendations, the research team is not discovering the contextually appropriate messages that should be delivered in an intervention. These constraints on the development and testing of recommendations are related to the underlying philosophy that takes away the collaboration with local families found in the Designing by Dialogue model.

The Program Theory Approach model is very similar to Designing by Dialogue in terms of its open-ended assessment of infant and young child feeding, but it is limited by its attempt to streamline message testing. The Behavior Change Communication Strategy matrices do help guide the formative research that needs to be conducted, but the methodologies to collect that data are left to users to decide and choose. The innovative aspect is the assessing of current programming structures in relation to programming structures needed in the future. This aspect is a practical approach considering the prevalence of non-governmental organizations (NGO)

operating in the developing world. While other models may identify such operations in their general assessment, this model provides guidance for working with them which improves the feasibility and efficiency of implementing the recommendations coming out of the formative research.

However, the efficiency of this model is ultimately marred by its not using household trials to test the new recommendations. Pre-testing messages in single interviews may save time and effort, but the output is not the same. In the final evaluation of the program, the researchers determined that a major reason why some of the promoted practices were not adopted was due to the presence of persistent and prohibitive cultural beliefs. Perhaps these attitudes might have been discovered during a round of household trials. Only individual acceptability can be measured in the model's message testing interviews.

In conclusion, all of these models were earnestly developed to identify reasonable solutions to improve infant and young child feeding. They all do some things well, and they all have some weaknesses. The major lesson from comparing all of these formative research models and thinking about my own experience using Designing by Dialogue is to not under- or overestimate the potential solutions by limiting how you develop them (the Positive Deviance Approach and *Pro*PAN) and how you test them (the Positive Deviance Approach, *Pro*PAN, and the Program Theory Approach). The second lesson is that comprehensiveness can mean having more things operationalized (*Pro*PAN) or making sure that users know how to collect all the data that they need (Designing by Dialogue and the Program Theory Approach). What really matters is what potential users require from a manual. Users with less experience and time may need the step-by-step delivery provided by *Pro*PAN. Users with more tolerance for ambiguity may appreciate the open-ended

design of the other two models. As long as the first issue over potential solutions is appropriately dealt with, these models can co-exist effectively with one another.

Formative research recommendations

Ultimately, the final question to consider is whether or not formative research can be done any better than what these models describe. From my dissertation research, I have some conclusions about what formative research needs to include that is not addressed by these research models.

In every case, the context of infant and young child feeding will need to be assessed. Every model does this, and all the models state that more or less may be done given the availability of existing information about the problem. The one thing that I would add/emphasize is familiarity with the local diet (common recipes, composition of foods, etc). Designing by Dialogue and the *Pro*PAN manual do this to some extent to prepare for the 24 hour dietary recalls. However, this process is generally left out of the timeline estimates. This process could be added to the recipe trials; however it would be necessary if a large scale dietary assessment were to take place prior to recipe trials. Essentially, this process should take around one week prior to beginning the assessment. Informants such as village health workers or other community leaders familiar with foods fed to infants are useful for teaching common recipes.

CHAPTERS TWO and THREE discuss ways to use formative research to develop potential solutions for improving infant and young child feeding. Essentially recommendations can come from other levels of context besides the desired feeding behavior. In CHAPTER THREE, I call them barrier-specific recommendations. Even though Designing by Dialogue and the Program Theory Approach might have developed similar types of recommendations, the notion that these were

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recommendations targeting the contextual barriers and not the behavior directly was not explicitly discussed. In other words, the recommendation should address why mothers are not doing the ideal practice verses simply telling mothers what to do. Additionally, recommendations could target other audiences or contextual aspects that are the underlying barrier. The Program Theory Approach came close to recognizing this by having a BCC strategy matrix that noted who the messages should be targeted to and one of their examples was grandmothers and fathers. However, they ultimately did not follow through with that recommendation. Lastly, all of these formative research models focus on developing recommendations that affect feeding behaviors using locally available resources. The food aid package used in the Program Theory Approach was an existing commodity in that program. None of these models mention technology-based supplements as potential solutions to improve infant and young child feeding. However, the effects of this omission mostly affect the third core element, testing of potential solutions.

Testing of potential solutions is a crucial step that needs to be done effectively because it is when you are going to learn the most about how to improve the feeding practices. This is why TIPs is the fundamental methodology in Designing by Dialogue. Therefore, household trials are essential for this element. I recommend TIPs for testing behavior change messages. Second, as mentioned above, technology-based supplements could be added to the mix of solutions and need to be tested in a similar manner to behavior change messages or other recipes. Rapid assessment methods such as focus groups or sensory testing are useful to test basic acceptance of products and recipes. For the household trials of products, we found in CHAPTER FOUR that it was valid to take away the negotiation part of the TIPs because if mothers were given a choice, initial acceptance was based on their taste preference, not the infants' ability to consume either product. Third, in CHAPTER THREE, we

conducted two rounds of TIPs illustrating the use of household trials to test multiple levels of an intervention. After the first round using only locally available resources, one can assess the remaining gaps in nutrient intake, conduct a second round with another type of interventions such as a technology-based supplement, and then assess the interaction of those layered interventions. There is a freedom in formative research not found in larger interventions, and that should be capitalized on by taking the time to conduct more than one round of household trials.

Finally, I propose a modified Designing by Dialogue framework that would include these recommendations and incorporate methodologies and/or tools from the other research models as needed, particularly the dietary assessment tools from *Pro*PAN and the BCC Strategy matrices from the Program Theory Approach (**Table 5.2**). The timeframe for this framework would not necessarily be longer than other research models, and would mostly be determined by how many sites need to be included in the formative research. I kept the basic Designing by Dialogue framework in part because that is what I have worked with, but also because it is open-ended which allows one to add and subtract methodologies as needed.

Conclusions

In this section, I compared and contrasted the four formative research models described in the Introduction. I found major differences in the core elements included, methodologies to test potential solutions, and the amount of operationalization in the models. Based on these differences, I discussed my perception of each model's feasibility and efficiency which were mostly affected by the ways the potential solutions are tested. I ended this section with my recommendations for a future formative research framework.

Table 5.2 Possible framework for IYCF formative research

Core element	Task	Methodologies and/or Tools	Timeframe
Assessment of infant feeding context	Assess general situation including existing programs	Literature review, key informant interviews	1-2 weeks
	Understand local infant diet	Key informant interviews, recipe creation, food composition table development	1 week
Development of potential solutions	Develop list of common problems and potential recommendations using locally available resources or behavior change	Recipe trials with mothers and/or key informants, Filling in BCC Strategy matrix	1 week
Test potential solutions	Test recommendations	TIPs	2-3 weeks
Re-assessment of infant feeding	Identify remaining problems, nutrient gaps, etc.	Analysis of 24 hour dietary recalls in TIPs	1 week
Development of more potential solutions	Identify other intervention strategies, technology-based products, etc	Literature review	Done at the same time as above
Test new solutions in context of previous ones	Rapidly assess acceptability, assess at-home feasibility	Sensory trials, TIPs	2-3 weeks in nearby/similar context
	Analyze and report findings		2 weeks

CONTRIBUTION TO THE LITERATURE

This research comes at a pivotal moment in child undernutrition research. A recent series in The Lancet has meticulously calculated the current prevalence of child undernutrition and predicted that fully implementing our entire available infant and young child feeding interventions will only reduce 30% of child undernutrition. This dissertation addresses ways of using formative research to improve the design of and potentially the efficacy of future interventions.

Current recommendations for complementary feeding interventions are based on two broad contexts: food secure and food insecure areas. Other aspects of context are recognized in the literature, but are not well delineated. CHAPTER TWO uses formative research to explore how contextual determinants beyond food insecurity affect complementary feeding and the selection of possible intervention strategies. This research is unique in that it compares two settings in Sub-Saharan Africa in order to unpack common generalizations that are often made at the global scale.

Lipid-based nutrient supplements (LiNS) have had inconclusive effects on child growth during the complementary feeding period. Previous efficacy trials in Sub-Saharan Africa using LiNS have not assessed intake from other complementary foods or the potential to improve it. CHAPTER THREE uses formative research to understand the potential to benefit from improving the underlying local diet while providing a lipid-based nutrient supplement (LiNS). This research is important at this juncture as future trials using LiNS are being planned in the same Sub-Saharan contexts.

In-depth household trials have previously been used in formative research for nutrition education intervention. Formative research for interventions using processed-complementary foods (PCF) has consisted of short-term acceptability trials using sensory panels and infant feeding observations away from home. Large efficacy

trials using PCF have reported problems with infant consumption and feeding of the trial food. CHAPTER FOUR compares the information learned about the acceptability of a soy-rice based PCF with and without milk powder from 1-day sensory panels and 2-week Trials of Improved Practices (TIPs). This research is the first to describe a modified TIPs methodology using PCF. It also adds to the literature regarding by testing the need to include milk powder to increase palatability.

DISSERTATION CONCLUSIONS

CHAPTER TWO

1. Income poverty as a definition of food insecurity does not provide adequate information about a context to determine whether or not a food-based supplement would be necessary. Other important contextual determinants might include the local ecosystem and local agriculture.

2. Supplements should complement the local diet and the potential for behavior change in order to avoid replacement of nutritious foods. Building community capacity to maximize local diets will help ensure the sustainability of the program if provision of a supplement was suspended.

3. Many complementary feeding practices are derived from indigenous learning around infant feeding. Indigenous learning determines existing maternal knowledge and existing channels of infant feeding education outside of the health system. Developing infant feeding education around existing indigenous ways of knowing and learning would contribute to more sustainable behavior change.

4. Some infant feeding problems are the result of unhealthy family eating behaviors when infants are given family foods.

CHAPTER THREE

1. Conducting two rounds of TIPs enabled us to determine the potential benefit of infant feeding counseling in addition to the provision of Nutributter.

    a. Counseling to improve complementary diets substantially improved infant diets. In contexts where some nutritious local foods are available but are not being fed to infants, counseling helps to ensure improved intakes when compliance is not optimal.

    b. Counseling combined with provision of Nutributter had a positive impact on total infant food intake according to maternal reports.

2. Provision of a fortified supplement is important for adequate intakes of iron and zinc in contexts lacking flesh foods.

3. We tested counseling messages based on the conclusions about education in Chapter Two. We found that counseling messages which recognized and took into account existing maternal and indigenous knowledge led to a transformative learning experience and subsequent behavior change. The behavior change was evident from the dietary intake assessments. Initiating this transformative learning experience for mothers in our study led to their independently educating other mothers. This would confirm our other suggestion from Chapter Two that utilizing the community-based indigenous learning systems, such as using elders to impart messages, is a feasible and effective channel for nutrition education.

CHAPTER FOUR

1. Milk powder did not improve infant acceptability of a soy-rice based PCF. We confirmed findings from other studies that there is little or no correlation between maternal and infant acceptance.

2.   Conducting a 2-week in-depth TIPs methodology to assess acceptability of the soy-rice based PCF was useful to identify pitfalls that were not found in the 1-day sensory tests and that could negatively impact the efficacy of long-term PCF feeding trials.

    a. Final fortification levels should be set only after maternal feeding and infant consumption capacities are determined.

    b. Measures beyond simple, clear instructions must be taken to guard against replacement of existing positive feeding practices and food safety concerns associated with an instant product.

RECOMMENDATIONS

These are recommendations in addition to the recommendations listed in review of formative research models.

1.   Formative research has been recommended prior to complementary feeding interventions. I would like to reiterate that recommendation because it is frequently not being done (3).

2.   To improve adherence to this recommendation, I would also like to recommend that such formative research be better documented either in separate publications, extended methods sections, or a program theory framework as used in the Program Theory Approach. This is important so that intervention designs are better justified in the context of reporting findings.

3.   In addition to documenting the formative research, there should also be better documentation of the context through-out the intervention in separate publications of descriptive case studies or extended methods sections. There should be more recognition of context-based decisions that affect intervention

outcomes and may potentially affect how we translate the research into practice.

4. I recommend incorporating contemporary theories from adult learning and "non-western" ways of knowing and learning into our interventions using nutrition education.

5. Formative research should be conducted to assess the feasibility of training community members outside of the health system to improve the indigenous education around infant feeding and care. Guidance should be taken from the Hearth Model using the Positive Deviance Approach for its emphasis on community-based involvement.

6. Formative research should be conducted to assess the feasibility of providing family-based nutrition education to improve infant and family diets. Guidance should be taken from literature in developed countries on family-based interventions to prevent child obesity.

7. Research is needed on food composition of indigenous foods so that interventions recommending the use of them may know the nutritive value of new recipes.

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