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# Assessing the Impact of WaterGuard and Micronutrient Sprinkles Use on Diarrheal Prevalence Among Kenyan Children Aged 6 to 35 Months

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# Assessing the Impact of WaterGuard and Micronutrient Sprinkles Use on Diarrheal Prevalence Among Kenyan Children Aged 6 to 35 Months

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B.S. Georgia Institute of Technology 2007

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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 Environmental Health 2011

# Abstract

# Assessing the Impact of WaterGuard and Micronutrient Sprinkles Use on Diarrheal Prevalence Among Kenyan Children Aged 6 to 35 Months

By Ami Shah

*Background:* In 2007, CDC partnered with the Safe Water and AIDS Project in Kenya to launch the Nyando Integrated Child Health and Education project (NICHE) to evaluate the effectiveness of community-based distribution of micronutrient Sprinkles among children between 6 and 59 months. Following the baseline survey in 2007, 12-month and 24-month follow-up surveys were conducted in 2008 and 2009. Data from the first year of the study demonstrated high Sprinkles coverage, acceptability and efficacy on iron deficiency anemia. In August 2010, a 42-month follow-up survey was conducted in 60 study villages, and data regarding the use of Sprinkles and a point-of-use chlorination system, WaterGuard, were obtained. While results from previous NICHE surveys demonstrated good uptake of Sprinkles and WaterGuard in Nyando District, the effects of using both products on diarrhea have not been evaluated. **Objective:** To evaluate how different combinations of WaterGuard and Sprinkles utilization impact diarrhea prevalence in children between 6 and 35 months. Methods: Data from the 42-month follow-up cross-sectional survey of 867 children, aged 6-35 months were analyzed using logistic regression, which adjusted for clustering at the village-level. Questionnaires administered to mothers or caretakers of eligible children provided data on demographics, WaterGuard use, Sprinkles use and diarrhea in the past 24 hours.

*Results:* 11.1% of children currently used Sprinkles, whereas 53.8% of children reported current use of WaterGuard. The odds of diarrhea among individuals who currently used WaterGuard only were 0.63 times the odds of diarrhea among individuals who used neither WaterGuard nor Sprinkles. Infrequent users of Sprinkles (those consuming between 1 and 4 sachets in the previous 7 days) had the highest prevalence of diarrhea compared to non-users and frequent users. Factors crudely associated with diarrheal prevalence included age, socioeconomic status, wasting, and Sprinkles dose (*p*-value < 0.10). The presence of chlorine residual confounded the relationship between exposure and outcome; however, chlorine residual in drinking water was not protective against diarrhea (OR = 1.613, *p*-value = 0.0515).

*Conclusions:* The use of WaterGuard and Sprinkles individually and together was protective against diarrhea. However, only the use of WaterGuard showed a statistically significant impact on reducing diarrheal prevalence.

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#### **INTRODUCTION**

Children are among the most vulnerable individuals to the consequences of disease and poverty. At highest risk are children under age five in developing countries who lack the most basic, yet essential resources for healthy living. As a result, many under fives are plagued by health problems from the time of conception.<sup>i, ii</sup> In 2009, the World Health Organization estimated that nearly 9 million children under age 5 die annually, and close to 4 million newborn babies die within the first month of life.<sup>iii, iv</sup> Additionally, nearly 70 percent of these deaths are due to preventable or treatable conditions that could be circumvented with affordable and sustainable interventions.<sup>iii</sup> In Sub-Saharan Africa, nearly 4.6 million children die before reaching the age of 5 and a wide range of literature suggests numerous pathways by which growth and development can be stymied during this critical time period.<sup>i</sup> Within the first two years of life, infants and young children are highly susceptible to health adversities stemming from ill health, low nutrition, and harmful environmental and social factors that influence physical and mental growth and development. Young children are also likely to be more adversely affected by social and environmental factors more so than adults because of their own rapidly changing environments and critical changes in biology. Consequently, much of the damage done to physical growth and development after the age of 2 is largely irreversible.<sup>v, vi</sup>

Poverty, being a root cause of many public health crises, is instrumental in many of the issues faced by children under age 5.<sup>i</sup> Several studies illustrate how children growing up in impoverished settings are more likely to experience harmful environmental exposures, have poorer health and nutrition, and have parents with little education.<sup>i, v, vi, vii</sup> As a result of these circumstances, children are at increased risk of sustaining the cycle of poverty.<sup>i</sup> These obvious connections are well known throughout the realm of public health, yet under fives are still among the most vulnerable groups and predominantly endure health ailments that are both acute and chronic. And although the consequences of poverty significantly impact adults by diminishing their of physiological capacity, ultimately, the repercussions trickle down to the child, who bears the burdens of growing up impoverished and unable to reach its potential.

Unlike many diseases that are specific to various demographics and age groups, the lack of access to safe water and malnutrition adversely impact a wide spectrum of individuals, though the burden in developing countries is disproportionately experienced by women and children, especially girls.<sup>xxv</sup> Still, of foremost concern are the disadvantages incurred by children under age 5 as a result of malnutrition and lack of access to safe water. Both problems are intertwined as they stem from poverty, are driven by social and environmental circumstances and ultimately result in similar negative health outcomes that are themselves interlinked and often take on cyclical patterns, over multiple generations (Appendix A: Figure 2A).<sup>i, vi, vii</sup>

According to the World Health Organization (WHO), nearly one quarter of the global disease burden and a third of the disease burden among children can be attributed to modifiable environmental factors including malnutrition and lack of access to safe water sources.<sup>viii</sup> In regards to safe water, studies indicate that nearly 10 percent of the global burden of disease worldwide could be prevented with improvements to drinking water, sanitation, hygiene, and water management.<sup>ix</sup> Currently, 1.1 billion people in developing countries lack access to improved water supplies such as piped water sources and boreholes and 2.6 billion lack basic sanitation.<sup>x, xi, xxvi</sup> As a result, it is understandable that diarrheal disease is a sizeable contributor to mortality in children under age five living in developing countries. Worldwide, efforts are being made to achieve the 2015 Millennium Development Goal of halving the proportion of people without sustainable access to safe drinking water and basic sanitation. Currently, some parts of the world are on track to meet this goal.<sup>xii</sup> However, in Sub-Saharan Africa, only 60 percent of the population currently has access to safe drinking water, indicating that progress is still needed.<sup>xii</sup>

#### Diarrhea

Diarrheal disease accounts for nearly 2 million deaths annually among children under 5 and was attributed to 15 percent of all under-five deaths in 2008.<sup>viii, xii, xiii, xiv</sup> A systematic review by Hamer et al indicated that nearly 40% of all childhood deaths due to diarrheal disease would occur in Sub-Saharan Africa by the year 2000.<sup>xv</sup> As a result of this and similar research findings from various studies, several programs focusing on safe water, sanitation, and hygiene have been established in many African countries.

Most commonly, diarrhea is caused by ingestion of pathogens in drinking water, food or from unclean hands.<sup>ix</sup> A single bout of diarrhea causes rapid dehydration and can be fatal if treatment is delayed.<sup>xvi</sup> Furthermore, the additional consequences of diarrhea seem to be compounded as individuals often exhibit a diminished appetite, impaired absorption of essential nutrients, and develop a high risk for recurrent infections, and long-term gastrointestinal disorders.<sup>i, ix, xvii, xxiii</sup> Infants and children under age 5 are especially vulnerable to these consequences because immunity may develop at a snail's pace, especially if the child comes from a poor or malnourished background.<sup>xviii</sup> Due to the consequences of malnutrition, which can in turn be a result of ingesting unsafe drinking water, having inadequate sanitation and poor hygiene, nearly 860,000 children under age 5 die annually.<sup>ix</sup> Therefore, both control and prevention efforts must ensure that proper nutrition is a critical component to safe water interventions, as malnutrition among populations who lack access to safe water

Especially in the Sub-Saharan region, uncontaminated drinking water is often a scarce, distant, or unobtainable resource. Therefore, in settings where reliable water treatment and distribution systems are unavailable, diarrheal disease is often endemic.<sup>xxiii</sup> Greater investment in low-cost and sustainable methods of water treatment such as point-of-use chemical disinfection and safe water storage within the household are approaches needing further investigation. As indicated in a systematic review by Fewtrell et al, point-of-use chlorine disinfection may be among the most efficacious methods for significantly reducing diarrhea in areas where people lack access to safe water sources.<sup>xix, xxii</sup> Such strategies could aid in reducing the incidence of diarrheal disease and under 5 mortality in areas where access to safe water is impractical and improvements in the microbiological quality of drinking water are needed.<sup>x, xviii, xx, xxiii</sup>

An increasing amount of evidence indicates that household water treatment and safe storage are associated with significant health gains where available water is contaminated.<sup>ix, xxi, xxii, xxiii</sup> In many developing countries

obtaining water from uncontaminated sources can impose opportunity costs of time, energy and the risk to physical wellbeing. Thus, sustainable and more convenient solutions for water treatment are of the essence. In Sub-Saharan Africa, the burdens of water collection fall predominantly upon women and children (mainly girls), who bear significant losses in future productivity as a result of premature mortality by engaging in this time-consuming and perilous activity.<sup>xxv</sup> On average, a woman responsible for collecting water walks more than 1000 meters (the appropriate distance indicated by the 2005 MDG target) or more than half an hour to collect and carry back water to the household.xxiv During this trip, she is at high risk of being exposed to water-related illnesses such as sleeping sickness, malaria and guineaworm and physical injury.xxv As a result of her engagement in water collection activities for the household, she is also foregoing the pursuit of an education and failing to join the workforce, both of which are factors rooted in determining future socioeconomic status and wealth. Likewise, the physical stress of carrying the water over irregular terrain and long distances takes an enormous toll on her current and future wellbeing. Opintan and others acknowledge that aside from the physical burdens endured, an "annual expenditure of over 10 million person-years of time and effort by persons carrying water from distant and often polluted sources" is also incurred.<sup>xx</sup> In other words, the risks of diminishing physical capacity, future productivity and potentially using unsafe drinking water for daily activities are assumed. In the least, if such methods of obtaining drinking water will be employed by many individuals in the years to come, it is of great importance to ensure that the water is made safe for use following collection.

#### Diarrheal Treatment: WaterGuard

According to the Kenyan Demographic Health Survey (DHS) administered in 2003, nearly 75% of residents in Nyanza Province, western Kenya reported not having access to a safe water supply.<sup>xliii</sup> This exceeds the proportion of individuals without coverage in the entire Sub-Saharan region almost twice over.xii Not surprisingly, Nyanza province also experienced the third highest prevalence of diarrheal disease in Kenya. xxvi, xxvii Since the results of the last Kenyan DHS, efforts have been made to reduce the prevalence of diarrheal disease in Nyanza Province through the promotion and use of WaterGuard—a 1% sodium hypochlorite disinfectant solution used for point-of-use treatment of drinking water.<sup>x, xxvi</sup> This locally produced disinfectant solution is easy to use and has been shown to prevent diarrhea. xxviii Studies have suggested a 20-48% reduction in diarrheal incidence when household disinfection with a chlorine solution such as WaterGuard was conducted.<sup>x, xxix</sup> In 2005, Population Services International Kenya (PSI Kenya) sold over 800,000 bottles of WaterGuard. However, a significant percentage of the population in this region still struggles with poor access to this product.

#### **Malnutrition**

Like diarrhea, malnutrition is another substantial contributor to disease and mortality among vulnerable populations. Its three principle constituents include: 1) protein-energy malnutrition (PEM); 2) micronutrient deficiencies; and 3) over-nutrition and obesity.<sup>xxx, xxxi</sup> As defined by Atinmo et al, "malnutrition results from the imbalance of nutrients and energy provided to the body (too low) relative to its needs (too high)," but can also be triggered and

augmented by the consequences of diarrheal disease.<sup>i, ix, xxxii</sup> Although all three types of malnutrition together account for more than 50% of deaths among children under age five in developing countries, PEM and micronutrient deficiencies alone-the two forms of undernutrition-contribute to one third of all deaths among children in this age group.<sup>xxx, xxxiii, xxxiv</sup> Children affected by malnutrition at an early age become increasingly susceptible to being disadvantaged later on in life. Beginning at conception, a malnourished mother is considered to be at high risk of having a low birth-weight baby, who will be at risk of short-term and long-term morbidity and disability in the future.xxxv Close to 30 million low birth-weight babies are born annually, many as a result of having a malnourished mother.xxxv A severe consequence of maternal malnutrition is the experience of intrauterine growth retardation (IUGR), which occurs when the mother is unable to gain enough weight during pregnancy and already exhibits short stature and low weight.<sup>vi, xxxvi</sup> Consequently, IUGR infants often suffer from increased risk of diarrhea, pneumonia, and recurrent infection due to impaired immune function.<sup>vi</sup> Several studies have also indicated mild to severe adversities in terms of physical, mental, and developmental ailments due to acute and chronic malnutrition experienced while in the womb and after birth.vi, v, xxx, xxxii Decreased socioeconomic status, human capital and physiological capital in the future have also shown direct correlations with chronic malnutrition and tend to fall disproportionately on children living in developing countries. xxxvii

Chronic malnutrition, or stunting, is characterized by low height-for-age and occurs over long periods of time.<sup>xxx, xxxv</sup> As a result, the consequences of stunting are often unobserved until later on in life when the repercussions are irreversible. Research has shown strong correlations of stunting with poor mental development, poor education, and lowered future productivity and physical capacity.<sup>xxxviii</sup> Current estimates indicate that 25-30% of children in low-income countries are stunted.<sup>xxxviii</sup>

Acute malnutrition, also called wasting, is associated with rapid weight loss, starvation and a low weight-for-height ratio.<sup>xxx, xxxv</sup> The World Health Organization estimates that close to 20 million children around the world suffer from severe acute malnutrition.<sup>iii</sup> Consequently, these children are faced with the risks of serious illness and early death.<sup>iii</sup> However, unlike chronic malnutrition, acute malnutrition can be reversed by providing ready-to-use therapeutic foods or highly fortified foods such as Plumpy-Nut or micronutrient Sprinkles to wasted individuals.<sup>iii</sup> Even so, wasting continues to be a serious problem faced by under fives in many developing countries.

Both chronic and acute malnutrition are caused by dietary insufficiency. A lack of micronutrients being key to malnutrition among vulnerable populations in developing countries requires further scrutiny and greater investment in micronutrient interventions.

#### **Micronutrient Malnutrition**

Micronutrient deficiencies are attributed to inadequate amounts of minerals and vitamins in the daily diet which are essential to human health, growth, and development.<sup>xxxix</sup> Critical components of nutritional health including iron, zinc, vitamin A, iodine and folate, are often lacking in the diets of women and children living in developing countries. As a result, a high prevalence of diarrhea, anemia, and immune system problems within these populations is observed. xxxix Micronutrient deficiencies account for 7.3% of the global disease burden, especially in settings where food stuffs are limited in vitamin and mineral content or when essential nutrients are not bioavailable to the consumer. xxxix Two micronutrients of interest are iron and zinc, both of which are integral to daily life and wellbeing. If not consumed in adequate amounts, severe impairments to growth and development can occur. For example, in some parts of Sub-Saharan Africa, where low bioavailability of iron is problematic, iron deficiency anemia, especially in children under age 5, is highly prevalent.xliii Likewise, children who lack the required daily amount of zinc through dietary intakes are often struck with frequent episodes of severe diarrhea and declines in immune function.xl These and other important micronutrients are critical in preventing chronic and acute forms of malnutrition that further impact the body's ability to properly develop and heal after experiencing biological stress.

#### Micronutrient Malnutrition Treatment: Iron, Zinc and Sprinkles

Iron is essential for several aspects of growth and development, especially in children under the age of 5.<sup>xli</sup> Consuming sufficient amounts of iron on a daily basis can help avoid adverse health outcomes such as iron deficiency anemia. Recent figures indicate that one in four individuals is iron deficient.<sup>xli</sup> Iron deficiency, being the most common cause of childhood anemia in developing countries, has been the focus of many public health organizations and nongovernment organizations (NGOs) in developing countries.<sup>xlii</sup> Due to the high iron requirements of individuals living in areas where iron is low in the diet, early childhood is one of the riskiest periods for iron deficiency and iron-deficiency anemia.<sup>xli</sup> This can be seen in Sub-Saharan Africa, where low iron bioavailability and little use or availability of commercially-available fortified foods promotes iron deficiency anemia.<sup>xliii</sup> Interventions to prevent and treat iron deficiency typically include provision of iron supplements, fortification of staple and complementary foods with iron, and dietary diversification. However, implementation of iron programs has been sadly unsuccessful.

In response to many attempts at treating iron deficiency anemia, micronutrient Sprinkles was developed to allow home-fortification of complementary foods for delivering iron and other essential micronutrients.<sup>xlii</sup> One sachet of Sprinkles conveniently delivers the US Recommended Dietary Allowance (RDA) of 14 essential minerals and vitamins required for children 6-59 months of age.<sup>xlii</sup> In regions where nutrition may be restricted for infants and young children due to insufficient resources, micronutrient Sprinkles containing iron and other critical nutrients can result in significant improvements in hemoglobin concentrations and anemia status among children who were previously anemic.<sup>xlii</sup>

Similarly, zinc is another essential element in micronutrient Sprinkles that is required for healthy growth and development. Zinc plays a critical role in the body's metabolism and is the second most abundantly distributed trace element in the body after iron.<sup>xlvi</sup> Individuals at high risk for zinc deficiency are often deficient due to malnutrition and frequently suffer from substantial losses of body fluid and essential salts as a result of experiencing severe bouts of acute diarrhea.<sup>xlvi, li, lii</sup> Findings by the World Health Organization indicate that zinc deficiency contributes to an estimated 1.8 million deaths globally every year and in Sub-Saharan Africa, approximately 68% of the population is zinc deficient.<sup>xliv</sup> Furthermore, though mortality due to diarrhea is declining, studies indicate that diarrheal incidence per child remains unchanged at approximately 3.2 episodes per year.<sup>xlvi, li</sup> As a result, zinc deficiency in conjunction with diarrhea is also commonly observed among children in developing countries where zinc intakes remain low.<sup>xliv, xlv, xlvi, lii</sup> When left untreated, permanent growth retardation, mild to severe bouts of diarrhea, and decreased immunity are just some of the repercussions of zinc deficiency.<sup>xlvi, lii</sup>

Although zinc is found throughout the body, humans lack natural stores.xlvi, xlvii As a result, dietary intake, absorption and losses determine levels of zinc in the body.<sup>xlvii</sup> In many low-income settings, people may lack the resources for obtaining adequate daily zinc intakes even though a variety of foods including poultry, beef, seafood and unleavened grains have zinc. Therefore, zinc supplementation is still required to bring vulnerable and deficient populations up to daily requirements for leading healthy and productive lives. Especially for children 6 months and older, studies have indicated that zinc supplementation through complementary feeding practices can have a significantly positive impact on lowering the severity and duration of diarrheal episodes and even aid in preventing diarrhea occurrence. xlviii, xlix, l, xlviii Several randomized control trials replicated these positive associations of zinc supplementation and reductions in prevalence and incidence of diarrhea among young children and established its efficacy as a reasonable treatment for acute diarrhea, especially among zinc deficient and malnourished children. li, xlviii Consequently, in 2004, the World Health Organization and UNICEF recommended the incorporation of zinc

supplementation as an additional treatment to low osmolarity oral rehydration therapy (ORS) and child feeding for treating acute childhood diarrhea.xlviii

Zinc being a key component of micronutrient Sprinkles, is delivered in 5 mg amounts per Sprinkles sachet.<sup>xliv</sup> The National Institutes of Health recommends about 3 mg of zinc per day for children between 6 and 36 months. Therefore, the consumption of one Sprinkles sachet per day is more than sufficient for ensuring adequate daily zinc intake.<sup>lii</sup>

#### The Nyando Integrated Child Health and Education Project

In 2007, the Centers for Disease Control and Prevention (CDC) partnered with the Safe Water and AIDS Project (SWAP) and other research partners in western Kenya to launch the Nyando Integrated Child Health and Education Project (NICHE). The goal of the NICHE Project is to evaluate the impact of community-based marketing and mobilization of local institutions to sell micronutrient Sprinkles along with other health products, including WaterGuard. Aside from Sprinkles and WaterGuard, several health products including soap, condoms, modified clay pots and bednets, are marketed to all families living in the project area, especially to those families with children ages 6-59 months. These health products are distributed by community vendors who have been offered small loans in the form of microcredit<sup>1</sup> for promoting health-related activities. As a result, vendors are able to buy health products at wholesale and subsequently educate and sell these products at retail to their neighbors for income-generating purposes. Some additional objectives of the NICHE project

<sup>&</sup>lt;sup>1</sup> Small loans offered to impoverished individuals in an effort to encourage entrepreneurship and incomegeneration as a means to exit the cycle of poverty.

are to assess the feasibility of Sprinkles distribution in western Kenya when integrated with an existing health promotion and an income-generating program and also to measure the impact of Sprinkles use on important health outcomes among young children under age three. Likewise, assessing the utilization, feasibility and effectiveness of WaterGuard among these same children has been well-integrated into the NICHE project's goals during the 42-month follow-up.

A baseline assessment of children under age 5 among 60 villages in Nyando District was conducted in 2007 and subsequently, follow-up crosssectional surveys were administered to measure impact on selected biomarkers and anthropometry among children aged 6-59 months. Active biweekly surveillance of enrolled children was conducted to determine Sprinkles use and health status and qualitative data collection was conducted to assess acceptability of Sprinkles over time. Prior to data collection, 30 intervention villages and 30 comparison villages were randomly selected from Nyando Division (population 80,000), where the population is largely impoverished and lacks adequate sanitation and infrastructure.<sup>xxxiv</sup> Details of the sampling methodology are described elsewhere.<sup>liii</sup> In the first year of the study, Sprinkles was only marketed and distributed in intervention villages and not marketed in comparison villages. However, monitoring of use and biological impact took place in both intervention and comparison villages. Following a 12-month follow-up survey in March 2008, Sprinkles sales were scaled-up to the comparison villages and biweekly household surveillance continued. A 24-month follow-up survey was conducted in March 2009 and a 42-month evaluation was completed in early September 2010. In conjunction with data on the efficacy of Sprinkles and utilization

practices, the 42-month follow-up survey also collected extensive information on WaterGuard utilization and knowledge among study participants. Given that the first year of the NICHE study demonstrated several successes of micronutrient Sprinkles in terms of consumer acceptability, Sprinkles coverage in Nyando District, and positive clinical impact on anemia status among children, recent data from the 42-month follow-up will allow for further evaluation of the efficacy of both Sprinkles and WaterGuard on other important health outcomes within this population.

#### **METHODS**

#### Composition of 2010 NICHE Follow-up Survey

The third NICHE follow-up survey followed a cluster cross-sectional survey design. Data were collected from children between the ages of 6 and 35 months residing in all 60 study villages originally chosen within Nyando District, western Kenya. This questionnaire, which was administered by NICHE enumerators to mothers or primary caretakers of each eligible child in the household, was comprised of three components: 1) a household module to gauge socioeconomic status of each household and knowledge and use of WaterGuard; 2) a maternal module for understanding maternal education, feeding practices and Sprinkles knowledge; and 3) a child questionnaire to determine each eligible child's health status and Sprinkles use. Following the administration of the threepart questionnaire, laboratory and anthropometry measurements were taken and recorded for each eligible child in the household. As a result, information on the prevalence of diarrhea, anemia, stunting, wasting, and malaria are among some of the health outcomes evaluated for this study. Data were collected and double-entered with EpiInfo into a Microsoft Access database by study personnel. Of 1348 children sampled, 867 age-eligible children were enrolled in this study (enrollment rate of 64.3%). Among the 499 children excluded from the study, 6.6% refused to participate, 56.9% were outside of the age range for eligibility, 24.8% were unavailable for enrollment, 8% were lost to follow-up, and 3.6% did not have laboratory data available. The 849 participants who were analyzed for this study represented a total of 729 households situated in the 60 villages (or clusters) in the Nyando District (Figure 1).

Using the data provided in the 42-month follow-up survey, associations between Sprinkles and WaterGuard use and prevalence of diarrhea among children 6 and 35 months were thoroughly investigated. Data regarding hospitalization and reason for hospitalization have been briefly presented in this report (Table 2); however, no analyses on this data were possible due to extremely low sample sizes and a high percentage of missing values regarding reason for hospitalization (50% data missing). Additional information regarding demographic characteristics, various health indicators including stunting, wasting and anemia, and utilization of additional health products sold by community vendors are provided as well (Appendix: Table A2).

#### **Data Cleaning and Analysis**

The existing Microsoft Access dataset was obtained from the 42-month NICHE follow-up survey conducted between August and September of 2010. Data management and analysis was performed using SAS 9.2 software (SAS Corporation, Cary, NC). Because only one complete (three-component) questionnaire was administered per household, data cleaning entailed filling in household and maternal data for additional eligible children in each household for whom complete household and maternal questionnaires were not obtained. As a result, household and maternal data for 130 children were back-filled in SAS 9.2 using corresponding unique household identifiers to ensure that data regarding socioeconomic status and household and maternal modules were available on all children enrolled. Given that multiple variables<sup>2</sup> contributed to the overall socioeconomic status of a child in a household, a principle components analysis developed by the World Bank was used to characterize each household into Kenya socioeconomic quintiles (Table 1).<sup>liii, xxxiv</sup> For 20 cases in which one or more raw socioeconomic variables had missing values, the lowest value for that variable was chosen so that no child was excluded from the analysis due to missing socioeconomic status information. Subsequently, outcome, exposure, and other covariates were coded to reflect binomial values for the purposes of regression analysis.

Unique household and individual identifiers were cleaned using NICHE's 42-month follow-up sampling frame and cluster forms, which served as accurate references and were filled out by enumerators at the time of questionnaire administration. Cluster forms were double-checked by the data manager for accuracy and corrected if errors were recognized. Additionally, because laboratory and anthropometric data collected from the 42-month follow-up were

<sup>&</sup>lt;sup>2</sup> Raw socioeconomic variables include electricity, the number of rooms in the home, whether the home is owned or rented, the possession of a radio, television, refrigerator, bike, car, motorcycle, mobile phone, telephone land line, and domestic worker and the material from which the walls, floors, and roof of the home are made.

entered in a separate database from questionnaire data, cleaned household and individual identifiers were essential for merging both datasets.

Following enrollment and data collection from 882 subjects, complete laboratory data were not available for 18 enrolled children and 15 children who were enrolled in the study did not meet the age eligibility criteria. As a result, these 33 additional children were excluded from the analysis. Also, because diarrheal prevalence was the outcome of interest, 8 children who lacked information on diarrhea within the past 24 hours prior of survey administration were excluded. As a result, a final sample size of 841 eligible children residing in 725 households was used for data analysis.

#### **Primary Outcome: Diarrhea**

Diarrhea prevalence within the past 24 hours was the primary outcome of interest. Due to clustering within the study design and diarrhea exhibiting a binary distribution, complex logistic regression was used to analyze potential associations.

To evaluate how the dose of Sprinkles impacted the prevalence of diarrhea, a polychotomous variable was developed from the number of Sprinkles sachets consumed within the past seven days to analyze whether Sprinkles dose altered the model outcome. Dose categories included "none," "infrequent" and "frequent" use of Sprinkles. Nonusers reported consuming no Sprinkles sachets within the past seven days; infrequent users consumed between one and four sachets in the past seven days; frequent users consumed five or more sachets in the past seven days. Children with missing values for Sprinkles dose were excluded from the analysis of Sprinkles dose and prevalence of diarrhea (n = 26).

# **Covariates**

In addition to diarrheal prevalence, assessing the general health status of all children surveyed was important for this study. Therefore, three important anthropometric indicators were assessed—stunting (low height-for-age), wasting (low weight-for-height), and anemia status (mean hemoglobin)—in order to gauge nutritional status of each study participant. Anthropometric measures including height, weight and age were used to calculate z-scores (using 2005 WHO growth standards) to determine if a child was stunted<sup>3</sup>, wasted<sup>4</sup> or underweight<sup>5</sup> and are presented in Table 2. Hemoglobin measurements obtained from fingerpricks were used to determine a child's anemia status<sup>6</sup>. Blood smears were obtained from study participants to test for the presence of malaria.

#### **Exposures of Interest: Health Product Utilization**

Exposure was divided into four product utilization groups: 1) uses WaterGuard only; 2) uses Sprinkles only; 3) uses both products; or 4) uses neither product. Although users and non-users of WaterGuard and Sprinkles were defined by current use of either product rather than ever use, ever use for WaterGuard and Sprinkles is presented in this report (Appendix: Tables A3 & A4).

Although WaterGuard use is a household-level variable, utilization was modeled at the individual level in order to remain consistent with the analysis of diarrhea prevalence and Sprinkles utilization. The number of children living in

<sup>&</sup>lt;sup>3</sup> Stunted is a length-for-weight z-score < -2 SD for children under age 2 or a height-for-weight z-score < -2 SD for children over age 2.

<sup>&</sup>lt;sup>4</sup> Wasted is a weight-for-height z-score < -2 SD.

<sup>&</sup>lt;sup>5</sup> Underweight is a weight-for-age z-score < -2 SD.

<sup>&</sup>lt;sup>6</sup> Anemia indicative of hemoglobin < 11.0 g/dl.

households that currently treated their household drinking water with WaterGuard at the time of the survey was determined based on respondent recall. Additionally, enumerators tested household drinking water for the presence of chlorine residual if water was available and respondents did not refuse testing. Respondents who did not report on current use of WaterGuard were excluded from the data analysis (n = 46). Similarly, individuals who refused chlorine testing of their current drinking water or did not have water available at the time had to be excluded from the final analysis (n = 108).

In order to determine Sprinkles use among participants, respondents reported on both their current and ever use of Sprinkles for each eligible child in the household. Current use was based on respondent recall of the child's consumption of Sprinkles in the past 24 hours prior to administration of the questionnaire. Sprinkles ever use was indicative of the respondent reporting that the child had consumed Sprinkles any time before participating in the 42-month follow-up study. Respondents who did not report on current Sprinkles use were excluding from the final analysis (n = 6).

After determining the crude estimates of current use of both products within the study population, participants were categorized into the four utilization groups mentioned.

#### Statistical Analysis

Because the outcome of interest and all variables analyzed for this report reflect a binomial distribution (yes or no), logistic regression was used to analyze potential associations. Adjusting for clustering at the village-level was possible by using the Proc Surveylogistic command in SAS 9.2 and specifying clustering at the village-level. Rationale for variable selection was based upon findings from the literature on diarrhea and malnutrition and the clinical and biological importance of covariates in relation to diarrheal prevalence. Variables exhibiting more than two levels such as age and maternal education, were dichotomized so to not lose significant information from the data. Age was dichotomized into younger than 24 months and 24 months or older. Maternal education was dichotomized into up to the completion of primary school and some secondary school or higher. As mentioned earlier, Sprinkles dose was also separated into three categories of consumption so to ensure equal group size.

#### Assessment of Confounding and Interaction

Odds ratios and confidence intervals for utilization categories and predictor variables of diarrhea were derived from regression analysis, adjusting for clustering. Chi-squared goodness-of-fit tests provided corresponding pvalues, which were instrumental for determining which variables would be incorporated and eliminated throughout the modeling process (*p*<0.10). Predictor variables in the full model included sex, age, stunting, wasting, anemia status, use of WaterGuard to treat household drinking water, ever use of WaterGuard, ever use of Sprinkles, maternal education level, receipt of promotional items, attendance at SWAP events, presence of chlorine residual in the household drinking water, Sprinkles dose and socioeconomic status and some interactions terms between covariates and the exposure. Prior to generating the final logistic model, covariates were analyzed for multicollinearity. A variance inflation factor (VIF) greater than or equal to 10 suggested multicollinearity and such covariates were not included during model generation. Initial assessment for potential confounders, interactions and effect modifiers involved identifying statistically significant associations between each covariable and exposure and outcome separately (p<0.10) (Table 9). Thereafter, a hierarchical backward elimination approach<sup>7</sup> without replacement was manually conducted to determine which variables remained in the reduced model (Appendix A: Table A5). All potential confounders and interaction terms were initially included in the full model and eliminated one at a time based on the hierarchically well-formulated model structure<sup>7</sup> and statistical significance (p=0.10). After deriving the initial, reduced model, final assessment of confounding was conducted by adjusting for potential confounders of diarrhea and product utilization individually. Actual confounding was determined if the crude odds ratio derived from the reduced model changed by more than 10% when adjusting for the potential confounder. Potential confounders that did not fit this criterion were then eliminated from this preliminary model to yield the final, reduced model.

#### **RESULTS**

Household and individual demographics information for the study population is presented in Table 1. Of 882 children enrolled in the NICHE followup survey, demographic information on only 849 age-eligible children residing within 729 households has been presented in this report as complete survey and laboratory data for these children were available. The sex ratio was approximately 1:1 among eligible children enrolled in the study population. The mean child age was 21.4 months (standard deviation  $\pm 8.3$  months).

<sup>&</sup>lt;sup>7</sup> Hierarchical backward elimination approach is described in Kleinbaum & Klein (2002).

Measurements of various health indicators among study participants are presented in Table 2. According to anthropometric data collected for this study, 29.9% of children were stunted and 3.8% were wasted. Positive malaria smears were obtained from 268 children and 668 households were tallied for the presence of a bednet. Seventy percent of children exhibited a mean hemoglobin of 10.9 g/dl or lower, indicating anemia. Average hemoglobin concentration across the study population was 9.65 g/dl (standard deviation  $\pm 1.9$  g/dl).

A total of 207 children reported experiencing an episode of diarrhea within 24 hours prior to questionnaire administration but only six of these children were hospitalized within the past two weeks. Of those hospitalized, 2 children reported being hospitalized as a result of diarrhea and 11 children failed to report the reason for hospitalization (Table 2).

In regard to product utilization, 95% of all households indicated that they had used WaterGuard in the past but only 373 households (51.2%) reported that currently treating their water with WaterGuard (Table 3). Although 633 households reported using WaterGuard for treating their drinking water to make it safe, 122 households tested positive for chlorine residual in their current drinking water. Respondents for 494 children indicated ever use of Sprinkles by the child and 93 reported that the child was currently using Sprinkles. According to responses regarding the number of sachets consumed in the past seven days, the average number of Sprinkles sachets consumed during the week prior to survey administration was 1.06 sachets.

The majority of children (75%) did not consume Sprinkles during the week prior to survey administration, whereas approximately 10% were infrequent

users and 10% were frequent users of Sprinkles (Table 7). Graph 1 depicts diarrheal prevalence among non-users, infrequent and frequent Sprinkles users. The data suggest that infrequent users had a significantly higher prevalence of diarrhea within the past 24 hours in comparison to frequent users (28.4% of infrequent users versus 15.2% of frequent users, OR=0.452, p=0.0848). A statistically significant difference in prevalence of diarrhea was observed between frequent users of Sprinkles and non-users at the 90% confidence level (OR = 0.537, p=0.945).

To understand the crude relationship between the use of WaterGuard and Sprinkles and diarrhea, utilization groups were modeled with diarrheal prevalence (Table 6). After adjustment for clustering, the regression indicated a statistically significant protective effect against diarrhea among individuals using WaterGuard only in comparison to individuals using neither Sprinkles nor WaterGuard (OR=0.657, p<0.009) (Table 6). Current use of Sprinkles alone was also a statistically significant predictor of diarrhea (OR = 0.388, p=0.078). However, the use of both products together did not significantly reduce the odds of diarrhea within the previous 24 hours in comparison to those using neither WaterGuard nor Sprinkles (OR=0.614, p=0.2567).

#### Modeling Results

Sprinkles dose was selected as a potential confounder and interaction term with product utilization after statistically significant associations at a 90% confidence level with product use and diarrhea were observed ( $\chi^2_{diarrhea}$ =0.0772, 90% CI ;  $\chi^2_{product use}$ <0.0001, 90% CI) (Table 9). However, further examination of this relationship indicated neither confounding nor interaction as a result of the

dose of Sprinkles. Additionally, no indication of confounding by sex, age, socioeconomic status, or wasting was found upon further investigation of the reduced model according to the 10% criterion for confounding applied here. On the contrary, adjustment for chlorine residual in the household drinking water indicated confounding in the case where both Sprinkles and WaterGuard or WaterGuard alone were used by the consumer (Table11). In contrast to what was expected, chlorine residual in the household drinking water did not exhibit a protective effect against diarrhea within this study population (OR = 1.613, p=0.0515) (Table 12). There was no statistically significant difference between users of Sprinkles only when adjusting for chlorine residual (Table 11).

Analysis of 684 children in the final logistic model indicates that there is a protective association of all three combinations of WaterGuard and Sprinkles utilization on diarrheal prevalence in this population. However, these associations are confounded by the use of chlorine disinfection products for treatment of household drinking water after adjustment for clustering. The most statistically significant association with diarrhea was found among users of WaterGuard alone. The odds of experiencing an episode of diarrhea in the 24 hours prior to participation in the NICHE study for users of WaterGuard only were 1.6 times less than the odds for individuals who currently did not use either product after adjusting for clustering (p = 0.02). However, as shown in Table 12, the presence of chlorine residual in household drinking water did not indicate a protective effect from diarrheal incidence (OR = 1.613, 90% CI 1.1 – 2.4).

#### **DISCUSSION**

As hypothesized, using WaterGuard and Sprinkles is associated with

reduced prevalence of diarrhea in this study population. This association is especially observed among users of the WaterGuard only. The data also suggest a modest association between Sprinkles use and diarrhea and a similar protective association among users of both Sprinkles and WaterGuard; however, these findings are not statistically significant at the 90% confidence level.

Chlorine was found to be a confounder of the relationship between product utilization and diarrhea over the past 24 hours within this population. However, the data showed that the presence of chlorine residual in household drinking water was not protective against diarrhea among the children analyzed. This finding could have been influenced by several factors. First, close to a 19% reduction in sample size occurred in the regression analysis of the final model. In addition, nearly 13% of data on chlorine residual among households was missing due to participants refusing chlorine testing or not having drinking water available for testing. Human error at time of testing for chlorine residual could have also influenced this outcome. Also, discussion with enumerators and NICHE staff members introduced the possibility that reagents used for chlorine testing in the field could have degraded over time due to adverse field conditions such as time spent traveling by enumerators during periods of elevated temperature.

Still, the findings of this study do support evidence in the literature that suggests using point-of-use water treatment systems such as WaterGuard can be protective against diarrhea. Similarly, the results of this study in regards to utilization of Sprinkles alone are also coherent with findings in the literature that there is a close link between adequate intake and absorption of essential micronutrients is protective against diarrhea. However, we did not find a statistically significant difference in diarrhea prevalence between individuals using both Sprinkles and WaterGuard and individuals using neither product (0.614, p=0.2567) (Table 12). Given that malnutrition and diarrheal disease are intertwined, it was expected that children exhibiting poor micronutrient intakes (or children not consuming Sprinkles) and also consuming potentially contaminated water would experience higher prevalence of diarrhea than their counterparts who use both products. This was unexpected because many studies have shown diarrhea to be inhibitory of normal ingestion of foods and adsorption of nutrients that are essential for growth, cognitive function and healthy immune system function.<sup>liv</sup> Similarly, point-of-use chlorination treatments have been shown to be highly effective for inactivating most enteric pathogens in contaminated water. Therefore, simultaneous use of both products was expected to show a statistically significant effect on reducing diarrheal prevalence.liv However, due to the lack of power in this study, statistically significant associations between the use of both products was not observed and further investigation is necessary.

#### Strengths and Limitations

The major strengths of this study include the large sample size used for the crude and adjusted analyses and the variety of data that was collected for understanding how health product utilization impacts diarrheal prevalence and other important health indicators of children between 6 and 35 months in Nyando District. As a result, a variety of health outcomes within this study population can be evaluated using the data from the 42-month follow-up survey. Additionally, clinical measurements of health status were a major strength of this study. Anthropometry, hemoglobin measurements, and blood smears collected from study participants were straight-forward and removed the likelihood of misclassification bias in reference to health outcomes among study participants.

Cleaning essential variables in the dataset was also convenient due to the fact that data was double-entered into two separate databases and cluster forms and a sampling frame were provided for reference.

There were some limitations to this study that were inherent as a result of study design and the methods used for data collection and analysis. First, significant amounts of information for the different predictor variables were missing, causing the initial sample size used for analysis to be reduced by approximately 18.3%. Similarly, eligible children were also excluded during the enrollment phase of the study due to refusal by the respondent or head of the household or because of loss to follow-up after three visits by enumerators. As a result, the power of the analysis was diminished and analysis was liberally conducted at the 90% confidence level. Still, p-values for important predictors of diarrhea remained small and very close to 0.05, even at 90% confidence.

Severity of diarrhea could not be evaluated because data regarding reason for hospitalization was unavailable on 11 of 24 children who reported hospitalization in the past two weeks. As a result, it is possible that there is underreporting of hospitalization due to diarrhea in this population.

One major limitation of this study was that neither "current use" nor "ever use" of WaterGuard and Sprinkles were optimal gauges of product utilization as they fail to measure "continuous use." Continuous use would be more reflective of product utilization over time and clearer associations would likely be observed. However, due to the lack of variables that measured "continuous use," current use was chosen as the exposure of interest.

Although chlorine testing was conducted in the field among 636 households in the study population, we cannot verify that households were using WaterGuard and not an alternative chlorine disinfectant, such as PUR, which is also distributed by SWAP vendors in Nyando District. Likewise, no information in this existing dataset establishes when disinfection was conducted in households where testing chlorine residual for chlorine residual was conducted. Furthermore, it is not possible to determine whether chlorine disinfection within households is conducted regularly.

With the exception of laboratory and clinical data that was collected and analyzed by NICHE enumerators and investigators, data on diarrhea within the past 24 hours and product utilization were dependent on respondent recall. As a result, there is a possibility of both misclassification of the exposure and outcome due to recall bias introduced by participants. Consequently, estimates of association may be inflated as a result of intentional and unintentional overreporting by participants.

#### **Conclusions and Recommendations**

Although the study's inability to generalize to the Kenyan population at the national level could be viewed as a limitation, the purposes of this report were to evaluate how the use of WaterGuard and Sprinkles impacted diarrheal prevalence within a population where SWAP activities have been ongoing since 2007 and Sprinkles utilization in particular has shown efficacy in improving child health status. The results of this study indicate a statistically significant association between the use of WaterGuard and diarrhea in the past 24 hours. Although use of both WaterGuard and Sprinkles and Sprinkles alone showed a protective effect against diarrhea, we did not find any statistically significant associations with reduction in diarrheal prevalence at the 90% confidence level among these two exposure groups. We also found that frequent users of Sprinkles had statistically significant reductions in diarrhea in comparison to non-users.

We recommend that future studies consider product use as a continuous exposure to better understand patterns and regularity of utilization practices. It would also be informative for future studies to investigate trends of diarrheal prevalence over time by evaluating data from the 12 and 24-month follow-up surveys in conjunction with the 42-month follow-up.

Until now, a detailed assessment of the factors influencing diarrhea among children between 6 and 35 months in this population has not been conducted. As a result, we hope that the findings presented here will help uncover important associations between the use of WaterGuard and Sprinkles and diarrheal disease. Furthermore, it is our goal that our findings will influence future research and regional policies to help improve child health in western Kenya.

# **Figure 1. Selection of Subjects for 42-Month Follow-up Survey**



	Respondents (%)
No. Children Enrolled (N)	882
No. Children Analyzed (n)	849
No. Households Analyzed	729
Mean No. of Children per Household	1.16
Mean No. of Households per Cluster	12.15
Sex	
Boys	428(50.9)
Girls	421 (49.1)
Mean Child Age (months)	21.4
Median Child Age (months)	23
Mean Child Age per Household (months)	21.5
Household Socioeconomic Status"	
Poorest	124 (17.4)
Second Poorest	167 (22.9)
Third Poorest	192 (26.4)
Fourth Poorest	117 (16.1)
Wealthiest	128 (17.6)
Own Home <sup>c</sup>	711 (97.5)
Rent Home <sup>c</sup>	21 (2.9)
No. of Households with electricity <sup>c</sup>	12 (1.6)
Maternal Education per Household	
None	12 (1.6)
Some or Completed Primary School	595 (81.6)
Some or Completed Secondary School	113 (15.5)
Any Higher Education <sup>d</sup>	5 (0.7)
Hygiene and Sanitation Indicators	
Households with Soap	650 (89.2)
Households with access to a flush toilet or latrine <sup>e</sup>	537 (73.7)
Households whose drinking water source is piped water	90 (12.3)

# **Table 1. Household and Individual Demographics**

<sup>a</sup>Household SES was based on a Principle Components Analysis of the matriarchal unit developed by the World Bank. Variables included in the Household SES included the possession of material goods such as radios, televisions, refrigerators, bikes, cars, motorcycles, land lines, mobile phones, the hiring of domestic workers, flooring, roof, and wall material, presence of electricity in home and home ownership status

<sup>b</sup> 728 households represented here because ses differed between 2 children residing within the same household.

<sup>c</sup> These variables have already been considered in the Household SES, but are being presented here for informational purposes.

<sup>*d</sup>* Any trade school or university <sup>*e*</sup> Only 7 households reported the possession of a flush toilet</sup>

# Table 2. Crude Measurements of Adverse Health Outcomes Among **Respondents**

	N (%)
Has this child had diarrhea within last 24-hours? <sup>a</sup>	
Yes	207 (24.4)
No	634 (74.7)
Has this child been hospitalized in the past 2 weeks (14 days)?	
Yes	24 (2.8)
No	817 (96.2)
No. of Children Hospitalized for Diarrhea <sup>b</sup>	2
Mean Hemoglobin per Child	9.65
No. Children Who are Anemic (Hb ≤ 10.9)	595 (70.1)
No. Children Who are not Anemic (Hb ≥ 11.0)	235 (27.7)
No. Children Stunted (height-for-age z-score <-2 SD)	254 (29.9)
No. Children Wasted (weight-for-height z-score <-2 SD)	32 (3.8)
No. Children Underweight (weight-for-age z-score <-2 SD)	105 (12.4)
No. Children with Positive Malaria Smear <sup>c</sup>	268 (31.6)
Observed Bednet in Household <sup>d</sup>	
Present	668 (91.6)
Absent	56 (7.7)

<sup>*a*</sup> Diarrhea indicative of  $\geq$  3 loose or watery stools in a 24-hour period

<sup>b</sup> n(missing) = 11 <sup>c</sup> Determined via laboratory testing of blood spots for Malaria <sup>d</sup> 4 households refused to let enumerators observe bednets and data is missing on 12 households

	N (SD)
Household WaterGuard Use	
Have you ever treated your water with WaterGuard?	
Yes	699
No	29
Is the water in your household drinking water currently treated with WaterGuard?	
Yes	373
No	310
Drinking water tested for chlorine residual	
Present	120
Absent	516
Sprinkles Use	
Has this child ever used Sprinkles?	
Yes	494
No	340
Has this child consumed Sprinkles within the past 24 hours?	
Yes	93
No	742
	1.06
Median number of Sprinkles sachets consumed over last 7 days per child <sup><math>a</math></sup>	(±2.43)

# **Table 3. WaterGuard and Sprinkles Utilization Among Respondents**

<sup>a</sup> The recommended number of Sprinkles sachets to be consumed per day is 1 (per week is 7).

# <u>Table 4. "Current Use" of WaterGuard and Sprinkles at Household</u> <u>and Individual-Levels</u>

Current Use <sup>a</sup>	Number Respondents	Number Eligible Children	Number of Households
Using WaterGuard			
Yes	/95	428	373
No		367	310
Using Sprinkles			
Yes	835	93	N/A
No		742	N/A

<sup>a</sup> Current use of Sprinkles is indicative of use by the child within the past 24 hours prior to survey administration. Current use of WaterGuard is indicated by the respondent reporting use of WaterGuard to treat current household drinking water.

N/A = not applicable

# **Table 5. Exposure Categorized by "Current Use"**

Exposure Groups ("Current Use")	Number Eligible Children	Number Households
Use Sprinkles Only	22	22
Use WaterGuard Only		
	355	314
Use Both	70	63
Use Neither	342	291
Total	789	690

# <u>Table 6. Comparison of Diarrheal Prevalence Among Utilization</u> <u>Groups</u>

Group	N (%)	% Diarrhea in Past 24 Hours	Adjusted OR (90% Cl)	p-value
Do not use WaterGuard or Sprinkles	342 (43.4)	28.9		<0.0001
Use both WaterGuard and Sprinkles	70 (8.9)	20.0	0.614 (0.302-1.246)	0.2567
Use WaterGuard Only	355 (45.0)	21.1	0.657 (0.505-0.856)	0.009
Use Sprinkles Only	22 (2.8)	13.6	0.388 (0.160-0.939)	0.078

Sprinkles Dose <sup>a</sup>	N (815)	% Diarrhea in Past 24 Hours	Adjusted OR <sup>b</sup> (90% CI)	P-Value
None (0 sachets)	635	25.0	-Reference-	N/C
Infrequent (between 1 and 4 sachets)	88	28.4	1.188 (0.771-1.830)	0.5118
Frequent (≥ 5 sachets)	92	15.2	0.537 (0.292-0.990)	0.0945*

## **Table 7. Percent Diarrhea per Sprinkles Dose Groups**

<sup>a</sup> Dose based on number of Sprinkles sachets consumed within past 7 days

<sup>b</sup> Adjusted for clustering at village-level

N/C = not calculated

\*p<0.10

# **Graph 1. Percent Diarrhea Among Non-users, Infrequent Users, and Frequent Users of Sprinkles**



Variable	N (841)	% Diarrhea in Past 24 hours	Unadjusted OR (90% CI)	Adjusted OR (90% CI) $(N = 761)^{a}$	Adjusted P-value
Sex			1.118	1.118 1.245	
Male <sup>‡</sup>	100	23.58	(0.859 -	1.345	0.1483
Female	107	25.66	1.455)	(0.904-1.870)	
Age			0.679	1 261	
<24 months	128	27.83	(0.518-	1.201	0.2282
≥24 months <sup>‡</sup>	79	20.73	0.888)*	(0.919 1.729)	
SES			0.712	1 406	
Quintiles 1-3	147	26.73	(0.535-	(0.953-2.075)	0.1490
Quintiles 4-5 <sup>‡</sup>	60	20.62	0.948)*	(0.955 2.075)	
Maternal Education			0.721	1.510	
<= Complete primary school	180	25.50	0.731 (0.496-1.077)	1.512 (0.881-2.595)	0.2083
>= Some secondary school <sup>‡</sup>	26	20.00	(0.490-1.077)	(0.001-2.393)	
Attended launch			0.074	1.155	
Yes‡	81	23.14	0.874	1.155	0.4883
No	125	25.61	(0.008-1.145)	(0.820-1.027)	
<b>Received promotional item</b>			0.942	1.072	
Yes‡	145	23.73	(0.631 - 1.127)	1.003 (0.713-1.585)	0.8012
No	62	26.96	(0.031-1.127)	(0.713-1.385)	
Treat drinking water with WaterGuard			0.808	1.231 (0.758-1.999)	0.4803
Yes‡	176	24.08	(0.555-1.178		
No	31	28.18			
Ever used WaterGuard			0.075	1.110	
2666 Yes	199	24.60	0.975	1.449	0.5626
No‡	8	25.00	(0.492-1.955)	(0.303-4.131)	
Ever used Sprinkles			0.7/7	1.198	0.3915
Yes‡	112	22.67	(0.588-1.002)		
No	94	27.65	(0.388-1.002)	(0.847-1.090)	
Sprinkles Dose in Past 7 Days				Poforonco	N/C
None <sup>‡</sup>	159	25.04		-Kelefelice-	IN/C
Infrequent	25	28.41	0.812 (0.654-1.007)	1.176 (0.695-1.990)	0.6111
Frequent	14	15.22		0.666 (0.364-1.216)	0.2666
Stunted			1 1 1 1	0.041	
Yes	65	25.90	1.114	0.941	0.7763
No <sup>‡</sup>	13	23.88	(0.037-1.402)	(0.000-1.340)	
Wasted			2.501	2.501	1
Yes	14	43.75	(1.370 - 1.994)	0.1250	
No <sup>‡</sup>	190	23.72	4.566)*	(0.931-4.179)	
Anemic	_		1.316	1.364	0.1523
Yes	152	25.85	(0.969-1.788)	3) (0.955-1.950)	

# Table 8. Factors Associated with Diarrhea in Past 24 Hours at 42-month Follow-up

No‡	49	20.94			
Chlorine Residual			1.262	1.516	
Present	40	30.08	1.362	(0.995-2.310)	0.1041
Absent <sup>‡</sup>	144	24.00	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		

<sup>*a*</sup> Adjusted for clustering at village-level

\*Statistically significant OR, logistic regression p <0.10 \*Reference

Reference

N/C = not calculated

# Table 9. Assessment of Potential Confounders and Interaction Terms:Identification of Variables Associated with Both the Outcome andExposure

Variable	Diarrhea	Utilization
	(Chi-square)	(Chi-square)
Sex	0.4850	0.5505
Age	0.0175*	0.8196
SES	0.0504*	0.5336
Maternal Education	0.1815	0.0007*
Attendance at SWAP Events	0.4124	<.0001*
Receipt of Promotional Items	0.3332	0.0007*
Use WaterGuard to Treat Drinking Water	0.3514	<.0001*
WaterGuard Use Ever	0.9587	
Sprinkles Ever Use	0.1016	<.0001*
Sprinkles Dose in Past 7 Days <sup>‡</sup>	0.0772*	<0.0001*
Stunting	0.5353	0.0415*
Wasting	0.0098*	0.9409
Anemia Status	0.1394	0.7383
Chlorine Residual in Household Drinking Water	0.1438	<.0001*

\*Statistically significant, p <0.10

\*Possibility of confounding and/or interaction and 90% confidence level

# **Table 10. Covariates Included in the Reduced Logistic Model**

Odds Ratio	90% Confidence Interval	Chi-square p-value*
0.650	0.313 - 1.350	0.3324
0.645	0.470 - 0.855	0.0224
0.586	0.221 - 1.558	0.3687
1.360	1.010 - 1.831	0.0891
1.499	1.133 - 1.982	0.0172
1.535	1.029 - 2.289	0.0778
2.142	1.059 - 4.332	0.0754
1.742	1.150 - 2.639	0.0280
	Odds Ratio 0.650 0.645 0.586 1.360 1.499 1.535 2.142 1.742	90%       Odds Ratio     Confidence Interval       0.650     0.313 - 1.350       0.645     0.470 - 0.855       0.586     0.221 - 1.558       1.360     1.010 - 1.831       1.499     1.133 - 1.982       1.535     1.029 - 2.289       2.142     1.059 - 4.332       1.742     1.150 - 2.639

\*p < 0.10

	Exposure Levels <sup>a</sup>		
	Use WaterGuard and Sprinkles	Use WaterGuard Only	Use Sprinkles Only
Crude ORs	0.650	0.645	0.586
(90% CI)	(0.313 -0.1350)* (0.470 - 0.885)*		(0.221 - 1.558)
	Adjusted ORs for Potential Confounders (90% CI)		
Sex (female vs male)	0.635	0.650	0.600
	(0.306 - 1.318)	(0.471 - 0.896)*	(0.226 - 1.590)
Age $(< 24 \text{ menths})$ ( $> 24 \text{ menths})$	0.659	0.637	0.582
Age (< 24 months vs 224 months)	(0.316 - 1.374)	(0.466 - 0.871)*	(0.232 - 1.458)
SES (lower SES vs higher SES)	0.661	0.638	0.561
SES (IOWEI SES VS Higher SES)	(0.323 - 1.353)	(0.466 - 0.873)*	(0.219 - 1.436)
Wasting (wasted vs pat wasted)	0.647	0.642	0.603
wasting (wasted vs not wasted)	(0.312 - 1.342)	(0.467 - 0.882)*	(0.214 - 1.697)
Chlorine Residual in Drinking	0.782	0.746	0.598
Water (present vs absent)‡	(0.372 - 1.643)*	(0.551 - 1.011)*	(0.235 - 1.527)

# **Table 11. Assessment for Confounding in the Reduced Model**

<sup>a</sup> Reference group: Uses neither WaterGuard nor Sprinkles

\*Statistical Significance at Exposure Level, p < 0.10

<sup>‡</sup>Confounder

# **Table 12. Exposure and Predictor Variables Included in the Final Model of Product Utilization and Prevalence of Diarrheal**

Variables	Adjusted OR (90% CI) <sup>a</sup>	P-value
Use Neither WaterGuard nor Sprinkles	-Reference-	N/A
Use WaterGuard and Sprinkles	0.614 (0.297 - 1.268)	0.2688
Use WaterGuard Only	0.623 (0.455 - 0.854)	0.0136*
Use Sprinkles Only	0.575 (0.219 - 1.508)	0.3452
Chlorine Residual in Drinking Water (Present vs Absent)	1.613 (1.077 - 2.417)	0.0515*

<sup>*a*</sup> Adjusted for clustering

\*Statistically significant p-value, logistic regression p <0.10

N/A = not applicable

# **APPENDIX A**

# Figure A1. Nyando District Kenya<sup>h</sup>



# **Table A1. Number of Households Reporting Visitation by a SWAP** <u>Vendor</u>

Visited by a SWAP Vendor	Number of Households (%)*
Yes	287 (39.6)
No	425 (58.6)

\*13 missing

# **Table A2. Percent of Households Reporting having Purchased SWAP Products**

SWAP Products	Number of Households Who Purchased Product (%)
WaterGuard	188 (25.9)
PUR	39 (5.4)
Modified Clay Pot	2 (0.28)
Insecticide-treated Bednet	58 (8)
Condoms	4 (0.55)
Sprinkles	220 (30.3)
Fortified Flour	5 (0.69)
Soap	67 (9.2)
Savlon	5 (0.69)

# <u>Table A3. "Ever Use" of WaterGuard and Sprinkles at Household and</u> <u>Individual-Levels</u>

Ever Use <sup>a</sup>	Number Respondents	Number Eligible Children (%)	Number of Households	
Using Sprinkles				
Yes	834	494 (59.2)		
No		340 (40.8)		
Using WaterGuard				
Yes	841	809 (96.2)	697	
No		32 (3.8)	28	

<sup>a</sup> "Ever use" represents a respondent reporting "Yes" to having ever used the product in the past.

# **Table A4. Exposure Categorized by "Ever Use"**

Exposure Groups ("Ever Use")	Number Eligible Children	Number Households
Use Sprinkles Only	10	9
Use WaterGuard Only	318	293
Use Both	484	439
Use Neither	22	20
Total	834	761 <sup>ª</sup>

<sup>*a*</sup> Sprinkles use was gauged at the individual level, resulting in an overestimation of the total number of households.

# <u>Table A5. Manual Hierarchal Backward Elimination of Variables<sup>‡</sup></u> <u>from Full Model to Final Model</u>

Model	AIC	Likelihood Ratio	% Concordant	Variable(s) Eliminated
cat, sex3, age, ses, edu, anemic, stunted, wasted, attend, recstat, spuse, wguse, usewg, chlor, sprkdose, sex3*cat, age*cat, ses*cat, edu*cat, attend*cat, recstat*cat, chlor*cat, sprkdose*cat	717.998	0.0094	69.5	wguse
cat, sex3, age, ses, edu, anemic, stunted, wasted, attend, recstat, spuse, usewg, chlor, sprkdose, sex3*cat, age*cat, ses*cat, edu*cat, attend*cat, recstat*cat, chlor*cat, sprkdose*cat	720.223	0.0072	69.4	ses*cat
cat, sex3, age, ses, edu, anemic, stunted, wasted, attend, recstat, spuse, usewg, chlor, sprkdose, sex3*cat, age*cat, edu*cat, attend*cat, recstat*cat, chlor*cat, sprkdose*cat	717.082	0.0057	69.4	chlor*cat
<pre>cat, sex3, age, ses, edu, anemic, stunted, wasted, attend, recstat, spuse, usewg, chlor, sprkdose, sex3*cat, age*cat, edu*cat, attend*cat, recstat*cat, sprkdose*cat</pre>	717.29	0.0099	68.3	attend*cat
cat, sex3, age, ses edu, anemic, stunted, wasted, attend, recstat, spuse, usewg, chlor, sprkdose, sex3*cat, age*cat, edu*cat, recstat*cat, sprkdose*cat	715.468	0.0107	67.3	sprkdose*cat
cat, sex3, age, ses, edu, anemic, stunted, wasted, attend, recstat, spuse, usewg, chlor, sprkdose, sex3*cat, age*cat, edu*cat, recstat*cat	715.709	0.0189	65.9	stunted
cat, sex3, age, ses, edu, anemic, wasted, attend, recstat, spuse, usewg, chlor, sprkdose, sex3*cat, age*cat, edu*cat, recstat*cat	713.717	0.0138	65.9	spuse
cat, sex3, age, ses, edu, anemic, wasted, attend, recstat, usewg, chlor, sprkdose, sex3*cat, age*cat, edu*cat, recstat*cat	713.381	0.0099	65.8	sprkdose
cat, sex3, age, ses, edu, anemic, wasted, attend, recstat, usewg, chlor, sex3*cat, age*cat, edu*cat, recstat*cat	738.967	0.0069	65.6	recstat, recstat*cat
cat sex3 age ses edu anemic wasted attend usewg chlor sex3*cat age*cat edu*cat	733.913	0.0033	65.0	usewg
cat, sex3, age, ses, edu, anemic, wasted, attend, chlor, sex3*cat, age*cat, edu*cat	731.992	0.0022	64.7	anemic
cat, sex3, age, ses, edu, wasted, attend, chlor, sex3*cat, age*cat, edu*cat	745.751	0.0033	64.3	sex3*cat
cat, sex3, age, ses, edu, wasted, attend, chlor, age*cat, edu*cat	740.846	0.0011	64.2	age*cat
cat, sex3, age, ses, edu, wasted, attend, chlor, edu*cat	739.429	0.0010	63.8	edu, edu*cat
cat, sex3, age, ses, wasted, attend, chlor	745.349	0.0025	61.6	attend
cat, sex3, age, ses, wasted, chlor	745.906	0.0028	60.4	final model

<sup>\*</sup> Variable definitions: **cat**= exposure categories (3-level), **sex**=sex, **age**=child age in months,

wasted=<-2 SD, attend=attendance at SWAP events, recstat=receipt of promotional items, spuse=Sprinkles "ever use,"wguse=WaterGuard "ever use," usewg=use WaterGuard to make water safe, chlor=chlorine residual in household drinking water, sprkdose=number of Sprinkles sachets consumed in past 7 days (3-level), sex\*cat=interaction between sex and exposure, age\*cat=interaction between age and exposure, ses\*cat=interaction between socioeconomic and exposure, edu\*cat=interaction between maternal education and exposure, attend\*cat=interaction between attendance at SWAP events and exposure, recstat\*cat=interaction between receipt of promotional items and exposure, chlor\*cat=interaction between chlorine residual in household drinking water and exposure, sprkdose\*cat=interaction between Sprinkles dose and exposure

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