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Morbidity Evaluation of an Innovative Feeding Toolkit to Improve Complementary Feeding in Malawi Shows No Significant Increase in Diarrhea

By

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Master of Public Health

Global Epidemiology

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By

Jasmine E. Ko

B.A.
Emory University
2015

Thesis Committee Chair: Amy Webb Girard, PhD

An abstract of
A thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
in partial fulfillment of the requirements for the degree of
Master of Public Health
in Global Epidemiology
2017

Abstract

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by Jasmine E. Ko

Objective. The aim of the present study was to test the association between an innovative feeding toolkit and the impact of the intervention on morbidity. We additionally assessed predictors of childhood diarrhea.

Design. A cluster randomized controlled study, where clusters were randomized to one of two groups. Households in the intervention were eligible to receive a toolkit consisting of a bowl with demarcations on age-appropriate meal volumes; a slotted spoon designed to promote optimal food consistency; and nutrition education. Caregivers in the control received nutrition education only.

Setting. Mduwa, Mkanda, and Zulu Traditional Authorities in Mchinji District, Malawi.

Subjects. 1,331 caregivers of children 6-17 months at baseline were enrolled in June/July 2015. 962 of the same households and 48 additional households were followed up with in June/July 2016. Participants were analyzed as intent-to-treat, per protocol, and per uptake.

Results. In per protocol logistic regression analyses with diarrhea as the primary outcome, there appeared to be no significant effect modification between the toolkit and a-priori effect modifiers. We observed no statistically significant association between the intervention and diarrheal morbidity (OR: 0.92; 95% CI: 0.60, 1.40). Food security and age category were significant predictors of childhood diarrhea (aOR: 0.62; 95% CI: 0.40, 0.95; aOR: 0.63; 95% CI: 0.49, 0.80, respectively).

Conclusions. We observed no beneficial effect or unintended consequences associated with the feeding toolkit and morbidity. While younger age is an expected risk factor for diarrhea, nutrition-sensitive interventions should be considered to address food security and its impact on diarrhea.

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Chapter I: Background

Worldwide, nearly half of all deaths of children under five years of age are attributable to undernutrition (1). Despite major 21^{st} century advances in public health, maternal and child undernutrition is still the underlying cause of 3.1 million child deaths annually, or 45% of all child deaths in 2011 (2). The prevalence of undernutrition is distributed unequally across the world, with low- and middle-income countries bearing the greatest burden of underweight, stunting, and wasting (2). The UNICEF Conceptual Framework for undernutrition recognizes income poverty as an underlying cause of household food insecurity, inadequate care, unhealthy home environments, and lack of healthcare—the influencers of inadequate dietary intake and disease (3). Due to this relationship between poverty and undernutrition, low-income countries in south-central Asia and sub-Saharan Africa have the highest prevalences in undernutrition indicators, with 30% and 22% of children under five in 2011, respectively, underweight (2).

The health effects of undernutrition are serious, and if experienced during the first 1,000 days (starting from conception through the child's second birthday), can be permanent (4). Undernutrition affects fetal growth, brain development, motor development, and cognitive development (2). If stunting is experienced early in life, a child is more prone to experience adverse functional consequences later in life, such as poor cognition and educational performance, low adult wages, and lost productivity (4). According to a pooled analysis of ten prospective studies in Africa, Asia and South America, all degrees (mild, moderate, severe) of anthropometric deficits (underweight, stunting, wasting) were associated with an increased risk of under-five mortality (5). Further, all degrees of anthropometric deficits increased the hazards of dying from respiratory tract infections and diarrheal diseases (5). In fact, malnutrition is the primary cause of immunodeficiency worldwide (6). Immunodeficiency, defined as the inability to form a normal immune response to infectious disease agents, can develop from a state of malnutrition, and mostly affects children, adolescents, and the elderly (6). In turn, repeated events of infectious disease can also lead to a state of malnutrition—thus forming a cyclical relationship that intricately links the two. Undernutrition due to an inadequate diet leads to weight loss, lowered immunity, mucosal damage, invasion by pathogens, and impaired growth and development in children (6). When a child is undernourished, they are more vulnerable to infections because of a decrease in the epithelial integrity of the respiratory and gastrointestinal tracts and an overall increase in the body's inflammatory response (6). Once infection has occurred, consequences include fever and diarrhea, which lead to nutrient losses that further damage immune responses and increase the body's demand for energy (6). The two most common categories of infection, diarrhea and acute respiratory infections, can have serious consequences if persistent (7). With childhood diarrhea, repeated episodes can lead to severe dehydration, growth faltering, loss of key micronutrients such as zinc and copper, and even death (8). The causal pathway between respiratory infections and growth is less clear, but appears to work through the increase in energy demands because of persistent fever (7).

While the cyclical relationship between nutrition and infection is well-established, more research is needed concerning the interaction between nutrition and infection (7). For example, limited research has examined whether infection reduces the effectiveness of nutrition interventions with respect to child growth, or the reverse—if poor nutrition reduces the effectiveness of infection control strategies, such as handwashing interventions or rural sanitation programs (7). In terms of the former, researchers hypothesize that a child's infectious disease status could differentially influence the impact of a nutritional intervention. For example, in 2003, Hadi and colleagues initiated a randomized double-blind placebo-controlled trial in Indonesia to test the effect of high-dose vitamin A supplementation on child growth (9). The authors concluded that the vitamin A supplementation improved linear child growth the most for children who had a low burden of respiratory illness or a low vitamin A intake, but was less effective for children who had a high burden of respiratory illness or a high vitamin A intake (9). This study is one of only a few studies that explore the differential effect of a nutrition intervention dependent on infectious disease status (7).

Because of the severe health consequences of malnutrition and the gap in knowledge about the interaction between infectious diseases and nutrition interventions, implementation and evaluation of nutrition interventions should be prioritized within the public health community. Key global health stakeholders have declared that nutrition interventions are of critical importance to public health. Goal 2 of the United Nations' newly formed Sustainable Development Goals calls to "End hunger, achieve food security and improved nutrition, and promote sustainable agriculture" by year 2030 (10). Similarly, the World Health Organization (WHO) adopted a resolution in 2012 with a global target to reduce the number of under-five stunted children by 40% by year 2025 (11). An example of an essential area of nutrition that requires intervention is Infant and Young Child Feeding (IYCF). IYCF programs focus on improving feeding practices caregivers employ to provide breast milk and complementary foods to their children, which directly impacts their child's nutritional status (12, 13). According to WHO and UNICEF, in developing countries, the energy needs from complementary foods for infants with average breast milk intake are approximately 200 kcal per day at 6-8 months of age, 300 kcal per day at 9-11 months of age, and 550 kcal per day at 12-23 months of age (14). While a caregiver may be reaching the adequate number of daily feedings, the energy intake depends on the energy density of the complementary foods given and the amount consumed at each feeding (12). If the energy density of the complementary foods is less than 0.8 kcal/g or if the child eats less than the assumed capacity, meal frequency needs to increase accordingly to ensure adequate energy requirements (14). Thus, children may not be receiving adequate dietary energy intake if his or her complementary foods were of low energy density or of smaller quantities (12).

Improvements in IYCF programs are urgently needed because knowledge is lacking on two levels: on the ground level, among caregivers of infants and children, and on an academic level, among public health practitioners who are attempting to measure and improve child nutrition. Despite the importance in breastfeeding and complementary feeding practices, data collected from 2002 to 2008 show that only 36% of infants in low-income countries were exclusively breastfed for their first six months of life (15). Further, only one-third of children 6-24 months old in low-income countries met the minimum criteria for dietary diversity (15). These gaps in IYCF practices are seen primarily in low-income countries in sub-Saharan Africa, southeast Asia, and Latin America (15). According to a qualitative analysis conducted by Rasheed and colleagues in Bangladesh, a large proportion of children do not consume adequate complementary foods to meet energy requirements, and caregivers demonstrate a lack of knowledge around the quality and quantity of complementary foods (16).

A review of IYCF programs globally shows that there are few examples of successful, full-scale IYCF programs (17). According to Lutter et al., this gap is due to a lack of a core set of policies and programs that can lead to large-scale improvements, like stunting on a community level (17). Rigorous evaluations of current IYCF programs are seldom done, which prevents a scale-up of existing programs (17). Further, systematic reviews of complementary feeding programs find that although improvements in practices are seen, the degree of improvement is small (18). In terms of public health indicators, the first major set of guidelines for IYCF practices were published in 1991, and provided indicators to assess infant breastfeeding and breastfeeding promotion across different countries, but only contained one indicator on complementary feeding (13). Since then, the nutrition community has advocated for revisions to existing breastfeeding indicators and for additions to complementary feeding indicators. Important developments in these IYCF indicators occurred in 2007, when the WHO convened the "Global Consensus Meeting on Indicators of Infant and Young Child Feeding" to develop and discuss a revised set of population-level indicators for breastfeeding and complementary feeding (13). The purpose of these indicators was to develop population-level indicators for assessment, targeting, and monitoring and evaluation (13). While the increase in the number of complementary feeding indicators illustrates progress towards improving complementary feeding practices, the authors acknowledge the lack of evidence and consensus on other aspects of complementary feeding, such as responsive feeding and food texture (13). As a response to this lack of knowledge among caregiver and researchers, researchers have been investigating methods to improve maternal nutritional knowledge and develop volume and consistency indicators for complementary foods. A review conducted by Imdad and colleagues illustrates that complementary feeding interventions such as provision of appropriate complementary food and maternal nutritional counseling both lead to significant increase in weight and height in children 6-24 months of age (19). However, the improvements were only moderate, and the existing interventions do not address the measurement gaps in IYCF indicators.

Although researchers have started to make progress in evaluating ways to improve IYCF practices in malnourished communities in order to impact child growth outcomes, it is additionally crucial to assess whether IYCF programs have the ability to impact morbidity outcomes. In 1984, Black and colleagues published the results of a longitudinal cohort study of children in rural Bangladesh, which stated that nutritional interventions alone were unlikely to result in a reduction of diarrheal incidence, but were more likely to impact diarrhea duration (20). However, more recently, according to the results of a targeted biofortification intervention for improving vitamin A intake among young children in northern Mozambique, promoting household cultivation of orange sweet potatoes reduced the prevalence of childhood diarrhea (21). Because Vitamin A is associated with restoring and maintaining gut mucosal integrity, biofortification of orange sweet potatoes reduced diarrhea prevalence by 11.4% among all children and by 18.9% in children under three years of age (21). Within this study, the duration of diarrhea episodes was also significantly reduced among those randomized to the orange sweet potatoes group (21). Other IYCF programs, such as promotion of exclusive breastfeeding, have also been associated with decreasing infectious disease morbidity, such as acute respiratory infections and diarrhea. From 1993 to 1995, a prospective observational study was conducted on a Bangladeshi birth cohort of 1,677 infants who were followed from birth to 12 months of age (22). According to this study, infants who received partial or no breastfeeding had a 2.40- and 3.94-fold higher risk of deaths attributable to acute respiratory infections and diarrhea, respectively, compared to infants who were exclusively breastfed (22).

In the summer of 2015, researchers at Emory University and Concern Worldwide initiated a cluster randomized study to evaluate the efficacy of an innovative feeding toolkit in the Mchinji District in the Central Region of Malawi. In 2014, the worldwide rate of stunting of children under five years of age was 23.8% (23). In comparison, in Malawi, the national rate of stunting for children under five years of age in 2010 was 47.1%, with an even greater prevalence in rural areas (24). The prevalence of diarrhea in the past two weeks for children under five years old was 18% (24). In terms of meeting IYCF recommendations, in 2010, only 19% of Malawian children aged 6 to 23 months were fed in accordance with the WHO IYCF practices (24). Despite the large number of nutrition interventions that have been implemented in the country since the 1970s, the Government of Malawi's Commission for National Nutrition and Education Communication Strategy stated that the general consensus among stakeholders is that almost all the nutrition intervention efforts have failed to reduce stunting (25). The feeding toolkit, intended to address these gaps in nutrition, consists of a bowl with demarcations on age-appropriate meal volumes, a slotted spoon designed to promote optimal food consistency, and nutrition education. Feeding bowls are an example of an IYCF intervention aimed at providing complementary feeding assistance to caregivers. According to qualitative research conducted by The Manoff Group, increasing the volume of complementary foods consumed is very difficult (26). Some reasons caregivers fail to meet volume requirements are that they do not know how much food to give and do not think it is possible for small children to eat the volume of food required. Feeding bowls are an innovative way to cue caregivers to offer the correct volume of complementary foods required as children age. In 2008, The Manoff Group tested feeding bowls for acceptability and use as part of larger qualitative study in several Latin American countries, including El Salvador, Nicaragua, and Bolivia (26). The researchers utilized qualitative methods only and concluded that the feeding bowl was very acceptable, made instruction and counseling easier, served as effective reminder of feeding, and was inexpensive and very scalable (26).

Considering the pressing need for effective IYCF interventions in communities such as rural Malawi, innovative interventions such as feeding bowls must be rigorously tested in real communities for both intended effects and unintended consequences. Intended effects include not only an increase in volume and consistency of complementary foods consumed and an improvement in growth outcomes, but also include a decrease in the prevalence of morbidity outcomes, such as diarrhea. The interconnected nature of nutrition and infection demands evaluations of IYCF interventions that address how adequate complementary feeding can influence morbidity from undernutrition. Additionally, IYCF programs must evaluate unintended consequences that potentially could arise from the intervention itself. Interventions may inadvertently cause an increase in undesirable practices, such as forced feeding, improper storage of cooked foods or inadequate hygiene. Diarrheal incidence peaks at around 6 to 11 months of age, as children begin eating complementary foods that are potentially contaminated and begin crawling and exposing themselves to pathogens (27). According to research conducted in Bangladesh by Islam and colleagues, around 40% of complementary food samples in their study were contaminated with *E. coli* (28). Additionally, the researchers found that the consumption of contaminated complementary foods appeared to be associated with diarrhea and malnutrition (28). Because of the potential for an intervention such as a feeding bowl to increase undesirable health behaviors, evaluations of an intervention's success must also be accompanied by an evaluation of these unintended consequences.

In conclusion, malnutrition remains a significant contributor to the disease burden for children under five in low- and middle-income countries around the world. Because poor nutrition leads to negative health effects that are potentially irreversible for children, nutritional interventions need to be prioritized, especially during the critical first 1,000 days of a child's life. While the cyclical nature of infection and nutrition has previously been established, more research is needed concerning the effect that infectious disease burden can have on the success of nutrition interventions. IYCF interventions are an especially important type of nutritional intervention that need to be improved because of the pervasive gap in knowledge of caregivers and the absence of volume and consistency IYCF indicators. Improvements in IYCF programs have to potential to impact not only child nutrition and growth outcomes, but also infectious disease morbidity, such as diarrhea and respiratory tract infections. In order to achieve these goals, it is imperative that the public health nutrition community implements and rigorously evaluates innovative infant and young child feeding programs in communities with the highest burden of malnutrition.

Abstract

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Keywords. Nutrition intervention, IYCF, feeding bowl, nutrition and infection

Introduction

Worldwide, nearly half of all deaths of children under five years of age are attributable to undernutrition (1). Despite major 21st century advances in public health, maternal and child undernutrition is still the underlying cause of 3.1 million child deaths annually, or 45% of all child deaths in 2011 (2). The health effects of undernutrition are serious, and if experienced during the first 1,000 days of a child's life (from conception through the child's second birthday), can be permanent (3). Undernutrition affects fetal growth, brain development, motor development, and cognitive development (2). According to a pooled analysis of ten prospective studies in Africa, Asia and South America, all degrees of anthropometric deficits were associated with an increased risk of under-five mortality (4). Further, all degrees of anthropometric deficits increased the hazards of dying from respiratory tract infections and diarrheal diseases (4). Consequences of infection, such as fever and diarrhea, can lead to nutrient losses that further damage immune responses and can lead to an increased need for energy (5). While the cyclical relationship between nutrition and infection is well-established, more research is needed concerning the interaction between nutrition and infection (6). For example, limited research has examined whether infection reduces the effectiveness of nutrition interventions with respect to child growth, or the reverse—if poor nutrition reduces the effectiveness of infection control strategies, such as handwashing interventions or rural sanitation programs (6).

Infant and Young Child Feeding (IYCF) interventions focus on improving feeding practices that caregivers employ to provide breast milk and complementary foods to their children, an especially important type of nutritional intervention, as appropriate IYCF practices directly impact a child's nutritional status (7, 8). Despite the importance in breastfeeding and complementary feeding practices, World Health Organization (WHO) data collected from 2002 to 2008 show that only 36% of infants in low-income countries were exclusively breastfed for their first six months of life (9). Further, only one-third of children 6-24 months old in low-income countries met the minimum criteria for dietary diversity (9). These gaps in IYCF practices are seen primarily in sub-Saharan Africa, southeast Asia, and Latin America (9). A review of IYCF programs globally shows that there are few examples of successful, full-scale IYCF programs (10). This gap is due to a lack of a core set of policies and programs around IYCF that can lead to large-scale improvements, such as stunting on a community level (10). Rigorous evaluations of current IYCF programs are seldom done, which prevents a scale-up of existing programs (10). Further, systematic reviews of complementary feeding programs find that although improvements in practices are seen, the degree of improvement is often small (11).

Feeding bowls are an innovative way to address gaps in IYCF knowledge and practices. In 2008, The Manoff Group tested feeding bowls for acceptability and use as part of larger qualitative study in several Latin American countries, including El Salvador, Nicaragua, and Bolivia (12). The researchers utilized qualitative methods only and concluded that the feeding bowl was very acceptable, made instruction and counseling easier, served as effective reminder of feeding, and was inexpensive and very scalable (12). In 2012, researchers at Emory University and the Georgia Institute of Technology in Atlanta, GA designed, manufactured, and piloted a new feeding toolkit intended to address difficult-to-convey nutrition recommendations related to appropriate feeding frequency, meal volume, and meal consistency. The toolkit consisted of a bowl with demarcations on age-appropriate meal volumes and meal frequency, a slotted spoon designed to promote optimal food consistency, and a counseling card that provided pictorial instructions on how to use the toolkit as well as pictorial prompts for dietary diversity, and hygiene/handwashing practices (Figure 1). Intended effects of the feeding toolkit included improved IYCF practices and improved child growth. The toolkit was tested for feasibility and acceptability in Bihar, India and Western Kenya, where it was determined to have the potential to shift dietary practices (13, 14).

The present study evaluates the effects of this novel IYCF intervention in Malawi, a country in sub-Saharan Africa with one of the lowest per capita GDPs in the world, on child morbidity outcomes. In 2014, the worldwide rate of stunting of children under five years of age was 23.8% (15). In comparison, in Malawi, the national rate of stunting for children under five years of age in 2010 was 47.1%, with an even greater prevalence in rural areas (16). In 2010, only 19% of Malawian children 6 to 23 months old were fed in accordance with the WHO IYCF practices (16). The prevalence of diarrhea in the past two weeks among children under 5 years of age was 18% (16). Other child nutrition programs conducted in similar locations have shown a successful impact on child morbidity. For example, a targeted biofortification intervention for improving vitamin A intake among young children through household cultivation of orange sweet potatoes in northern Mozambique reduced the prevalence of childhood diarrhea prevalence by 18.9% in children under three years of age (17). While a decrease in diarrhea prevalence is desired, there is also a potential for the intervention to result in unintended consequences in morbidity associated with poor bowl and spoon hygiene and inappropriate use of the bowl to store cooked foods. Improper preparation and storage of complementary foods in similar locations have been associated with a high proportion of *E*. coli contamination (18). Given the potential for such an intervention to result in both positive and unintended impacts, the investigators aimed to comprehensively examine the effect of the toolkit on child morbidity.

Methods

From June to July 2015, Concern Worldwide Malawi initiated a cluster randomized controlled cohort study to examine the impacts of a novel IYCF intervention on child feeding practices, growth, and morbidity. Caregivers were surveyed at baseline for information such as household demographics, current IYCF practices, and child anthropometry and health, and then randomized to either the intervention or control arm of the study. From October to November 2015, community Care Groups received their allocation, with households in the intervention eligible to receive a feeding toolkit and nutrition education and households in the control eligible to receive nutrition education only. From June to July 2016, the households were followed up with an endline survey similar to the one utilized at baseline.

Study Population

The intervention used a Care Group model, a method for mobilizing community-based volunteers who regularly meet with project staff (19), to deliver nutrition education and the feeding toolkits to their community peers. Nutrition education was disseminated from Concern Worldwide staff to community Promoters, who then instructed a group of Lead Mothers to deliver the information to their neighboring women. Previously established Care Groups from Concern Worldwide's (CWW) Mchinji, Malawi office were considered for enrollment into the study. 172 Care Groups with a minimum of eight Lead Mothers and with verifiable participant names and phone numbers were eligible for participation. A total of 60 Care Groups were randomly selected from this list for enrollment. Based on previous literature (20), a sample size of 586 caregivers per arm was estimated to detect a statistically significant difference in weight-for-age Z score (WAZ) between the intervention and control group for each of the three age categories (6-8, 9-11, and 12-17 months) for an overall effect of 0.16, assuming a 1.6 design effect for clustering. Further, assuming an attrition rate of 10-15%, an enrollment of 650 caregivers per arm, or 1,300 total caregivers, was needed.

Participants were consented prior to eligibility screening. Eligibility requirements for enrollment at baseline included: (1) Residing in the Zulu, Mduwa, or Mkanda Traditional Authority (TA) within the Mchinji District of Malawi; (2) Participating in one of the sixty Care Groups sampled; (3) Being the primary caregiver of at least one child between the ages of 6 and 17 months. If a household had more than one child of eligible age, the youngest child was included in the study. Children with serious health conditions or the inability to consume complementary foods for medical reasons were ineligible for enrollment in the baseline survey.

Study Design

During June to July of 2015, immediately following eligibility screening, caregivers were consented into participating in the baseline survey questionnaire. Screening and baseline enrollment was halted after 51 Care Groups were interviewed, as the desired sample size of participants was reached. Following the baseline survey, participants (n=1,331) were randomized at the Care Group level to either the Intervention (n=25 Care Groups, 587 participants) or the Control (n=26 Care Groups, 744 participants). Households that were included in the baseline survey were included in the endline survey in June and July of

2016. Exclusion criteria for the endline survey were equivalent to the baseline survey. Households who moved away, could not be located, or whose enrolled child died during the follow-up period were not included in the endline study (Figure 2). Some participants received the incorrect allocation or received an allocation although they were not interviewed at baseline (Figure 2).

Survey Instrument

The baseline questionnaire consisted of survey questions and anthropometric measurements of the eligible child. The survey instrument was created in English, translated to the local language (Chichewa), pilot-tested in the community, and ultimately conducted by local enumerators trained by research staff on survey content and standard anthropometry methods. The survey included 11 sections: (1) Consent and Identification; (2) Basic Child Information; (3) Demographics; (4) Household Asset Index; (5) Household Food Security Index; (6) Water, Sanitation, and Hygiene (WASH); (7) Infant and Young Child Feeding Practices; (8) Dietary Diversity; (9) Care Groups; (10) Knowledge of Infant and Young Child Feeding Recommendations; and (11) Anthropometric and Health Assessment of Child. The endline questionnaire contained the same 11 sections as the baseline survey, but additionally included questions regarding receipt and usage of the intervention feeding toolkit.

Variable Specification

Child age in months was coded into three categories at both baseline (6-8 months, 9-11 months, 12-17 months) and at endline (12-17 months, 18-23 months, >2 years). Questions pertaining to household demographics, household asset, and WASH were adapted from the 2010 Malawi Demographic and Health Survey (16) for cultural context and relevance. Water access was dichotomized into improved (piped water, tube well or borehole, or protected well) and not improved (open well, open spring, or surface water). Defecation location was similarly dichotomized into improved (flush toilet, personal pit latrine, shared pit latrine) and not improved (hole, bucket, no facility). A household wealth index was calculated from asset data using methods described by the Demographic and Health Surveys (DHS) Wealth Index guide (21) and by Vyas and Kumaranayake (22). Variables used in index construction are those reasonably assumed to reflect household long term wealth (ownership of assets, sanitation facilities, and source of drinking water). Principal component analysis was used to determine weights of each of the included variables, and these weights were used to construct the index below equation. Based on the wealth index score, household were assigned a quintile (1=lowest wealth index, 5=highest wealth index).

$$\text{Wealth Index} = \alpha_1 \cdot X_1 + \alpha_2 \cdot X_2 + \cdots + \alpha_n \cdot X_n$$

(Where α is the weight of the nth variable and X is the standardized value of the nth variable)

Household food security and minimum dietary diversity questions were modeled after methods developed by the World Health Organization (WHO) and the Food and Nutrition Technical Assistance Project (FANTA). As per FANTA's Household Food Insecurity Access Scale (HFIAS) version 3 (23), households were asked for a 4-week diet recall and were then assigned to one of four groups: food secure, mildly food insecure, moderately food insecure, or severely food insecure. In analyses, food security was dichotomized into food secure (food secure and mildly food insecure) and food insecure (moderately food insecure and severely food insecure). Minimum dietary diversity was measured by a 24-hour recall adapted from the WHO's *Indicators for assessing infant and young child feeding practices, Part II: Measurement* (24) and dichotomized into adequate dietary diversity (4 or more food groups) and inadequate dietary diversity (less than 4 food groups). Breastfeeding indicators for assessing IYCF practices (ever breastfed, current breastfeeding) were adapted from the WHO manual (24).

Length was measured using infantometers (GPC Medical LTD, Model No. GPS115) and length boards (UNICEF, Product No. S0114530). Weight was measured using hanging scales, and enumerators were instructed to remove the child's shoes and as much clothes as possible. Mid-upper arm circumference (MUAC) was measured using measuring tapes (UNICEF, Product No. S0145620). At endline, enumerators were instructed to take duplicate measures, and if the difference exceeded 0.5 kilograms for weight, 1.0 centimeter for length/height, or 0.5 centimeters for MUAC, they were instructed to take a third measurement. An average of the two most plausible measurements was used to generate z-scores. Length-for-age (or height-for-age), weight-for-age, and weight-for-length z-scores (LAZ/HAZ, WAZ, WLZ, respectively) were computed using the WHO Growth Standards macro for SAS (25). Implausible values for LAZ (<-6 or >6), WAZ (<-6 or >5), and WLZ (<-5 or >5) were excluded from analysis. Stunting, underweight, and wasting were defined according to z-score cut-offs specified by the WHO child growth standards (26).

Morbidity outcomes were measured by caregivers' two-week recall, defined as (1) any diarrhea within the past two weeks; and (2) any recent illness within the past two weeks, including fever, diarrhea, vomiting, cough, and difficulty breathing. Diarrhea was defined according to the WHO definition ("the passage of 3 or more loose or liquid stools per day, or more frequently than is normal for the individual") (27).

Statistical Analyses

Data were downloaded from the online server and entered into Statistical Analysis Software (SAS 9.4, SAS Institute, Inc, Cary, NC). Endline data were matched to baseline data by identifiable information such as child name, child date of birth, child sex, head of household name, village, and/or name of Lead Mother and were assigned a unique five-character identifier. Participants who could not be matched were analyzed separately from those who were positively matched (Figure 2). Inconsistencies between baseline and endline measures of demographic information, such as child's date of birth and sex, were reconciled on a case-by-case basis by examining duplicate data and anthropometric measurements and by consulting CWW staff. Data that could not be reconciled were assumed to be randomly distributed and were excluded from analyses. Descriptive analyses were used to describe independent variables at baseline and endline. Logistic regression models were fitted using SAS-callable SUDAAN 11.0 (Survey Data Analysis [SUDAAN] 11.0, Research Triangle Institute) to account for the clustering effect of Care Group and Traditional Authority.

Objective I: The effect of the intervention feeding toolkit on morbidity outcomes was analyzed with cluster adjusted multivariable logistic regression. Additionally, interaction between the intervention toolkit and the following a-priori effect modifiers were considered: household food security, household dietary diversity, improved water source, and age. In our qualitative focus group discussions, participants stated that food insecurity and availability of diverse foods influenced their use of the feeding toolkit. Poor water quality and young age are associated with an increase in diarrhea (27, 28), which could influence the effect of the toolkit on morbidity. Diarrheal incidence peaks at around 6 to 11 months of age, as children begin eating complementary foods that are potentially contaminated and begin crawling and exposing themselves to pathogens (28). Step-wise backwards elimination was used to eliminate insignificant ($P < 0.10$) interaction terms from the full model. Data were analyzed for each outcome specifying: 1) intent-to-treat allocation, 2) per protocol allocation and 3) per uptake/use of toolkit. The exposure in our intent-to-treat analysis was defined as the randomization group at baseline. The exposure in our per protocol analysis was defined as the allocation actually received by the participant. The exposure in our per uptake analysis was defined as reporting using the toolkit for every meal in the past 7 days.

Objective II: Independent variables associated with diarrhea at endline were assessed as a cross-sectional study using multivariable logistic regression, merging children from both the intervention and control groups. Variables established as predictors of childhood diarrhea in other studies (29) were included in our initial logistic regression model (sex, food security, stunting, water source, defecation location, age, caregiver primary school, head of household primary school, socio-economic status, dietary diversity, and current breastfeeding). Variables in binary screening with a p-value ≤ 0.25 were further considered into multiple logistic regression to avoid unstable estimates, based on methods described in other studies (29). Step-wise backwards elimination was used to eliminate insignificant predictors ($P < 0.05$) from the full model.

Results

A total of 1,367 children were screened at baseline, and 1,331 were randomly assigned at the Care Group level to one of two intervention groups (Figure 2). Baseline anthropometric and demographic characteristics of the two groups were similar (Table 1). At baseline, a high proportion of households in both the intervention and control groups were severely food insecure (54.6% and 57.6%, respectively). The proportion stunted in both the intervention and control groups (31.4% and 28.1%, respectively) was lower than the under-five 47.1% stunting rate reported in the 2010 DHS (10), but the children were much younger than five years old. The prevalence of any recent illness at baseline was high in both the intervention and control groups (73.6% and 74.7%, respectively), with diarrhea being the most common illness reported among those who reported an illness (52.3% and 52.5, respectively).

Forty-eight children who were not interviewed at baseline were gained during follow-up, having received an allocation during the intervention period. At endline, 362 children (~27%) were lost to follow-up. An analysis of baseline characteristics in the intervention group for those lost to follow-up compared to those retained at follow-up showed a significant difference in caregiver age ($p<0.01$), where caregivers who were lost to follow-up were younger (24.4 ± 5.7 years) than those who were retained (26.2 ± 7.2 years). In the control group, baseline percentages of head of household employed outside of the home were significantly higher ($p<0.01$) among those lost to follow-up (72.9%) compared to those retained (65.2%). There were no other significant differences in baseline characteristics between those retained and those lost to follow-up.

Objective I (Intervention Effects on Morbidity): At endline, the proportion stunted in the per protocol intervention and control groups (45.7% and 41.0%, respectively) was similar to the 47.1% stunting rate reported in the 2010 DHS (10). The prevalence of any illness reported in the past two weeks at endline was not statistically different between those who received the intervention (75.4%) and those who received the control (76.7%) (p=0.59). The prevalence of diarrhea among those who reported any recent illness in the past two weeks was also not statistically different between those randomized to the intervention (21.8%) and those randomized to the control (22.9%) (p=0.71). Similarly, analyzing participants as intent-to-treat, or analyzing those who were randomized to the intervention or the control, showed no significant differences in morbidity between the two groups (Appendix A).

In per protocol logistic regression analyses with diarrhea as the primary outcome, there appeared to be no significant effect modification between the toolkit and a-priori effect modifiers. We observed no statistically significant association between the intervention and diarrheal morbidity (OR: 0.92; 95% CI: 0.60, 1.40). In per protocol logistic regression analyses with any recent illness as the primary outcome, there appeared to be significant effect modification between the toolkit and food security (p=0.06). In stratified analysis, the direction of association between the intervention and any recent illness appeared to be opposite by household food security status, although the effect was not significant (OR for food secure: 1.44; 95% CI: 0.81, 2.57; OR for food insecure: 0.78; 95% CI: 0.53, 1.13) (Table 2).

In per uptake logistic regression analyses with diarrhea as the primary outcome, there appeared to be no significant effect modification between the toolkit and a-priori effect modifiers. The odds of any recent illness for those who utilized the intervention did not appear to be statistically different from the odds of diarrhea for those in the control (OR: 0.94; 95% CI: 0.58, 1.53). In per uptake logistic regression analyses with any recent illness as the primary outcome, there appeared to be no significant effect modification between the toolkit and a-priori effect modifiers. The odds of any recent illness for those who utilized the intervention did not appear to be statistically different from the odds of diarrhea for those in the control (OR: 1.07; 95% CI: 0.74, 1.55).

Conclusions about the toolkit's impact on morbidity outcomes were similarly non-significant in intent-to-treat analyses (Appendix C, D).

Objective II (Independent Covariates of Diarrhea): Significant independent covariates of diarrhea at endline included food security (p=0.04) and age category (<0.01) (Table 3). Households that were food secure or mildly food insecure had a decreased odds of diarrhea, compared to households that were moderately or severely food insecure (aOR: 0.62; 95% CI: 0.40, 0.95). As expected, child age was a significant predictor of diarrhea; as age category increased, the odds of diarrhea decreased significantly (aOR: 0.63; 95% CI: 0.49, 0.80). The receiver operating curve (ROC) for the prediction model that contained food security and age category had a relatively low area under the curve (AUC=0.60) (Figure 2).

Discussion

We observed no statistically significant effects of the feeding toolkit on the odds of diarrhea or any recent illness in the past two weeks. In per protocol analyses with any recent illness as the primary outcome, we did observe significant effect measure modification (p=0.06), which in stratified analysis demonstrated an opposite direction in the effect of the toolkit by household food security status. The feeding toolkit had an odds ratio below 1.00 for those who were moderately or mildly food insecure but above 1.00 for those who were food secure or mildly food insecure. According to the results of our cross-sectional analysis, food security and older age were significantly protective over diarrhea.

To our knowledge, no other studies have examined the effects of a feeding bowl on morbidity outcomes. Other childhood nutrition interventions, such as the orange sweet potatoes intervention for improving vitamin A intake among young children in northern Mozambique, have shown statistically significant reductions in childhood diarrhea (17). Because Vitamin A is directly associated with restoring and maintaining gut mucosal integrity, biofortification of orange sweet potatoes was shown to reduce diarrheal prevalence. We likely did not see significant effects of the toolkit on morbidity because the feeding toolkit on its own does not directly promote the immune system. We hypothesized that the toolkit would improve complementary feeding practices, which in turn would impact child nutritional status and health. Our follow-up period of approximately eight months may not have been sufficient time to detect statistically significant effects of the toolkit on morbidity. However, the finding that the feeding toolkit demonstrated an opposite effect on any recent illness depending on household food security status is an important finding from a programmatic perspective. In-field partners expressed concern that the feeding toolkit would be an ineffective intervention among households that were too food insecure to meet the volume requirements. However, qualitative focus group discussions revealed that the participants used the bowl even when they were unable to fill it to the correct line. Our quantitative findings support these discussions, as it appears that the bowl may be most beneficial for households that are food insecure. This finding can assure stakeholders that the bowl is not only appropriate for food insecure households, but also can be more beneficial.

Further, it is important to note that we did not detect a significant *increased* odds of diarrhea or any recent illness, which is crucial in assuring the wellbeing of beneficiaries who receive this intervention. According to a systematic review conducted on the effect of multiple micronutrient powders (MNP), some MNP interventions were associated with an increase in diarrhea and dysentery (30). We acknowledged the potential for the intervention to result in unintended consequences in morbidity associated with poor bowl and spoon hygiene and inappropriate use of the bowl to store cooked foods. Improper preparation and storage of complementary foods in similar locations have been associated with a high proportion of *E*. coli contamination (18). With regards to diarrhea and other morbidity, we did not detect any significant unintended consequences associated with the feeding toolkit. Because this toolkit is a novel IYCF intervention, it is important to ensure that the intervention does not result in unintended consequences.

The secondary goal of this research analysis was to determine predictors of diarrhea across our entire study population. According to the results of our prediction model, food security and older age were significantly protective over diarrhea. These associations have been found in other studies as well (31, 20). However, in the context of Malawi, food security's significant association with diarrhea is a critical finding that should be prioritized. Because diarrheal morbidity is a large concern in low-income countries like Malawi, this finding could motivate governments and non-governmental organizations to focus on implementing sustainable, nutrition-sensitive interventions and programs to address food insecurity and its root causes, such as income poverty.

The present study has several limitations. Although we were able to detect a statistically significant interaction between the feeding toolkit and household food security status, the effect of the toolkit was not significant in stratified analyses. The loss-to-follow-up rate of approximately 27% was higher than the attrition rate of 10-15% that we predicted for our power calculations. While this attrition rate was acceptable for the overall effect of the toolkit on morbidity, a limitation of this study is that we were underpowered to study the effect of the toolkit on morbidity in stratified analyses. According to our analysis of those lost to follow-up compared to those retained at follow-up, older caregivers and caregivers whose head of household was not employed outside of the home were more likely to be retained in the study. This association is reasonable, as younger caregivers and those with employment outside of the home are more likely to move during the study period. While the association between loss-to-follow-up and age and head of household employment was significant, the proportion of households lost in the intervention and control groups were similar, so we expect a non-differential loss to follow-up with regard to intervention group.

Secondly, the initial study was designed as a cluster randomized control trial to evaluate the feeding toolkit's impacts on IYCF practices and child growth, not child morbidity outcomes or diarrhea. Because the examination of morbidity was considered after the initial study design, we were not able to collect more specific and detailed information on data such as WASH practices beyond basic information. In future iterations of this study, it would be advisable to collect more specific WASH information that would be relevant to infectious disease burden. Further, diarrhea was measured by a caregiver-reported two-week recall. In future studies, we would suggest that the period is shortened from two weeks to seven days, as literature on epidemiologic methods for diarrhea studies have established that this shorter period is more reliable for self-reported diarrhea (32). The investigators further acknowledge that because of budget and staff constraints, repeated measures that could account for potential seasonal effects in food contamination and food access were not possible. Although our AUC value for a model containing the two predictors was low, we did not expect large predictive capabilities, as the original study was not designed with diarrhea prediction in mind.

Rigorously evaluating innovative IYCF programs is an important step in improving and implementing evidence-based global health programs. Because this innovative feeding toolkit is being implemented in multiple locations across various low-income countries, an evaluation of both intended and unintended consequences is crucial in assuring key stakeholders and beneficiaries that the feeding toolkit is not associated with an increase in diarrhea or other morbidity. Every child has the right to good nutrition, and improving IYCF interventions is a crucial way to ensure the health of our children. Innovative interventions such as this feeding toolkit address the inequality gap in knowledge that exists between caregivers of children in low-income countries and caregivers of children in high-income countries. Given the importance of child nutrition, public health practitioners must continue to research innovative ways to empower and enable our most vulnerable populations.

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Tables and Figures

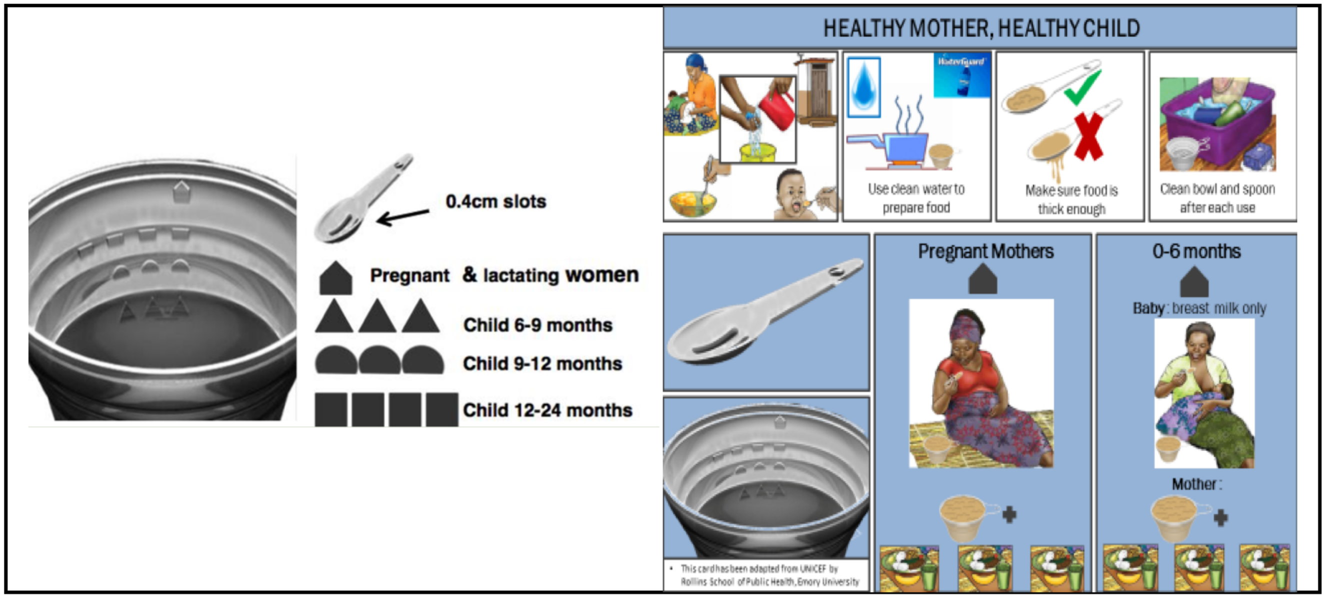

Figure 1. Feeding toolkit, comprised of a demarcated bowl, slotted spoon, and counseling card.

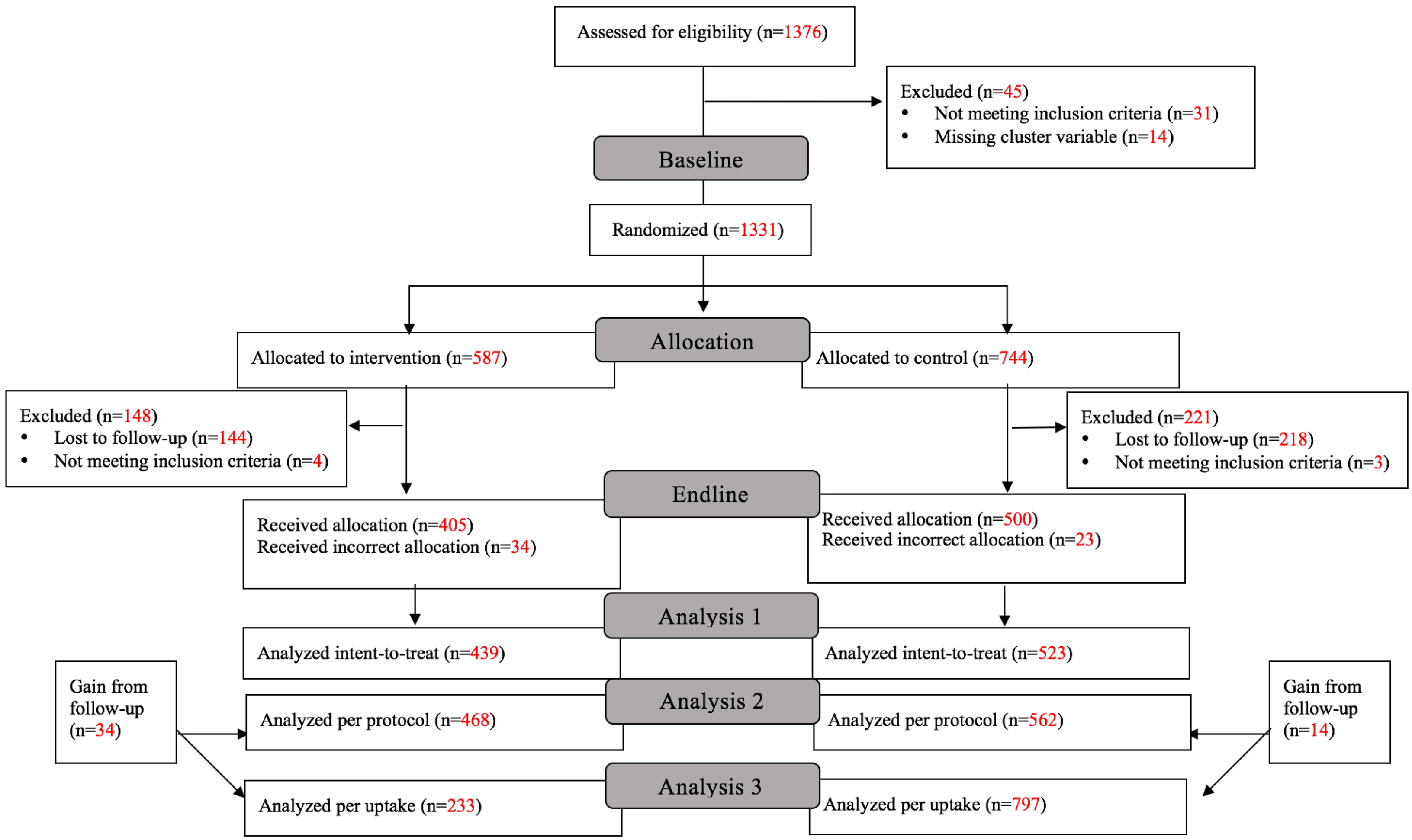

Figure 2. Flow chart of study enrollments and exclusions from baseline (June-July 2015) to endline (June-July 2016). Intervention group received feeding toolkit + nutrition education and control received nutrition education only. Participants who were gained during follow-up were not included in intent-to-treat analyses (n=48).

Table 1. Demographic and Household Characteristics of Participants by Randomization Group at Baseline and by Receipt of Feeding Toolkit Intervention at Endline, Mchinji, Malawi, 2015-2016.

	Baseline				Endline			
	Intervention (n=587)		Control (n=744)		Intervention (n=468)		Control (n=562)	
Characteristic	**N (%) or Mean (SD)**	**n**	**N (%) or Mean (SD)**	**n**	**N (%) or Mean (SD)**	**n**	**N (%) or Mean (SD)**	**n**
Child Anthropometrics and Health								
Age (months)	10.9 (3.3)	587	10.7 (3.2)	744	21.6 (3.5)	447	21.2 (3.3)	545
Sex (male)	293 (49.9%)	587	356 (48.0%)	742	225 (48.1%)	468	271 (48.4%)	560
WAZ Z-score	-0.7 (1.2)	587	-0.6 (1.2)	749	-0.8 (1.1)	444	-0.8 (1.1)	542
LAZ Z-score	-1.4 (1.3)	583	-1.2 (1.4)	729	-1.8 (1.3)	444	-1.7 (1.2)	539
Stunted	183 (31.4%)	583	205 (28.1%)	729	203 (45.7%)	444	221 (41.0%)	539
Underweight	88 (11.9%)	587	69 (11.8%)	741	55 (12.4%)	444	63 (11.6%)	542
Wasted	28 (4.8%)	585	40 (5.4%)	736	13 (2.8%)	462	8 (1.4%)	555
Illness within the last 2 weeks	432 (73.6%)	587	556 (74.7%)	744	353 (75.4%)	468	432 (76.7%)	562
Diarrhea	226 (52.3%)	432	292 (52.5%)	556	77 (21.8%)	353	99 (22.9%)	432
Household Demographics								
Household size	5.1 (1.8)	587	5.1 (2.0)	744	5.3 (1.9)	468	5.2 (1.9)	562
Number of children under 5 years old	1.6 (0.7)	587	1.6 (0.7)	744	1.5 (0.7)	466	1.4 (0.6)	561
Caregiver works outside of the home	322 (55.0%)	585	357 (48.1%)	751	405 (87.5%)	463	487 (87.3%)	558
Caregiver completed primary school	98 (16.7%)	587	134 (18.0%)	744	102 (21.9%)	465	132 (25.5%)	561
Head of household completed primary school	161 (27.9%)	577	217 (29.5%)	735	158 (34.5%)	458	226 (40.9%)	552
Household Asset Index		587		743		468		
Quintile 1 (lowest)	99 (16.9%)		147 (19.8%)		57 (12.2%)		72 (12.8%)	
Quintile 2	134 (22.8%)		170 (22.9%)		141 (30.1%)		160 (28.5%)	
Quintile 3	111 (18.9%)		133 (17.5%)		85 (18.2%)		106 (18.9%)	
Quintile 4	131 (22.3%)		130 (17.5%)		96 (20.5%)		103 (18.3)	
Quintile 5 (highest)	112 (19.1%)		163 (21.9%)		89 (19.0%)		121 (21.5%)	
Household Food Security Assessment		584		741		466		562
Food Secure	88 (15.1%)		108 (14.6%)		37 (7.9%)		45 (8.0%)	
Mildly Food Insecure	70 (12.0%)		101 (13.6%)		67 (14.4%)		85 (15.1%)	
Moderately Food Insecure	107 (18.3%)		105 (14.2%)		122 (26.2%)		146 (26.0%)	
Severely Food Insecure	319 (54.6%)		427 (57.6%)		240 (51.5%)		286 (50.9%)	
Dietary Diversity								
Adequate (≥4 food groups)	169 (28.8%)	587	201 (27.0%)	744	225 (48.1%)	468	251 (44.7%)	562
Water, Sanitation, and Hygiene (WASH)								
Improved source of drinking water	446 (76.0%)	587	552 (74.2%)	744	392 (83.8%)	468	440 (78.3%)	562
Improved defecation location	552 (94.0%)	587	711 (95.7%)	743	455 (97.2%)	468	545 (97.0%)	562
Infant and Young Child Feeding Practices								
Currently breastfeeding	577 (98.3%)	587	716 (96.2%)	744	305 (65.2%)	468	363 (64.6%)	562

Table 2. Multiple logistic regression analysis of any recent illness at endline among those who received the intervention feeding toolkit and the control.

Parameter	ß	S.E.	t-statistic	P-value	Confidence Interval[a] Lower Bound	Confidence Interval[a] Upper Bound
Full Model						
Intercept	1.57	0.53	2.99	0.0042	0.52	2.63
Intervention	-0.28	0.67	-0.41	0.6833	-1.63	1.07
Household food security[b]	-0.88	0.25	-3.55	0.0008	-1.38	-0.38
Dietary diversity (adequate)	-0.00	0.24	-0.01	0.9914	-0.49	0.48
Water source (improved)	-0.36	0.30	-1.20	0.2367	-0.97	0.25
Age category[c]	0.08	0.16	0.50	0.6190	-0.24	0.40
Intervention x household food security	0.64	0.36	1.78	0.0814	0.04	1.23
Intervention x dietary diversity	-0.40	0.34	-1.18	0.2415	-0.97	0.17
Intervention x water source	0.37	0.40	0.93	0.3546	-0.29	1.04
Intervention x age category	-0.05	0.22	-0.22	0.8276	-0.41	0.32
Reduced Model						
Intercept	1.45	0.14	10.08	0.0000	1.16	1.74
Intervention	-0.25	0.19	-1.36	0.1806	-0.63	0.12
Food secure	-0.92	0.22	-4.16	0.0001	-1.36	-0.47
Intervention x household food security	0.62	0.32	1.91	0.0611	1.17	1.91
Stratified Model (Food Secure)						
Intercept	0.54	0.16	3.35	0.0015	0.21	0.86
Intervention	0.37	0.29	1.28	0.2060	-0.21	0.94
Stratified Model (Food Insecure)						
Intercept	1.45	0.14	10.08	0.0000	1.16	1.74
Intervention	-0.25	0.19	-1.36	0.1806	-0.63	0.12

[a]90% confidence intervals (C.I.) for interaction terms, 95% C.I. else
[b]food secure or mildly food insecure vs. moderately or severely food insecure
[c]12-17 months, 18-23 months, >2 years

Table 3. Association between independent variables and diarrhea in the past two weeks at endline among all participants (n=1,030).

Variable	**cOR[a], 95% CI**	**P-value**
Child sex[b]	0.95 (0.69, 1.31)	0.7334
Household food security[c]	0.65 (0.43, 0.99)	0.0482
Stunted	1.21 (0.87, 1.69)	0.2562
Improved water	0.87 (0.58, 1.30)	0.5061
Improved defecation location	1.03 (0.39, 2.73)	0.9509
Age category[d]	0.63 (0.49, 0.80)	0.0002
Caregiver attended primary school	1.07 (0.73, 1.57)	0.7136
Head of household attended primary school	0.78 (0.55, 1.10)	0.1485
Socioeconomic status (dichotomous)	1.06 (0.76, 1.48)	0.7208
Adequate dietary diversity	0.77 (0.56, 1.07)	0.1217
Currently breastfeeding	1.03 (0.98, 1.08)	0.2334

[a]crude odds ratio
[b]male vs. female
[c]food secure or mildly food insecure vs. moderately or severely food insecure
[d]12-17 months, 18-23 months, >2 years

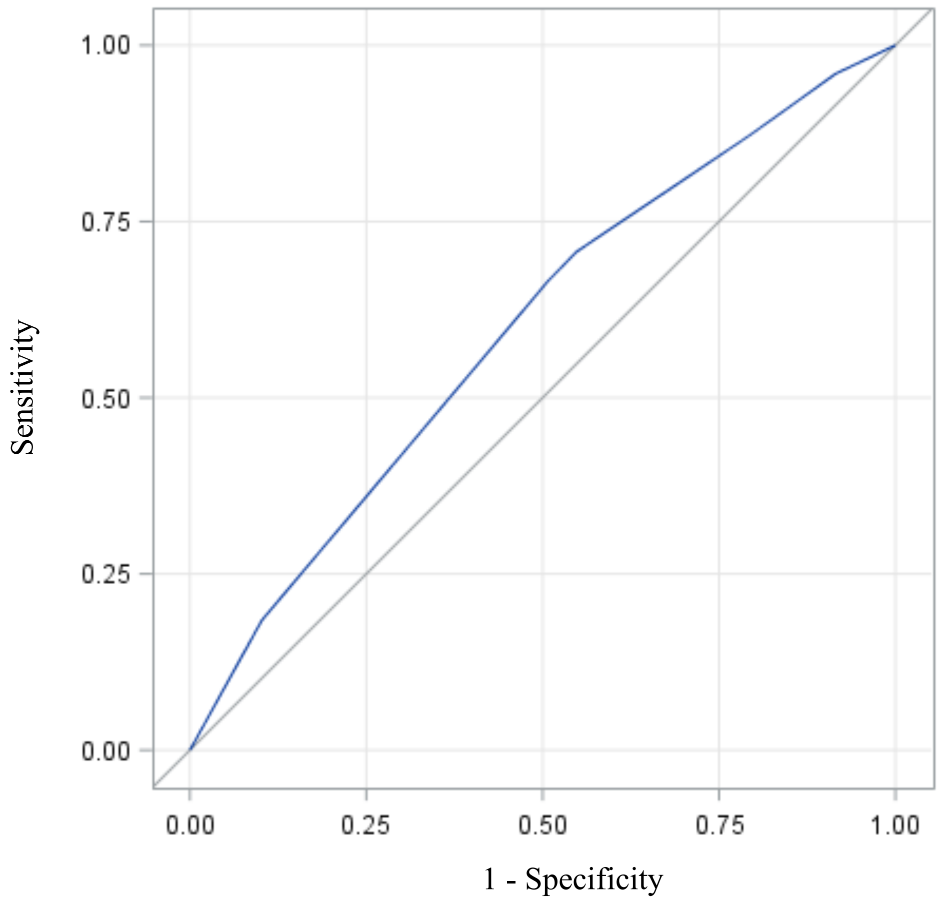

Figure 3. Receiver operator curve (ROC) for diarrhea prediction model that contains child age and household food security status for cross-sectional evaluation of entire study population (AUC=0.5979).

Appendices

Appendix A

Supplemental Table 1. Baseline Demographic and Household Characteristics of Participants by Receipt of Intervention, Mchinji, Malawi, 2015

	Intervention (n=468)		Control (n=562)	
Characteristic	**N (%) or Mean (SD)**	**n**	**N (%) or Mean (SD)**	**n**
Child Anthropometrics and Health				
Age (months)	11.0 (3.3)	432	10.6 (3.2)	537
Sex (male)	225 (48.1%)	468	271 (48.4%)	560
WAZ Z-score	-0.7 (1.1)	430	-0.6 (1.2)	532
LAZ Z-score	-1.4 (1.3)	426	-1.2 (1.4)	524
Stunted	139 (32.6%)	426	138 (26.3%)	524
Underweight	50 (11.6%)	430	62 (11.7%)	532
Wasted	28 (5.2%)	429	19 (4.4%)	542
Illness within the last 2 weeks	319 (74.0%)	431	410 (75.1%)	546
Diarrhea	169 (53.0%)	319	218 (53.2%)	410
Household Demographics				
Household size	5.2 (1.9)	431	5.1 (1.9)	546
Number of children under 5 years old	1.6 (0.6)	431	1.6 (0.7)	546
Caregiver works outside of the home	237 (54.9%)	432	260 (47.5%)	548
Caregiver completed primary school	75 (17.4%)	431	91 (16.7%)	546
Head of household completed primary school	121 (28.7%)	421	152 (28.0%)	543
Household Asset Index		431		546
Quintile 1 (lowest)	72 (16.7%)		102 (18.7%)	
Quintile 2	96 (22.3%)		122 (22.3%)	
Quintile 3	84 (19.5%)		110 (20.2%)	
Quintile 4	96 (22.3%)		102 (18.7%)	
Quintile 5 (highest)	83 (19.26%)		110 (20.2%)	
Household Food Security Assessment		430		542
Food Secure	67 (15.6%)		75 (13.8%)	
Mildly Food Insecure	47 (10.9%)		76 (14.0%)	
Moderately Food Insecure	76 (17.7%)		85 (15.7%)	
Severely Food Insecure	240 (55.8%)		306 (56.5)	
Dietary Diversity				
Adequate (≥4 food groups)	116 (26.7%)	434	138 (25.2%)	
Water, Sanitation, and Hygiene (WASH)				
Improved source of drinking water	319 (74.0%)	431	412 (75.5%)	546
Improved defecation location	409 (94.9%)	431	519 (95.1%)	546
Infant and Young Child Feeding Practices				
Currently breastfeeding	421 (97.7%)	431	525 (96.2%)	546

Appendix B

Supplemental Table 2. Endline Demographic and Household Characteristics of Participants by Intervention Group, Mchinji, Malawi, 2016

	Intervention (n=439)		Control (n=523)		
Characteristic	**N (%) or Mean (SD)**	**n**	**N (%) or Mean (SD)**	**n**	**P-value***
Child Anthropometrics and Health					
Age (months)	21.4 (3.4)	439	21.3 (3.3)	523	0.7620
Sex (male)	214 (48.8%)	439	253 (48.6%)	521	0.9540
WAZ Z-score	-0.9 (1.0)	436	-0.8 (1.1)	520	0.1231
LAZ Z-score	-1.8 (1.2)	436	-1.7 (1.2)	518	0.1318
Stunted	196 (45.0%)	436	215 (41.5%)	518	0.2840
Underweight	54 (12.4%)	436	59 (11.4%)	520	0.6201
Wasted	12 (2.8%)	433	7 (1.4%)	517	0.1202
Illness within the last 2 weeks	327 (74.5%)	439	405 (77.4%)	523	0.2852
Diarrhea	78 (23.9%)	327	88 (21.7%)	405	0.4949
Household Demographics					
Household size	5.2 (1.9)	439	5.1 (1.9)	523	0.5686
Number of children under 5 years old	1.5 (0.7)	437	1.4 (0.6)	522	0.4778
Caregiver works outside of the home	380 (87.4%)	435	460 (88.8%)	518	0.4914
Caregiver completed primary school	95 (21.8%)	436	124 (23.8)	522	0.4706
Head of household completed primary school	151 (35.1%)	430	209 (40.6%)	515	0.0849
Household Asset Index		439		523	0.8865
Quintile 1 (lowest)	56 (12.8%)		64 (12.2%)		
Quintile 2	134 (30.5%)		146 (27.9%)		
Quintile 3	80 (18.2%)		102 (19.5%)		
Quintile 4	84 (19.1%)		101 (19.3%)		
Quintile 5 (highest)	85 (19.4%)		110 (21.0%)		
Household Food Security Assessment		437		523	0.7265
Food Secure	39 (8.9%)		30 (7.5%)		
Mildly Food Insecure	63 (14.4%)		82 (15.7)		
Moderately Food Insecure	109 (24.9%)		140 (26.8)		
Severely Food Insecure	226 (51.7)		262 (50.1)		
Dietary Diversity					
Adequate (≥4 food groups)	210 (47.8%)	439	236 (45.1%)	523	0.4009
Water, Sanitation, and Hygiene (WASH)					
Improved source of drinking water	375 (85.4%)	439	416 (79.5%)	523	0.0175
Improved defecation location	429 (97.7%)	439	505 (96.6%)	523	0.2848
Infant and Young Child Feeding Practices					
Currently breastfeeding	301 (68.6%)	439	337 (64.4%)	523	0.2066

*t-test for continuous variables, chi-square test for categorical variables

Appendix C
Intent–to-Treat (Outcome=Diarrhea)

Model 1 (full)

$$diarrhea = E + \gamma_1 foodsecurity + \gamma_2 ddiversity + \gamma_3 improvedwater + \gamma_4 age + \delta_1 E * foodsecurity + \delta_2 E * ddiversity + \delta_3 E * improvedwater + \delta_4 E * age$$

Parameter	ß	S.E.	t-statistic	P-value	Confidence Interval* Lower Bound	Upper Bound
Intercept	0.50	0.49	1.02	0.3138	-0.49	1.48
Intervention	-1.10	0.70	-1.56	0.1249	-2.51	0.31
Food secure	-0.64	0.85	-0.75	0.4572	-2.35	1.07
Dietary diversity (adequate)	-1.05	0.52	-2.03	0.0479	-2.08	-0.01
Water source (improved)	-0.83	0.47	-1.76	0.2416	-1.79	0.12
Age category	0.00	0.40	0.01	0.9938	-0.80	0.81
Intervention x food secure	-0.18	0.52	-0.34	0.7323	-1.06	0.70
Intervention x dietary diversity	-0.52	0.31	-1.69	0.0964	-1.03	-0.01
Intervention x water source	0.83	0.47	1.76	0.0844	0.04	1.63
Intervention x age category	0.38	0.26	1.44	0.1558	-0.06	0.82

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

Model 2 (reduced)

$$diarrhea = E + \gamma_2 ddiversity + \gamma_3 improvedwater + \delta_2 E * ddiversity + \delta_3 E * improvedwater$$

Parameter	ß	S.E.	t-statistic	P-value	Confidence Interval* Lower Bound	Upper Bound
Intercept	-1.25	0.22	-5.79	0.0000	-1.69	-0.82
Intervention	-0.30	0.48	-0.62	0.5349	-1.26	0.66
Dietary diversity (adequate)	-1.22	0.55	-2.24	0.0294	-2.32	-0.13
Water source (improved)	1.11	0.87	1.27	0.2106	-0.64	2.86
Intervention x dietary diversity	-0.63	0.33	-1.92	0.0605	-1.17	-0.08
Intervention x water source	0.79	0.47	-1.68	0.0989	0.00	1.57

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

Model 3 (stratified by dietary diversity)

$$diarrhea = E + \gamma_3 improvedwater + \delta_3 E * improvedwater$$

DD=0

Parameter	ß	S.E.	t-statistic	P-value	Confidence Interval* Lower Bound	Upper Bound
Intercept	-1.39	0.32	-4.30	0.0001	-2.03	-0.74
Intervention	-0.85	0.65	-1.30	0.2001	-2.16	0.46
Water source (improved)	1.09	1.35	0.80	0.4245	-1.62	3.79
Intervention x water source	0.67	0.75	0.89	0.3761	-0.51	1.31

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

DD=1

Parameter	ß	S.E.	t-statistic	P-value	Confidence Interval* Lower Bound	Upper Bound
Intercept	-1.14	0.32	-3.56	0.0008	-1.79	-0.50
Intervention	-0.36	0.60	-0.60	0.5519	-1.57	0.85
Water source (improved)	1.15	1.16	0.99	0.3253	-1.17	3.47
Intervention x water source	0.88	0.65	1.36	0.1804	-0.68	1.58

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

Model 4 (stratified by improved water)

$$diarrhea = E + \gamma_2 ddiversity + \delta_2 E * ddiversity$$

W=0

Parameter	ß	S.E.	t-statistic	P-value	Confidence Interval* Lower Bound	Upper Bound
Intercept	-1.14	0.32	-3.56	0.0008	-1.79	-0.50
Intervention	-0.36	0.60	-0.60	0.5519	-1.57	0.85
Dietary diversity (adequate)	-1.21	1.58	-0.77	0.4460	-4.39	1.96
Intervention x dietary diversity	-0.49	0.91	-0.53	0.5970	-2.01	1.04

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

W=1

Parameter	ß	S.E.	t-statistic	P-value	Confidence Interval* Lower Bound	Upper Bound
Intercept	-1.76	0.18	-9.89	0.0000	-2.12	-1.40
Intervention	0.52	0.30	1.74	0.0880	-0.08	1.12
Dietary diversity (adequate)	-1.28	0.61	-2.08	0.0425	-2.51	-0.05
Intervention x dietary diversity	-0.70	0.37	-1.90	0.0633	-1.31	-0.08

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

Model	Intervention Toolkit Odds Ratio	95% Confidence Interval Lower Bound	Upper Bound
Model 1	0.33	0.08	1.37
Model 2	0.74	0.28	1.94
Model 3	-	-	-
DD=1	0.43	0.12	1.59
DD=0	0.70	0.21	2.34
Model 4	-	-	-
W=1	1.68	0.92	3.07
W=0	0.70	0.21	2.34

Appendix D
Intent-to-Treat (Outcome=Any Illness)

Model 1 (full)

$$illness = E + \gamma_1 foodsecurity + \gamma_2 ddiversity + \gamma_3 improvedwater + \gamma_4 age + \delta_1 E * foodsecurity + \delta_2 E * ddiversit + \delta_3 E * improvedwater + \delta_4 E * age$$

					Confidence Interval*	
Parameter	ß	S.E.	t-statistic	P-value	Lower Bound	Upper Bound
Intercept	1.73	0.54	3.20	0.0024	0.64	2.82
Intervention	-0.36	0.65	-0.55	0.5815	-1.67	0.95
Food secure	-0.12	0.64	-0.18	0.8556	-1.39	1.16
Dietary diversity (adequate)	-0.69	0.51	-1.34	0.1847	-1.72	0.34
Water source (improved)	0.30	0.59	0.50	0.6177	-0.89	1.48
Age category	0.02	0.32	0.06	0.9496	-0.63	0.67
Intervention x food secure	0.29	0.39	0.74	0.4644	-0.36	0.94
Intervention x dietary diversity	-0.33	0.33	-1.01	0.3167	-0.89	0.22
Intervention x water source	0.38	0.40	0.94	0.3491	-0.29	1.06
Intervention x age category	-0.01	0.21	-0.04	0.9703	-0.37	0.35

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

Model 2 (reduced)

$$illness = E$$

					Confidence Interval*	
Parameter	ß	S.E.	t-statistic	P-value	Lower Bound	Upper Bound
Intercept	1.23	0.12	9.95	0.0000	0.98	1.48
Intervention	-0.16	0.16	-1.01	0.3186	-0.48	0.16

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

	Intervention Toolkit	95% Confidence Interval	
Model	Odds Ratio	Lower Bound	Upper Bound
Model 1	0.70	0.19	2.58
Model 2	0.85	0.62	1.17

Appendix E

Model 1 (full)
Per Received (Outcome=diarrhea)

$$diarrhea = E + \gamma_1 foodsecurity + \gamma_2 ddiversity + \gamma_3 improvedwater + \gamma_4 age + \delta_1 E * foodsecurity + \delta_2 E * ddiversity + \delta_3 E * improvedwater + \delta_4 E * age$$

Parameter	ß	S.E.	t-statistic	P-value	Confidence Interval*	
					Lower Bound	Upper Bound
Intercept	0.15	0.47	0.33	0.7441	-0.79	1.10
Intervention	-0.76	0.64	-1.18	0.2438	-2.05	0.53
Food secure	-0.41	0.33	-1.26	0.2146	-1.07	0.24
Dietary diversity (adequate)	-0.05	0.45	-0.27	0.7913	-0.42	0.32
Water source (improved)	-0.49	0.20	-2.45	0.0176	-0.88	-0.09
Age category	-0.57	0.19	-3.05	0.0036	-0.95	-0.20
Intervention x food secure	-0.05	0.45	-0.12	0.9061	-0.81	0.70
Intervention x dietary diversity	-0.35	0.34	-1.01	0.3155	-0.92	0.23
Intervention x water source	0.67	0.47	1.43	0.1586	-0.11	1.45
Intervention x age category	0.16	0.24	0.65	0.5169	-0.25	0.56

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

Model 2 (reduced)

$$diarrhea = E$$

Parameter	ß	S.E.	t-statistic	P-value	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	-1.54	0.12	-12.39	0.0000	-1.79	-1.29
Intervention	-0.08	0.21	-0.39	0.6970	-0.50	0.34

Model	Intervention Toolkit Odds Ratio	95% Confidence Interval	
		Lower Bound	Upper Bound
Model 1 (full)	0.47	0.13	1.70
Model 2 (reduced)	0.92	0.60	1.40

Appendix F
Per Received (Outcome=Any Illness)

Model 1 (full)

$$illness = E + \gamma_1 foodsecurity + \gamma_2 ddiversity + \gamma_3 improvedwater + \gamma_4 age + \delta_1 E * foodsecurity + \delta_2 E * ddiversit + \delta_3 E * improvedwater + \delta_4 E * age$$

					Confidence Interval*	
Parameter	ß	S.E.	t-statistic	P-value	Lower Bound	Upper Bound
Intercept	1.57	0.53	2.99	0.0042	0.52	2.63
Intervention	-0.28	0.67	-0.41	0.6833	-1.63	1.07
Food secure	-0.88	0.25	-3.55	0.0008	-1.38	-0.38
Dietary diversity (adequate)	-0.00	0.24	-0.01	0.9914	-0.49	0.48
Water source (improved)	-0.36	0.30	-1.20	0.2367	-0.97	0.25
Age category	0.08	0.16	0.50	0.6190	-0.24	0.40
Intervention x food secure	0.64	0.36	1.78	0.0814	0.04	1.23
Intervention x dietary diversity	-0.40	0.34	-1.18	0.2415	-0.97	0.17
Intervention x water source	0.37	0.40	0.93	0.3546	-0.29	1.04
Intervention x age category	-0.05	0.22	-0.22	0.8276	-0.41	0.32

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

Model 2 (reduced)

$$illness = E + \gamma_1 foodsecurity + \delta_1 E * foodsecurity$$

					Confidence Interval*	
Parameter	ß	S.E.	t-statistic	P-value	Lower Bound	Upper Bound
Intercept	1.45	0.14	10.08	0.0000	1.16	1.74
Intervention	-0.25	0.19	-1.36	0.1806	-0.63	0.12
Food secure	-0.92	0.22	-4.16	0.0001	-1.36	-0.47
Intervention x food secure	0.62	0.32	1.91	0.0611	1.17	1.91

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

Model 3 (stratified by food security)
$illness = E$

F=1

					95% Confidence Interval	
Parameter	ß	S.E.	t-statistic	P-value	Lower Bound	Upper Bound
Intercept	0.54	0.16	3.35	0.0015	0.21	0.86
Intervention	0.37	0.29	1.28	0.2060	-0.21	0.94

F=0

					95% Confidence Interval	
Parameter	ß	S.E.	t-statistic	P-value	Lower Bound	Upper Bound
Intercept	1.45	0.14	10.08	0.0000	1.16	1.74
Intervention	-0.25	0.19	-1.36	0.1806	-0.63	0.12

Model	Intervention Toolkit Odds Ratio	95% Confidence Interval Lower Bound	Upper Bound
Model 1 (full)	0.76	0.20	2.93
Model 2 (reduced)	0.78	0.53	1.13
Model 3 (stratified)	-	-	-
F=1	1.44	0.81	2.57
F=0	0.78	0.53	1.13

Appendix G
Per Uptake (Outcome=Diarrhea)

Model 1 (full)

$$diarrhea = E + \gamma_1 foodsecurity + \gamma_2 ddiversity + \gamma_3 improvedwater + \gamma_4 age + \delta_1 E * foodsecurity + \delta_2 E * ddiversity + \delta_3 E * improvedwater + \delta_4 E * age$$

Parameter	ß	S.E.	t-statistic	P-value	Confidence Interval*	
					Lower Bound	Upper Bound
Intercept	0.04	0.46	0.08	0.9349	-0.88	0.96
Intervention	-0.24	1.67	-0.14	0.8856	-3.60	3.12
Food secure	-0.41	0.33	-1.26	0.2122	-1.07	0.24
Dietary diversity (adequate)	-0.05	0.19	-0.25	0.8032	-0.42	0.33
Water source (improved)	-0.47	0.20	-2.39	0.0203	-0.86	-0.08
Age category	-0.52	0.18	-2.85	0.0062	-0.89	-0.15
Intervention x food secure	-0.93	0.74	-1.26	0.2147	-2.18	0.31
Intervention x dietary diversity	-0.24	0.39	-0.61	0.5438	-0.90	0.42
Intervention x water source	0.95	0.60	1.60	0.1153	-0.04	1.95
Intervention x age category	-0.02	0.08	-0.25	0.8013	-0.15	0.11

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

Model 2 (reduced)

$$diarrhea = E$$

Parameter	ß	S.E.	t-statistic	P-value	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	-1.54	0.12	-12.39	0.0000	-1.79	-1.29
Intervention	-0.06	0.24	-0.25	0.8015	-0.55	0.43

Model	Intervention Toolkit Odds Ratio	95% Confidence Interval	
		Lower Bound	Upper Bound
Model 1	0.78	0.03	22.55
Model 2	0.94	0.58	1.53

Appendix H
Per Uptake (Outcome=Any Illness)

Model 1 (full)

$$illness = E + \gamma_1 foodsecurity + \gamma_2 ddiversity + \gamma_3 improvedwater + \gamma_4 age + \delta_1 E * foodsecurity + \delta_2 E * ddiversity + \delta_3 E * improvedwater + \delta_4 E * age$$

					Confidence Interval	
Parameter	ß	S.E.	t-statistic	P-value	Lower Bound	Upper Bound
Intercept	1.60	0.51	3.61	0.0026	0.59	2.62
Intervention	-0.03	1.34	-0.02	0.9814	-2.71	2.65
Food secure	-0.88	0.25	-3.55	0.0008	-1.38	-0.38
Dietary diversity (adequate)	-0.00	0.24	-0.01	0.9901	-0.49	0.48
Water source (improved)	-0.37	0.30	-1.21	0.2304	-0.97	0.24
Age category	0.07	0.15	0.44	0.6623	-0.24	0.37
Intervention x food secure	0.31	0.46	0.68	0.5024	-0.46	1.09
Intervention x dietary diversity	-0.09	0.35	-0.26	0.7946	-0.68	0.49
Intervention x water source	0.36	0.43	0.85	0.4007	-0.36	1.08
Intervention x age category	-0.01	0.05	-0.21	0.8360	-0.10	0.08

*90% confidence intervals (C.I.) for interaction terms, 95% C.I. else

Model 2 (reduced)

$$illness = E$$

					95% Confidence Interval	
Parameter	ß	S.E.	t-statistic	P-value	Lower Bound	Upper Bound
Intercept	1.20	0.11	10.70	0.0000	0.98	1.43
Intervention	0.07	0.18	0.39	0.6995	-0.30	0.44

	Intervention	95% Confidence Interval	
Model	Toolkit Odds Ratio	Lower Bound	Upper Bound
Model 1	0.97	0.07	14.12
Model 2	1.07	0.74	1.55

Appendix I

EMORY UNIVERSITY | Institutional Review Board

TO: Amy Girard, PhD
Principal Investigator
*SPH: Global Health

DATE: February 23rd, 2016

RE: **Expedited Approval**
IRB00086443
Infant and Young Child Feeding Practices in Mchinge District Malawi

Thank you for submitting a new application for this protocol. This research is eligible for expedited review under 45 CFR.46.110 and/or 21 CFR 56.110 because it poses minimal risk and fits the regulatory category F5 as set forth in the Federal Register. The Emory IRB reviewed it by expedited process on **February 23rd, 2016** and granted approval effective from **February 23rd, 2016** through **February 22nd, 2017**. Thereafter, continuation of human subjects research activities requires the submission of a renewal application, which must be reviewed and approved by the IRB prior to the expiration date noted above. Please note carefully the following items with respect to this approval:

- 45 CFR.46.110
- Complete HIPAA Waiver and Waiver of Informed Consent granted
  - HIPAA_Alteration 86443.doc (Version 0.01)
  - Waiver_Consent_Elements_of_Consent 86443.doc (Version 0.01)
- Protocol
  - Revised Protocol Feb 2016 (Version 0.02)

A complete HIPAA Waiver and Waiver of Informed Consent has been granted due to the secondary data analysis of subjects from study IRB00081427. It would be impracticable to reconsent subjects due to but not limited to the consent already obtained from study submission (IRB00081427). In developing a database and participant tracking system, these waivers have been granted.

Any reportable events (e.g., unanticipated problems involving risk to subjects or others, noncompliance, breaches of confidentiality, HIPAA violations, protocol deviations) must be reported to the IRB according to our Policies & Procedures at www.irb.emory.edu, immediately, promptly, or periodically. Be sure to check the reporting guidance and contact us if you have questions. Terms and conditions of sponsors, if any, also apply to reporting.

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Institutional Review Board

This determination could be affected by substantive changes in the study design, subject populations, or identifiability of data. If the project changes in any substantive way, please contact our office for clarification.

Thank you for consulting the IRB.

Sincerely,

Carolyn Sims, MPA
Research Protocol Analyst

Emory University
1599 Clifton Road, 5th Floor - Atlanta, Georgia 30322
Tel: 404.712.0720 - Fax: 404.727.1358 - Email: irb@emory.edu - Web: http://www.irb.emory.edu
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EMORY UNIVERSITY | Institutional Review Board

July 1, 2015

Amy Girard, Ph.D.
Rollins School of Public Health
Emory University
Atlanta, GA 30322

RE: Determination: No IRB Review Required
eIRB#: 81427
Title: *Improving volume and consistency of complementary feeding for infants and young children aged 6 to 23 months in the Zulu, Mduwa, and Mkanda Traditional Authorities, Mchinji District: Effectiveness of a Feeding Toolkit.*
PI: Amy Girard, Ph.D.

Dear Dr. Girard:

Thank you for requesting a determination from our office about the above-referenced project. Based on our review of the materials you provided, we have determined that it does not require IRB review because you, the project team, and Emory will not be "engaged" in research with human subjects. To reach this conclusion we consulted the current guidance on engagement issued by the U.S. Office for Human Research Protections. Specifically, Emory students will be assisting Concern Worldwide with quality control checks at baseline data collection for this project. This will involve reviewing questionnaires in the field to catch errors and monitoring the collection of anthropometric data for quality assurance. They will also assist with creating the de-identified dataset following the intervention. They will not be involved in the consent process and will not be involved in implementation or data collection. Based on their activities, the following HHS guidance on engagement of institutions in human subjects research is applicable:

B.1. Institutions whose employees or agents perform commercial or other services for investigators provided that all of the following conditions also are met:

a. the services performed do not merit professional recognition or publication privileges;
b. the services performed are typically performed by those institutions for non-research purposes; and
c. the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

Additionally, based on our review of the materials you provided, we have determined that it does not require IRB review because it does not meet the definitions of research with "human subjects" or "clinical investigation" as set forth in Emory policies and procedures and federal rules, if applicable. Specifically, you will receive a deidentified dataset from Concern Worldwide for analysis of the data from the larger project but will not have access to identifying information. Because no identifying information will be provided to you, you are not considered to be conducting research with "human subjects" and do not require IRB approval.

Please note that this determination does not mean that you cannot publish the results of your data analysis. If you have questions about this issue, please contact me.

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Before implementing any change to this protocol (including but not limited to sample size, informed consent, study design, you must submit an amendment request and secure IRB approval.

In future correspondence about this matter, please refer to the IRB file ID, name of the Principal Investigator, and study title. Thank you

Parul Reddy
Office Assistant (ETS)
This letter has been digitally signed

CC:

Faerber	Emily	GRS: GDBBS GMB-2
KEDERA	ELLAH	*SPH: Global Health

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All Communications should be addressed to:
The Secretary for Health

In reply please quote No. MED/4/36c

MINISTRY OF HEALTH
P.O. BOX 30377
LILONGWE 3
MALAWI

1st July 2015

Jennifer Weiss
Concern Worldwide

Dear Sir/Madam,

RE: Protocol # 1358: Use of child feeding bowls and child slotted feeding spoon to increase weight gain in children enrolled form 6-11 months of age for one year, in Traditional Authority Mkanda, Mchinji District : Effectiveness of a feeding toolkit

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review. Please be advised that the NHSRC has **reviewed** and **approved** your application to conduct the above titled study.

- **APPROVAL NUMBER** : **NHSRC # 15/5/1358**
  The above details should be used on all correspondence, consent forms and documents as appropriate.
- **APPROVAL DATE** : **1/7/2015**
- **EXPIRATION DATE** :This approval expires **on 1/07/2016**
  After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the NHSRC secretariat should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING** :All serious problems having to do with subject safety must be reported to the National Health Sciences Research Committee within 10 working days using standard forms obtainable from the NHSRC Secretariat.
- **MODIFICATIONS**: Prior NHSRC approval using standard forms obtainable from the NHSRC Secretariat is required before implementing any changes in the Protocol (including changes in the consent documents). You may not use any other consent documents besides those approved by the NHSRC.
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the NHSRC using standard forms obtainable from the NHSRC Secretariat.
- **QUESTIONS**: Please contact the NHSRC on Telephone No. (01) 789314, 0888344443 or by e-mail on mohdoccentre@gmail.com
- **Other:**
  Please be reminded to send in copies of your final research results for our records as well as for the Health Research Database.

Kind regards from the NHSRC Secretariat.

SECRETARY FOR HEALTH
2015 -07- 01
P.O. BOX 30377, CAPITAL CITY, LILONGWE 3

FOR CHAIRMAN, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE

PROMOTING THE ETHICAL CONDUCT OF RESEARCH
Executive Committee: *Dr.B.Chilima (Chairman), Prof. E. Molynuex (Vice Chairperson)*
Registered with the USA Office for Human Research Protections (OHRP) as an International IRB
(IRB Number IRB00003905 FWA00005976)

Chapter III: Summary, Public Health Implications, Possible Future Directions

Summary

The primary goal of this research analysis was to examine the effects of an innovative feeding toolkit on morbidity outcomes, mainly diarrhea, among infants and young children in rural Malawi. We hypothesized that use of the feeding toolkit would lead to improved complementary feeding practices among those who were randomized to the intervention group by cuing caregivers to the correct volume and consistency of complimentary foods required of children at each age category. With improved complementary feeding practices, we anticipated seeing a lower prevalence of diarrhea in the intervention group, compared to the control group, due to the hypothesized effect of the feeding toolkit on nutritional status. Along with our interests in the anticipated protective effect of the feeding toolkit on morbidity outcomes, we also were interested in assuring caregivers and stakeholders that the feeding toolkit did not produce any unintended consequences. When introducing the bowl into these rural communities, we anticipated that some caregivers may use the bowl in ways that were not recommended. For example, we considered the possibility of caregivers utilizing the bowl to store cooked foods, even though they were specifically advised to not use the bowl for storage. Further, we considered the possibility of poor bowl and spoon hygiene to negatively impact morbidity outcomes. After completing multiple analyses of the data (intent-to-treat, per-protocol, and per-uptake), we concluded that the feeding toolkit did not demonstrate significant effects on morbidity outcomes. While the point estimate for the odds ratio comparing the odds of diarrhea among those in the intervention group to the odds of diarrhea among those in the control group was protective (OR below 1.00), the confidence intervals for all analyses included the null.

The secondary goal of this research analysis was to determine predictors of diarrhea across our entire study population. Because we had access to a large dataset of children under five years of age in a low-income country, we determined that it was pertinent to run an analysis that looked for significant predictors of diarrhea. The variables that were determined to be significant predictors of diarrhea reported within the past two weeks were: food security, age category, and ever breastfed. Households that were food secure or mildly food insecure had a decreased odds of diarrhea, compared to households that were moderately or severely food insecure. As expected, child age was a significant predictor of diarrhea; as age category increased, the odds of diarrhea decreased significantly.

Public Health Implications

Rigorously evaluating innovative IYCF programs is an important step in improving and implementing data-driven global health programs. Because this innovative feeding toolkit is being implemented in multiple locations across various low-income countries, an evaluation of unintended consequences is crucial in assuring key stakeholders and beneficiaries that the feeding toolkit is not associated with an increase in diarrhea or other morbidity. Although we did not detect statistically significant effects of the toolkit on decreasing the odds of diarrhea or any recent illness, this finding could be because of the larger than anticipated loss-to-follow-up and our shorter follow-up period. It is possible that with greater retention and a longer follow-up period, the effects of the feeding toolkit on nutritional status could impact infectious disease morbidity. However, it is important to note that we also did not detect a significant *increased* odds of diarrhea or any recent illness, which is crucial in assuring the wellbeing of beneficiaries who receive this intervention. In our per protocol logistic regression analyses with any recent illness as the primary outcome, there appeared to be significant effect modification between the toolkit and food security. While the stratified results were insignificant, likely to due to the fact that we were underpowered to detect effects in smaller stratified samples, those who were moderately or severely food insecure had an odds ratio point estimate that was protective over any recent illness. This finding can assure stakeholders that the bowl does have a significant differential effect dependent on food security status, but in a different way that was expected. Public health practitioners in-country expressed hesitation that the feeding toolkit would be an inappropriate intervention for households that are food insecure, as they would not have enough food to fill to the recommended volume line. However, contrary to this assumption, households who were food insecure appeared to experience the most benefit from the toolkit, in terms of morbidity outcomes.

According to the results of our prediction model, food security was significantly protective over diarrhea. Because diarrheal morbidity is a large concern in low-income countries, this finding could motivate governments and non-governmental organizations to focus on implementing sustainable, nutrition-sensitive interventions and programs to address food insecurity and its root causes, such as income poverty.

Future Directions

This initial cluster randomized control trial was designed in order to evaluate the feeding toolkit's impacts on IYCF practices and child growth, not child morbidity outcomes or diarrhea. Because the examination of morbidity was considered after the initial study design, we were not able to collect more specific and detailed information on data such as WASH practices beyond basic information. For example, it would be pertinent for us to collect information on existence of handwashing facilities close to the latrine, the latrine location from well water (uphill, downhill, same level), etc. In future iterations of this study, it would be advisable to collect more specific WASH information that would be relevant to infectious disease burden. Further, diarrhea was measured by a caregiver-reported two-week recall. This measure was previously established in the study questionnaire prior to the inception of this paper's specific research aim. According to a synthesis of methods in epidemiological studies on diarrhea, the choice to rely on a period prevalence measure is ideal for this type of study, since we are aiming to detect a decrease in disease burden due to the intervention (29). However, in future studies, we would suggest that the period is shortened from two-weeks to seven days, as investigators have established that this shorter period is more reliable for self-reported diarrhea (29). Further, we would suggest that in future iterations of this study, the investigators conduct a validation study of a smaller subset of the study population. With this validation study, we would have staff follow-up with the subset households multiple times over the course of follow-up, rather than just one time at endline. While this design would be more expensive and time-intensive, we would get a better idea of the effects of the toolkit with repeated measures, rather than with just a point prevalence of diarrhea. The repeated measures could further account for potential seasonal effects in food contamination and food access.

Every child has the right to good nutrition, and improving Infant and Young Child Feeding (IYCF) interventions is a crucial way to ensure the health of our children. Innovative interventions such as this feeding toolkit address the inequality gap in knowledge that exists between caregivers of children in low-income countries and caregivers of children in high-income countries. Given the significance of child nutrition, public health practitioners must continue to research innovative ways to empower and enable our most vulnerable populations.

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