Evaluating the Effectiveness of a Latrine Intervention on Childhood Diarrheal Health in Nyando District

BY

COURTNEY BABB
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THESIS

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Defense Committee:

Dr. Supriya Mehta, Epidemiology
Dr. Ronald Hershow, Epidemiology
Dr. Ira Heimler, Environmental Health Science

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TABLE OF CONTENTS

CHAPTERS **PAGE**

LIST OF TABLES

LIST OF ABBREVIATIONS

CBT	Compartment Bag Test
CHW	Community Health Worker
CLTS	Community Led Total Sanitation
DALYS	Disability Adjusted Life Years
JTU	Jackson Turbidity Units
MUAC	Middle Upper Arm Circumference
MOPHS	Ministry of Public Health and Sanitation
MDG	Millennium Development Goal
NTU	Nephelometric Turbidity Units
ODF	Open Defecation Free
SAS	Statistical Analysis System
UN	United Nations
WHO	World Health Organization
YLD	Years Lost to Disability

SUMMARY

A study to measure the effectiveness of the Community Led Total Sanitation latrine intervention in Nyando District, Kisumu County, Kenya was conducted using a condensed cohort study approach. Interviews were administered with 210 parents or caregivers in the 100% latrine using community and 216 parents or caregivers in the non-latrine using community at the household level. The survey ascertained information on childhood diarrhea illness, water safety, latrine behaviors, breastfeeding, demographics, hygiene, behaviors, and co-morbidities. Water testing was conducted to determine *E. coli* and turbidity levels for 55 water sources in the locations. Anthropometric data was obtained for each child subject.

The non-ODF community had a non-significant slightly higher risk of diarrhea compared to the ODF community. Covariates including childhood HIV positivity, children stool disposal, and income were positively associated with diarrhea in the non-ODF community. The non-ODF location had safer water than the ODF, suggesting that the lack of association between ODF status and childhood diarrhea might due to unsafe water in the ODF community.

II. INTRODUCTION

A. Background

Diarrheal disease accounts for 9% of deaths in children under five years old. Kenya ranks amongst the top 15 countries in the world with the highest diarrheal disease burden (UNICEF, 2013). The majority of infections occur in Kenya's western Nyanza Province, where the under-five mortality rate is approximately 149 deaths per 1,000 live births (KNBS, 2008; UNICEF: ESARO, 2012). Kenya's 2008 health demographic survey reports a diarrheal disease prevalence of 16.2% two weeks preceding the survey in the Nyanza province location. "The World Health Organization's (WHO) Millennium Development Goal (MDG) #4 aims to reduce the child under five mortality rate by two thirds between 1990-2015, with diarrheal disease being a major cause of morbidity and mortality in the report". "Kenya is currently falling short of the goal with 98 deaths per 1,000 live births in 1990 and 73 deaths per 1,000 live births in 2014. The WHO's 2015 MDG goal is 33 deaths per 1,000 live births" (The Lancet, 2014). The WHO endorses behaviors to reduce diarrheal disease in under-fives. Improved sanitation and hygienic practices through latrine use and clean water sources are amongst the list of improved behaviors endorsed by the WHO (UNICEF, 2013).

Adequately disposing of human excreta is a major component of improving sanitation practices and hygiene in high diarrheal disease prevalent areas. Improved sanitation practices can reduce diarrheal disease rates by 32%-37% (Mara et al., 2010). Countries that practice open defecation have the highest number of under-five deaths (WHO, 2014). Community Led Total Sanitation (CLTS) is an approach where communities analyze their sanitation situation in order to build latrines in individual households to become open defecation free. This intervention was created in lieu of governmental organizations building latrine structures without influencing behavioral change in the communities (Mara et al., 2010). Sub-Saharan Africa showed an 11% decrease in diarrheal illness between 1990 and 2012 since the United Nations called for interventions to eliminate open defecation practices by 2025 (WHO, 2014). Although, Kenya's 2008 Demographic Health Survey states that diarrheal disease in less common among children with private facilities in households compared with those without private facilities, further studies are needed to quantify the incidence of disease. Community led total sanitation allows comparison between defined open defecation free (ODF) and non open defecation free communities (non-ODF), which is an optimal situation for comparing health outcomes among children. The majority of studies analyzing latrine interventions with health and behavioral outcomes were performed in India. There are a limited number of studies assessing the effectiveness of CLTS in Africa.

Removing feces from the environment reduces fecal contamination of water sources and drinking water in the community. Diarrhea disease is reduced when fecal contamination is limited (Patil et al., 2014). Flooding is a contributor to water contamination in the Nyanza Province during the rainy season (Tiondi, 2000). Few studies have evaluated water quality differences between ODF and non-ODF communities in CLTS areas in Sub Saharan Africa. Obtaining measures of fecal bacteria and turbidity from local water sources can determine the effectiveness of pit latrine usage using water quality analysis techniques.

Risk factors and etiology information for childhood diarrhea is limited in Sub Saharan Africa. Previous studies have cited malnutrition, HIV status, breastfeeding, water fetching distance, poor hygiene or diet, younger age, and factors relating to the caregiver of the child are likely to increase the spread or severity of diarrheal disease. (Arvelo et al., 2010; Gascon et al., 2000; Kahabuka et al., 2009; O'Reilly et al., 2012; Peter & Nkambule, 2012; Someswara et al., 1959; Strand et al., 2012). Strand et al. (2012) found that not being breast fed was associated with a 9.3 increased odds of having prolonged diarrheal illness for children under five. Determining risk factors for morbidity and mortality due to diarrheal disease is an important factor for evaluating CLTS' effectiveness. Comparing risk factors in children under five years old between communities will help to identify factors that cause diarrhea in the communities with and without latrine usage.

B. <u>Statement of the Problem</u>

Improving child health is the overall intent of environmental sanitation improvement programs. Determining the success of environmental improvement programs such as latrine programs is important for understanding the success of the program. Reducing diarrheal disease in children is a clear indicator of latrine program success. The identification of risk factors for diarrhea in children in latrine intervention communities allows for improvement in program implementation and sustainability for the future. High risk groups should be targeted in order to implement further sanitation and hygiene programs to lower diarrheal disease incidence. Latrine programs are new in Sub-Saharan Africa; as a result, there is a lack of studies analyzing latrine program success in the intervention areas. Previous studies were non-inclusive in terms of exposures and health measures or were confounded by study methodology shortcomings.

C. <u>Preliminary Study</u>

I conducted a study in the Nyando district of Kisumu County, Kenya in the fall of 2012. Childhood diarrheal incidence rates between ODF and non-ODF communities were compared. Demographic subgroups with higher rates of diarrheal illnesses in children were identified. The study showed no difference in diarrheal incidence between latrine and non-latrine usage groups. Further studies are needed to improve study quality, methodology, and to reduce biases and confounders. True understanding of diarrheal rates and risk factors will improve latrine interventions in the Nyando, Kenya community.

D. <u>Scientific Rationale of the Study</u>

Globally, diarrhea is the leading cause of mortality among child under age 5. Recent systematic reviews estimate approximately 1.87 million deaths per year on average (95% CI: 1.56-2.19) worldwide due to diarrheal illness. Diarrhea accounts for 19% of child deaths, with 78% of all diarrhea deaths occurring in the developing world (Boschi-Pinto et al., 2008; Irish et al., 2013). Kenya has an under-five mortality rate of 71 deaths per 1,000 live births (UN, 2014). The majority of premature deaths occur in Kenya's western Nyanza Province, where the under-five mortality rate is 149 deaths per 1,000 live births (UN, 2012). Kenya's most recent countrywide demographic survey reported a diarrheal disease prevalence of 16.2% two weeks preceding the survey in child under five in the Kisumu County region (KCBS, 2008). The World Health Organization defines diarrheal disease as the passage of unusually loose or watery stool, at least three times a day during a 24 hour period. Childhood diarrheal episodes can be categorized into acute or chronic illness (WHO, 2005). The most commons pathogens responsible for acute diarrheal episodes in children in developing countries include: rotavirus, diarrheagenic *Escherichia coli*, Shigella *spp.*, *Salmonella spp.*, *Campylobacter jejuni/coli*, *Vibrio cholerae*, *Aeromonas spp.*, and *Plesiomonas spp*. Protozoa and helminthes infections are also common developing areas where environmental sanitation is limited (O'Ryan et al., 2005). Clinical based stool testing in western Kenya isolated *Shigella spp.*, *Campylobacter spp.*, diarrheagenic *Escherichia coli.*, *Salmonella spp.*, and *Vibrio cholerae* 01 from 1997-2003 in both adults and children (Shapiro et al., 2001; Brooks et al., 2006).

Murray and López define disability adjusted life years (DALYs) as "capturing years of potential life lost (YPLL) to diseases and conditions with years lost to disability (YLD) with nonfatal diseases, conditions, or injuries" (Lopez & Murray,1998; Guerrant et al., 2002). Current estimates for worldwide diarrheal disease DALYS in children aged 0 to ≤4 years old assume 1.3 million DALYs, representing 1% of total 100.9 million global diarrheal DALYs. Long term disability in children with early diarrheal episodes includes growth shortfalls, fitness impairment, cognitive impairment, and school performance shortcomings. Early childhood diarrhea disabilities were evaluated using cryptosporidial infections (Guerrant et al., 2002). Other consequences of childhood diarrheal disease are severe malnutrition (marasmus or kwashiorkor), systemic infections, dehydrations, heart failure, and mineral deficiencies (Thapar & Sanderson, 2004; WHO, 2005).

According to the World Bank, "environmental health refers to aspects of human health, including quality of life, that are determined by physical, biological, social, and psychological factors in the environment". "Hazards related to poverty and under development include lack of safe water, inadequate sanitation and waste disposal, indoor air pollution, and vector-borne diseases" (World Bank, 2000; Mundial, 2001; Shyamsundar, 2002; Scott, 2006; Chai, 2009). "Respiratory infections and diarrheal diseases are the two biggest causes of death among the poorest 20% of the worlds countries a ranked by national GDP per capita" (Gwatkin & Heuveline, 1999; Shyamsundar, 2002; World Bank, 2000). Recent systematic reviews report greater proportions of severe diarrhea and pneumonia episodes in "African regions (26% and 30%, respectively). The highest numbers of childhood deaths (0-4 years) were in sub-Saharan Africa for diarrhea and pneumonia in 2011 (50% and 43%, respectively)" (Walker, 2013). When considering environmental health risks, water supply and sanitation equate to 10% of DALYS in Sub-Saharan Africa, which is the highest compared to all other regions in the world (Shyamsundar, 2002). The first plausible relationship between hygiene, sanitation, and diarrhea transmission was demonstrated by John Snow in 1854 through his discovery of London's Broad Street Pump as a vehicle for cholera transmission (Snow, J., 1855; Cairncross et al., 2010). Adequate waste disposal and hygiene interventions have been considered for reducing childhood diarrheal disease since Snow's investigation (Wagner & Lanoix, 1958; Feachem et al., 1983; Esrey, S. A. et al., 1985). "To promote interventions for diarrheal disease reduction and child health, the United Nations created Millennium Development Goal (MDG) Target 7C. Target 7C aims to halve the proportion of the world's population without access to safe water and basic sanitation by 2015. Millennium Development Goal #4 hopes to reduce the under 5 mortality rate by two-thirds by 2015" (Baum, et al., 2013; Bain et al., 2014; UN, 2015). As of reaching 2015, there are still 1 billion people practicing open defecation globally. There are still 700 million people worldwide without adequate drinking water to protect from outside contamination such as fecal matter. To date, 70% of the population in Kenya is living without an adequate sanitation facility. Forty percent of the population in Kenya is living without adequate drinking water (UN, 2015; WHO; 2014).

Many interventions have been rolled out to reduce diarrheal illness through sanitation improvement following prior to the creation of the 2015 MDGs. The World Health Organization categorized sanitation facilities as either improved or unimproved to promote adequate sanitation and therefore better health. "Improved sanitation facilities include flush or pour toilets (piped sewer system, septic tank, pit latrine), ventilated pit latrines, pit latrine with slab covers and composting toilets. Unimproved sanitation includes fields, bushes, forests, bodies of water, open spaces, pit latrines without a slab, composting toilets without flush capabilities, bucket latrines, hanging latrines, shared public facilities, or open defecation" (Galan, 2013; WHO: JMP, 2014).

Latrine construction has become a major component of sanitation improvement in developing countries. Community led total sanitation (CLTS) is a latrine construction program geared towards open defecation elimination to reduce diarrheal illness. Community Led Total Sanitation is an intervention geared towards achieving and sustaining open defecation free status (ODF) in communities. Communities facilitate their own analysis of their sanitation profile, and their open defecation practices and the consequences. "Community led total sanitation helps community members to design latrines, adopt improved hygienic practices, solid waste management, waste water disposal, care, protection, maintenance of drinking water sources, and other environmental measures" (Kar & Chambers, 2008; Mirasse, 2009; Bongartz et al., 2010; Mukherjee, 2012; Obuh, 2015). The community takes action and constructs toilets themselves from local resources. The goal of CLTS is to eliminate open defecation because it assumes that if only a few individuals continue to defecate in the open it represents a risk to the whole community. Community led total sanitation is active in over 40 countries including Africa, Asia, and Latin America, and the Middle East. It is endorsed by the World Bank, UNICEF, and NGOs (Mehta et al., 2010). The intervention was introduced to Sub-Saharan Africa in 2006. The result of estimation using demographic countrywide surveys and WHO/UN data, Ethiopia, Angola, and Sao Tome and Principe had the highest reduction of open defecation prevalence from 2005-2010 (-22%, -21%, and -10, respectively). Kenya is one of 23 countries to adopt the approach as a component of their national policy. Kenya contributes 0.5% of GDP to CLTS efforts. Kenya reportedly experienced only a 1% increase in open defecation prevalence during the 5 year time period (Galan et al., 2013).

The risk of post neonatal mortality in households without latrines was 3.12 times ($p<0.01$) compared to those with latrines in Bangladesh (Rahman et al., 1985). Children admitted to a pediatric clinic in Burkina Faso were 1.51 times more likely to have unsafe stool disposal practices in the home compared to controls (95% CI: 1.09, 2.06). Human stools were more frequently observed in the yards of cases than controls (RR: 1.38; 95% CI: 0.98-1.95) (Traore et al., 1994). Latrine presence at the household was associated with a 29% reduction (95% CI: 0.54, 0.92) in diarrhea risk in western Kenya in children under 5 (Garret et al., 2008). A Cochrane review of 13 studies assessed the effectiveness of interventions to improve human excreta disposal for preventing diarrheal disease. Eleven of the thirteen studies found the intervention was protective against diarrhea in children or adults. "Study validity was compromised by non random allocation of the intervention, insufficient number of clusters, lack of adjustment for clustering, unclear loss to follow up, and reporting bias. Reviews were also found to not have rigorous methodology. Other shortcomings include language barriers and case definition variation" (Clasen et al., 2010).

I conducted a pilot study in the Ahero district of Kisumu County, Kenya in 2012. The objectives of the study were: (1) to compare incidence rates of childhood diarrhea between latrine usage and non-usage communities (ODF vs. non-ODF), (2) identify demographic subgroups with higher rates of diarrhea illness in children under 5, and to (3) increase surveillance in Nyando district areas. Diarrheal illness data was conducted using household convenience sampling covering 403 children under age 5. Diarrheal illness was recorded using a 4 day recall period. The survey included information such as demographics, signs and symptoms, and health seeking behavior. In analyses, latrine using and non-using communities reported diarrheal illness incidence of 20.5% and 20.3%, respectively ($p=0.94$). Fever was highly reported in both communities (65.9% vs. 60.0%, $p=0.59$). Parents reported more persistent diarrheal episodes in children living in latrine using communities compared to non-latrine using communities (7-8 day diarrheal episode duration: 2.5% vs. 0.00%, $p<0.01$). Among childhood diarrheal cases, parents in latrine using communities visited health facilities for their child's diarrheal episodes more often compared to non-latrine using communities (95.1% vs. 64.1%, $p<0.01$). Parents were less likely to administered oral rehydration therapy to children with diarrhea in latrine using communities compared to non-latrine using communities (51.2% vs. 70.3%, $p<0.09$). The similarity between communities was antithetical and warrants further research. Further studies are needed to address possible interviewer bias, selection bias, questionnaire and sampling improvements, and further demographic factors that can influence diarrheal disease improvements between communities. True understanding of the diarrheal disease incidence between communities will contribute to achieving sanitation goals in Africa.

III. RELATED LITERATURE AND CONCEPTUAL FRAMEWORK

A. Diarrheal Disease

1. *Definitions*

The World Health Organization (2005) defines diarrheal disease as the passage of unusually loose or watery stools, for at least three times a day during a 24 hour period. Childhood diarrheal episodes can be categorized into acute or chronic illnesses. Acute watery diarrhea is the most common form of illness and lasts less than 14 days with dehydration and weight loss being the primary health complications. Acute diarrhea can result in bloody in stools (dysentery). Dysentery episodes may damage the intestinal mucosa or cause sepsis, malnutrition, and dehydration. Persistent diarrhea is a symptom of chronic illnesses. Chronic illness lasts 14 days or longer with malnutrition, serious non-intestinal infections, and dehydration as later stage complications. Severe malnutrition (marasmus or kwashiorkor) may result in diarrheal episodes with severe systemic infection, dehydration, heart failure, and mineral deficiencies as possible complications (Thapar, & Sanderson, 2004;WHO, 2005).

2. *Etiology*

Infectious diarrheal disease pathogens cause noninflammatory or inflammatory syndromes. Noninflammatory diarrhea is caused by pathogens that affect the small intestine by adhering to the mucosa by disrupting absorption. Inflammatory diarrhea is caused by organisms targeting the lower bowel by secreting cytotoxins or invading the intestinal epithelium to cause an acute inflammatory reaction. Noninflammatory diarrhea result in frequent, large volume, watery stools. Inflammatory diarrhea results in severe cramps and frequent, small volume, bloody and mucus filled stools. (McClarren et al., 2011). Noninflammatory disease causing organisms include *Vibrio cholerae*, enterotoxigenic *Escherichia coli*, rotavirus, norovirus, *Cryptosporidium parvum*, *Giardia lamblia*, HIV-1 infection, *Staphylococcus aureus*, *Clostridium perfringens*, and *Bacillus cereus*. Inflammatory diarrhea causing organisms include by enterohemmorrhagic *Escherichia coli, Clostridium difficile*, enteroaggregative *Escherichia coli*, *Shigella spp.*, *Salmonella spp.*, *Campylobacter jejuni*, and *Entamoeba histolytica* (Navaneethan & Giannella, 2008; Dupont, 2009)

3. Pathophysiology

In healthy adults, 8-9 liters of fluid enters the intestine each day (Thapar & Sanderson, 2004; McClarren et al., 2011). "Water and electrolytes flow bi-directionally between the intestinal lumen and the blood. Fluid absorption should be greater than secretion in the small intestine. Therefore, fluid absorption disruption causes an increased volume of fluid entering the colon. Diarrhea disease occurs when the amount of fluid in the large intestine exceeds the absorption capacity of the colon" (Alam & Ashraf, 2003). Normal stool fluid losses are roughly 150 milliliters (Thapar & Sanderson, 2004).

Fluid makes up a greater proportion of a child's body compared to adults. Children have higher metabolic rates, more febrile illnesses, and infections that lead to vomiting and diarrhea symptoms. These factors cause children to be at greater risk of developing acute dehydration from fluid loss compared to adults. Loss of 8% of the body weight in extracellular fluid causes severe dehydration and loss of >15% is fatal (Whitehead et al., 1996). An infant's normal extracellular fluid volume is 25% of their body weight. A loss of 8% of body weight in extracellular fluid results in severe dehydration (Darrow et al., 1949; Harrison, 1989).

B. Diagnosis

1. Laboratory

Bacterial culture is the gold standard to identify causative organisms of diarrhea from stool specimens. Culture analysis requires 3-5 days, therefore more rapid approaches to identify toxin-inducing bacteria using PCR have been developed (Lijima et al., 2004; Gadewar & Fasano, 2005). Toxin-inducing bacteria include *Salmonella enteric, Vibro parahaemolyticus, Campylobacter jejuni*, and Shiga toxin-producing *Escherichia coli* (Gadewar & Fasano, 2005). Molecular diagnostic techniques are used primarily in research laboratories. PCR is highly sensitive and specific in detecting infections in small samples and identifying multiple infections. Different toxins, pathogens, species can be identified using genetic assays (Pawlowski et al., 2009). These methods require only 3 hours of analysis (Gadewar & Fasano, 2005). Viewing ova and parasites via light microscopy is another traditional technique. Although microscopy is low cost, its sensitivity depends on the amount of infection, specimen freshness, and experience of the microscopist (Pawlowski et al., 2009). Stool culture has been shown to be expensive and ineffective with a cost estimation of roughly $900-1,000 per positive result. The scarce availability of advanced techniques allows for stool testing to remain as the gold standard regardless of costs. Costs are reduced by selecting patients requiring testing. Testing diagnosis is necessary to guide antibacterial therapy for inflammatory diarrhea, dysentery, continued illness following hospitalization, and persistent diarrhea (Cheng et al., 2005). Advanced testing in usually limited in rural Sub-Saharan African communities because of the "high cost of equipment, lack of expertise, and false positive results from stool contaminants or poorly processed equipment" (Njume & Goduka, 2012).

2. Clinical

The World Health Organization (2005) recommends a child with diarrhea to be assessed for dehydration, dysentery, persistent diarrhea, malnutrition, and serious non-intestinal infections in order to create an appropriate treatment plan. Patient history should be obtained from the mother or caretaker. Physical examination assessment addresses alertness, dehydration symptoms, skin turgor, stool condition, malnourishment exams, and other symptoms including fever. A child's degree of dehydration determines the necessary treatment plan (WHO, 2005).

C. Treatment

The World Health Organization's (2005) objectives of treatment include: (1) preventing dehydration (2) treating dehydration (3) preventing nutritional damage and (4) reduce the duration and severity of diarrhea and the occurrence of future episodes. Three "treatment plans" have been developed depending on dehydration severity. "Treatment Plan A" is for children without dehydration. At home prevention of dehydration and malnutrition is recommended. "Treatment Plan

B” is for children with some dehydration, and plan C is for children with severe dehydration. Plan’s B and C have a higher emphasis on dehydration treatment urgency compared to plan A.

1. Oral Rehydration Solution

Oral rehydration solution (ORS) is an iso-osmolar, glucose-electrolyte + added base (citrate) solution to reverse dehydration and metabolic acidosis. Oral rehydration solution was developed in the 1970s to reduce adverse effects of severe acute infectious diarrhea (Binder et al., 2014). The goal is to replace fluid loss by increasing absorption (McClarren et al, 2011). Fluid replacement is determined by the amount of fluid lost in a child. Oral rehydration solution should be provided in between meals every 3 or 4 hours. Three to four percent fluid loss (mild dehydration) requires 30 to 50 mL per kg of body weight. Greater than five to eight percent fluid loss (moderate dehydration) should receive 60 to 80 mL per kg of body weight (Koletzko & Osterrider, 2009). Efforts to improve ORS efficacy include creating an ORS mixture to reduce stool volume. Randomized control trials have tested cereal based ORS formulations (Binder et al., 2014). The lack of widespread ORS solution is attributed to its inability to reduce stool output (Dickinson & Surawicz, 2014). Complications such as vomiting, refusal to drink, or severe dehydration can cause children to be unable to drink ORS (Alam & Ashraf, 2003).

2. Vitamins and Minerals

The WHO (2005) recommends zinc supplementation at the initiation of a diarrheal episode to reduce duration, severity, and dehydration risk. Zinc should be administered via syrup or tablets to the child every 10-14 days (WHO, 2005). Many children in developing countries have vitamin deficiencies. Zinc is important for diarrheal disease because it has roles in immunity and wound healing. Vitamin A is relevant to diarrheal illness because it has roles in epithelium maintenance (Chandra, 1991; Thapar, 2004). Zinc supplementation has been shown to reduce the incidence, frequency, and severity, and persistence of diarrheal illnesses (Baqui et al., 2002; Bhatnagar et al., 2004; Bhandari et al., 2002; Strand et al., 2002; Thapar, 2004). Current recommendations are to administer 10 mg of zinc daily for infants under 6 months and 20 mg of zinc daily for 10-14 days in children with diarrheal illness (McClarren, 2011). Zinc should be administered in combination with ORS therapy (Binder et al., 2014). Folic acid, vitamin B6, vitamin B12, vitamin C, vitamin D2, vitamin E, and other minerals are also recommended during illness (Alam, 2003).

3. *Probiotics*

The WHO defines a probiotic as a "live microbial food ingredient" that is beneficial to health. Probiotics are shown to alleviate lactose intolerance symptoms, immune enhancement, reduce diarrheal illness duration, decrease mutagenicity of intestinal contents, decrease decal bacterial enzyme activity, and prevent recurrence of bladder cancer (Salminen, 1998; Alam, 2003; McClarren, 2011). The organisms are an emerging alternative therapy for gastrointestinal infections (Gadewar, 2005). The mechanisms of probiotic agents to reduce diarrheal illnesses are unknown. The WHO does not currently recommend probiotic agents for treatment. A reduction of diarrhea duration has been shown for rotavirus infection, but not in bacterial related diarrheal illnesses (Koletzko, 2009). Two randomized controlled trails have shown both efficacy and no efficacy for probiotic use by comparing probiotic versus placebo treatment groups with an outcome of antibiotic associated diarrhea. Probiotics showed a reduction in incidence of antibiotic associated diarrhea by 66% (RR 0.34; 95% CI: 0.24-0.49) in 3,818 patients with no significant difference in adverse events (Johnston et al., 2012; Dickinson, 2014). Another large randomized control trial showed no benefit of probiotics when compared to the placebo group (Allen et al., 2013; Dickinson, 2014).

4. *Dietary*

The WHO (2005) recommends continued breastfeeding of infants during illness. Infants should breastfeed as often as a long as they request during diarrheal illness. Infants who are not breastfed should be given their normal milk feed or formula during diarrheal episodes. Children at least 6 months or older who eat soft food should be given cereals, vegetables, milk and additional foods throughout the diarrheal episode (WHO, 2005). The WHO (2005) states that continued feeding provides the ill child with sufficient nutrients to support continued growth and weight gain through the diarrheal episode. Continued feeding also speeds the recovery of normal intestinal infection, which supports the ability to digest and absorb nutrient. When food is restricted, diarrhea will have longer duration and the child will lose weight (WHO, 2005). A randomized control trial yogurt study showed a reduction in diarrhea duration and stool frequency in fermented formula compared to regular infant formula groups in a sample of 112 well nourished children with acute watery diarrhea (62% vs. 35% p value<0.002). A study comparing the effects of yogurt feeding and illness improvement found that acute diarrhea duration and number of stools were significantly reduced 48 hours after treatment in yogurt treatment groups compared to milk treatment groups in children (62% vs. 35%; p value = <0.002) (Boudraa al., 2001; Gadewar & Fasano, 2005).

5. *Antimicrobials*

Currently, the WHO (2005) recommends antimicrobial treatment for children with dysentery, cholera, and *Giardia duodenalis*. Concerns with using antimicrobial therapy include costs, adverse effects, resistance, and diversion of attention from other treatments such as ORS and diet. Antimicrobial use requires disease etiology diagnosis, which is often not possible in resource poor areas due to costs, lack of laboratory facilities, and experience technicians. Most infectious diarrheas are “self limiting” (resolve over a period of time) with accurate dehydration and diet management (Alam, 2003). The WHO (2005) does not recommend anti-diarrheal drugs due to possible dangerous effects in children.

D. Transmission

1. *Routes of Transmission*

“Diarrheal disease causing pathogens are transmitted via human-to-human, human-to-human multiplying in the environment, human-to-animal-to-human via environment, and animal-to-human via environmental pathways. The first pathway occurs when feces enter the environment to be ingested by a new human host. The second pathway occurs when the pathogen multiplies in the environmental and is colonized by a new human host. Thirdly, the pathogen is colonized by an animal host and released back into the environmental. Finally, pathogens that normally cycle in animals crossover and colonize humans via the environment" (Curtis et al., 2000; Rego et al., 2005; Robins, 2011).

2. Infective Dose

Infective dose data is important for enteric pathogens to assess risk and disease severity. Infective dose determines virulence or a pathogen's ability to invade a host cell. Dose response data is obtained via volunteer, animal experiment, or epidemiological feeding studies. Salmonella studies have resulted in an estimated infective dose of between 10^5-10^9 organisms in volunteer and epidemiological outbreak studies (McCullough & Eisele, 1951; Kothary & Uma, 2001). Dysentery causing *Shigella* spp. have a lower infective dose than most organisms. The most prevalent *Shigella* spp. include *S. dysenteriae*, *S. flexneri*, and *S. sonnei* with estimated infective doses of less than 10 organisms, less than 140 organisms, and less than 500 organism respectively (Levine et al., 1973; Levine et al., 1977; Black et al., 1987; Mackowiak et al., 1992; Kotloff et al., 1995; Munoz et al., 1995; Kothary & Uma, 2001). Results of multiple studies have estimated the infective dose of *Escherichia coli* to be between 10^6-10^{10} organisms depending on the strain. Volunteer and epidemiological studies of *Vibrio cholera* strains measured doses of between 10^3 and 10^9 organisms. *Campylobacter* spp. studies measured in infective doses of between 500-800 organisms. Cryptosporidium parvum studies estimated between 10-56 oocysts required for infection. One cyst of *Entamoeba coli* produced infection in studies (Kothary & Uma, 2001).

E. Risk Factors

1. Stool Disposal

Safe disposal of feces is believed to be linked to diarrhea illness. Defecation near the home was found to be associated with an increased incidence of diarrhea (Curtis et al., 2000). There was a 64% increase in diarrhea in families where there was inadequate disposal of children's stools (Stanton &

Clemens, 1987; Han & Moe, 1990; Baltazar & Solon, 1989; Curtis et al., 2000). "Unsafe disposal of stools was associated with a 50% increased risk of hospitalization with diarrhea compared with homes with a latrine (95% CI: 1.09-2.06)" (Traore et al, 1994; Curtis et al., 2000). Construction of latrines was found to reduce post-neonatal mortality rates by 68% compared to families without latrines (Rahman et al, 1985; Curtis et al., 2000).

2. Hand Washing

Washing hands with soap interrupts diarrhea disease transmission routes. Primary hand washing removes fecal matter from stools and secondary hand washing occurs prior to preparing food, handling fluids, feeding or eating (Curtis et al., 2000). The presence of soap or a designated hand washing station in the home showed that children in households with soap has 1.3 fewer days of diarrhea compared to children in households without soap (95% CI: -2.6, -0.1) (Kamm et al., 2014). "Infants living in households that received handwashing promotion and plain soap had 39% fewer days of diarrheal illness (95% CI: -61, -16) compared with infants living in control neighborhoods in a study evaluating children at high risk of death from diarrhea in Karachi, Pakistan" (Luby et al., 2009; CCMimpact, 2011; On, 2013; Seguin & Niño-Zarazúa, 2013; WHO, 2014). Water and the cost of soap limits handwashing in family settings (Curtis et al., 2000).

3. *Water Quality*

The WHO/UNICEF's Joint Monitoring Program (JMP) for Water Supply and Sanitation uses the terms "improved" and "unimproved" to categorize and monitor the adequacy of drinking water sources worldwide. The JMP (2013) defines an improved drinking water source as a structure that adequately protects from contamination (ie. fecal matter) when properly used. "Examples of improved sources include: piped water into a dwelling/yard/plot, public tap or standpipe, tubewell or borehole, protected dug well, protected spring, or rainwater. Unimproved drinking water sources include: unprotected springs/dug wells, cart with small tank/drum, tanker-truck, surface water, and bottled water" (WHO: JMP, 2014; UniCeF, 2008; GeneseoWiki, 2013; JMP, 2013; Kayser, 2013;

Cumming, 2014; Kosec, 2014; Rhiney, 2014; Schäfer, 2014; Shaheed et al., 2014; NM, 2015; SSWM, 2015). Recent meta-regression analyses showed higher protective effects on diarrheal disease in low and middle income countries for basic piped water sources when comparing improved vs. unimproved community water sources (RR 0.86, 95% CI: 0.72-1.03) (Wolf et al., 2014). An analysis of microbial water quality in Puerto Plata, Dominican Republic assessed *Escherichia coli* concentrations in household drinking water by comparing improved versus unimproved water sources. The WHO recognizes *E. coli* as a fecal indicator for bacterium to measure water safety (Baum et al., 2012; OECD/WHO, 2003). Baum et al. (2014) utilized the WHO's water quality measures for *E. coli* levels of low, intermediate, higher risk, and very high risk categories. Of the samples taken from improved water sources, 47% were high to very high risk according to *E. coli* quality measures. Of the samples taken from the unimproved water sources, 47% were high to very high risk using *E. coli* quality measures (P =0.35) (Baum et al., 2014). Flooding can also affect water quality by inducing the transmission of enteric pathogens (Parker, 2000; Milojevic et al., 2012). Diarrhea was the most common infection and cause of death (34.7%) for adults and children following the 1988 rainy season floods of Bangladesh out of 46,740 patients evaluated for the study (Yusof et al., 1991). A more recent study assessing health outcomes following 1998 flooding in Bangladesh in 517 people in two affected districts measured a prevalence of 44.3% for diarrheal illness (Kunii et al., 2002).

4. *Flies*

Multiple studies have linked flies to diarrhea incidence (Curtis et al., 2000). Enterotoxigenic *E. coli* was isolated from flies in fly pools during May and June, which are the months with the highest incidence of ETEC infections in northeastern Thailand. "The majority of flies were *Musca domestica* species with ETEC *E. coli*, *Shigella* spp., non-O1 *Vibrio cholerae*, *Vibrio fluvalis* organisms isolated from household yards (69%), animal pens (38%), bathrooms (35%), and kitchens (8%)" (Echeverria et al.,1983; Nichols, 2010). Pit latrines are used to minimize diarrheal disease, but they can also become a feeding and breeding ground for flies" (Clasen et al., 2010; Irish et al., 2013). Flies transmit enteric pathogens by landing on, or consuming fecal waste, and transporting feces on body parts or regurgitating, and defecating on human food and fomites (Graczyk et al., 2001; Irish et al., 2013). "A Tanzanian study examining the association between latrine characteristics and fly presence resulted in a positive association between the absence of a roof on a latrine and the total number of flies collected (p=0.003). A mean of 14.6 flies (95% CI: 7.6-27.8) were caught in latrines with roofs compared to 121.2 flies (95% CI: 35.5-414.0) in latrines without roofs" (Irish et al., 2013).

5. *Food-borne*

"Potential transmission pathways for food-borne disease pathogen acquisition include a lack of hand washing before food preparation and handling, unsafe food storage, consuming contaminated food, inadequate cooking and reheating, unsanitary kitchens and cooking materials, and lack of hand washing before eating or feeding children. Foodborne pathogens are easily transmitted because of the "easy route" to the digestive system and the ability of pathogens to multiply on food" (Curtis et al., 2000). Thirty-seven food poisoning outbreaks were reported to the Ministry of Health's headquarters in Kenya from 1988 to 1993. The outbreaks were identified by obtaining annual records from laboratories and district hospitals. Thirteen of the 926 cases were confirmed cases of *Staphylococcus aureus, Clostridium perfringens*, *Clostridium botulinum*, plant poisoning, and chemical poisoning. Consumed foods reported included milk and milk products, meat and meat products, maize flour, bread scones, wheat products, vegetables, and lemon pie pudding. Kenya's Nyanza province had the higher number of reported cases of cholera from 1984-1993.Seventy-five percent of cases reported in Nyanza occurred in Kisumu District, 17% in South Nyanza, and 7.4% in Siaya District. Researchers concluded the low rate of food poisoning outbreaks was attributed to under-reporting and inadequate outbreak investigation (Ombui et al., 2001). An older study examined infant weaning and food storage in West Africa. *Bacillus cereus*, *Clostridium welchii*, *Staphylococcus aureus*, *E. coli*, and

Salmonella spp. were identified from samples. Researchers determined foods stored for longer than 8 hours were too hazardous to feed to infants during the weaning process (Barrell, & Rowland, 1979).

6. *Bottle-feeding*

Milk and bottles can become contaminated with pathogenic agents if a caregiver does not wash their hands adequately before feeding a child. Possible contamination of milk and bottles influences the need for breastfeeding to protect infants against infection (Curtis et al, 2000). A study in western Ethiopia examined maternal/caregivers behaviors in relation to diarrheal disease morbidity. Two hundred eighty one (61%) of mothers/caretakers reported washing their hands after defecation, 104 (22.6%) before preparing a child's food, and 106 (23%) after cleansing their child'd feces. Study participants reported that 28.9% of children had diarrhea 2 week prior to the study date and 22.4% of diarrhea episodes had blood or mucus in stools. Bottle feeding was increased diarrheal risk 3 fold compared with children who were not bottle fed (OR 3.16; $P<0.001$; 95% CI: 1.04-9.64) (Eschete, 2009).

7. *Livestock*

Animal feces may harbor *Salmonella* spp. *Campylobacter* spp., and *Cryptosporidium* organisms. Fly attraction to animal feces is another possible route of pathogen transmission (Curtis et al., 2000). Children who were exposed to chicken, cattle, or any livestock near their households were 3 times more likely to have giardiasis episodes compared to children without livestock near their households (OR= 2.79; p-value=0.025; 95% CI: 1.14-6.85). The risk of giardiasis episodes was 4 times higher for children exposed to cattle and chickens near the household in multiple regression analysis compared to children not exposed near the household (OR=4.36; p-value=0.004; 95% CI: 1.62-11.70). Livestock contamination suggests possible personal hygiene factors associated with safe drinking water and food preparation following animal contact in Arab- Bedouin children (Coles et al., 2009). Fecal samples were obtained from cattle, buffalo, and children in the Ismailia province of Egypt to measure *Cryptosporidium* organisms. *Cryptosporidium parvum* was identified in both animals and children's stools (Helmy et al., 2014).

F. Epidemiology

Diarrheal disease occurs worldwide, but children under five years old in developing countries are exposed and affected the most because of social, economic, and environmental conditions (Black, 1984; Keush et al., 2006). "Poverty is associated with poor housing crowding, dirt floors, lack of access to clean water, adequate fecal waste disposal, cohabitation with domestic animals that may carry pathogens, inadequate food storage. Poverty can also increase a child's vulnerability to infection because of inadequate diets and medical care. Impoverished conditions increase the frequency of diarrhea and diarrhea causing pathogens" (Elhag ; Jamison et al., 2006; Keush et al., 2006; Tetteh et al., 2013).

E. coli was identified as an enterotoxin producing pathogen that causes diarrhea in animals and humans in the late 1960s. Subsequent research identified E. coli as a major cause of diarrhea in developing countries (Black, 1984).

G. Diarrheal Disease Morbidity in Children

For low and middle income countries, children experienced roughly 2.9 episodes in 2010. "Incidence rates in Sub-Saharan Africa and Latin America are greater than in Asia or the Western Pacific" (Jamison, 2006; Keush et al., 2006). Children in Africa are estimated to have approximately 3.3 diarrhea episodes per child year. This results in an estimate of 1.7 billion diarrhea episodes among children less than 5 years of age these countries. In 2010, incidence rates were highest among infants 6-11 months of age with 4.5 episodes per year. The lowest incidence rate was 2.3 episodes per year in children between the ages of 24-59 months. Africa specific diarrheal disease estimates for children ages 0-5 months, 6-11 months, 12-23 months, 24-59 months, and 0-59 months are 3.4, 5.1, 4.2, 2.7, and 3.3 per child year respectively (Walker et al., 2012). Incidence data in developing countries is limited due to inadequate surveillance and biased studies (Keush et al., 2006). Oral fecal route transmission resulting in diarrheal disease is estimated to cause 85% of DALYS in African regions among young children. Unsafe human waste disposal, unsafe water, and poor hygiene are associated with 3.7% of DALYS (Skolnik, 2008).

H. Diarrheal Disease Mortality in Children

In 2010, 4.879 million children under the age of 5 years old died of infectious diseases. Of the total number of deaths worldwide, 801,000 deaths were due to diarrheal disease. Of these 801,000 deaths, 50,000 deaths were in neonates 0-27 days old with the remainder occurring among children age 1-59 months old. The largest burden of mortality in children less than 5 years occurred in Africa with 3.6 million deaths, 2.6 million of which were due to infectious diseases (Liu et al., 2012). Worldwide mortality due to "*Shig*ella infection is estimated to be 600,000 deaths per year among children under five or a quarter to a third of all diarrhea-related mortality in this age group" (Kotloff et al., 1999; Keush et al., 2006). Fluctuation in diarrheal disease mortality estimates are due to methodological variations in data from longitudinal active surveillance studies. Reduction is diarrheal deaths in under-fives at the end of the 20th century are due to disease management recommendations such as ORS at disease onset, continued breastfeeding and complementary foods during illness, and limiting antibiotic use to dysentery cases (Keush et al., 2006).

I. Prevention

1. Exclusive Breastfeeding Promotion

The WHO (2001) defined exclusive breastfeeding as "no other food or drink, not even water is permitted, except for supplements of vitamins and minerals or minerals or necessary medicines." The optimal duration of exclusive breastfeeding is sex months (WHO, 2001). "Exclusive breastfeeding protects infants from diarrhea because breast milk contains immune specific and non-immune non-specific antimicrobial factors and exclusive breastfeeding eliminates the intakes of potentially contaminated food and water. Breast milk provides the nutrients infants need up to 6 months of age and eliminates the adverse impact diarrhea has on nutritional status” (Keush et al., 2006). When investigating the effect of exclusive breastfeeding (EBF) by HIV-infected and uninfected mothers with infant morbidity and mortality, EBF infants experienced 1.8 diarrhea events (95% CI: 1.70-2.01) compared to 15.6 diarrheal events (95% CI: 14.62-16.59) in never breastfed infants (Rollins et al., 2013). In a systematic review and meta-analyses to understand the effects of breastfeeding and diarrhea incidence, prevalence, morality, and hospitalization, “not breastfeeding resulted in an increased risk of diarrhea incidence (RR: 2.65; 95% CI: 1.72-4.07) compared to predominant breastfeeding (RR: 1.26; 95% CI: 0.81-1.95) and partial breastfeeding (RR: 1.68; 95% CI: 1.03-2.76) in infants aged 0-5 months of age. Compared to exclusive breastfeeding, predominant (RR: 2.28; 95% CI: 0.85-6.13), partial (RR: 4.62; 95% CI: 1.81-11.76), and not (RR: 10.52; 95% CI: 2.79-39.6) breastfeeding increased diarrhea mortality risk among infants 0-5 months of age. Hospitalized risk was elevated for predominantly (RR: 2.28; 95% CI: 0.08-6.55), partially (RR: 4.43; 95% CI: 1.75-13.84), and not (RR: 19.48; 95% CI: 6.04-62.87) breastfeed compared to exclusively breastfed in infants 0-5 months of age” (CHERG, 2015; Lamberti et al., 2011).

2. Rotavirus Immunization

There are an estimated 440,000 vaccine preventable rotavirus deaths per years in infants in developing countries (Parashar et al., 2003; Keush et al., 2006). In 1998, a quadrivalent Rhesus rotavirus-derived cost effective vaccine reduced the frequency of dehydrating rotavirus (Tucker et al., 1998; Glass et al., 1999; Keush et al., 2006). Setbacks with recommendation led the questioning of the quality of the vaccine (Keush et al., 2006). A hospital based case control study in Brazil evaluating rotavirus vaccine effectiveness (VA) in preventing hospital admission of children with acute diarrhea estimated 76% (95% CI: 58-56) VA after two doses lasting for two years (Ichihara et al., 2014).

3. Cholera Immunization

Cholera vaccination to reduce morbidity and mortality of children in endemic areas has been difficult to develop. “An attenuated live vaccine and a heat killed vaccine combined with recombinant cholera toxin B subunit have been licensed” (Ryan & Calderwood, 2000; Graves et al., 2001; Keush et al., 2006; Jamison, 2006). Two doses of a killed cholera vaccine in individuals 2 years and older in Zanzibar during an outbreak resulted in 79% direct protection and herd protection in non-vaccinated residents between February 2009 and May 2010 (Khatib et al., 2012).

J. Intervention

1. Community Led Total Sanitation

John Snow demonstrated the plausible relationship between hygiene, sanitation and diarrhea transmission through his discovery of London’s Broad Street Pump as a vehicle for cholera transmission in 1854 (Snow, J., 1855; Cairncross et al., 2010). Since then, adequate waste disposal and hygiene interventions have been considered for reducing childhood diarrheal disease morbidity and mortality (Wagner & Lanoix, 1958; Feachem et al., 1983; Esrey, S. A. et al., 1985). “In 2012, 2.5 billion people did not have access to an improved sanitation facility” (Luby et al., 2009; On, 2013; Seguin & Niño-Zarazúa, 2013; WHO, 2014). This measure only decreased by 7% from 1990’s data. Many of these people are located in rural areas. Open defecation is practiced by 35% of Africa’s rural population. One billion people still openly defecate in fields, forests, bushes, or in open water bodies. Increases in the number of people practicing open defecation are believed to be due to population growth. In 2013, the United Nations announced that “open defecation perpetuates the vicious cycle of disease and poverty. those countries where open defecation is most widely practiced have the highest numbers of deaths of children under the age of five, as well as high levels of under nutrition, high levels of poverty and large disparities between the rich and poor”. The United Nation’s Millennium Development Goal target number 7C aims to “halve, by 2015, the proportion of people without access to safe drinking water and basic sanitation.” Africa will need to double the proportion of the population covered by improved sanitation facilities in order to reach the goal. Nine of the countries in Africa are on track to achieve the reduction, and only 2 of 9 are in sub-Saharan Africa (Cairncross et al., 2010; JMP, 2014).

Within efforts to improve sanitation in developing countries, the United Nations Millennium Task Force on Water and Sanitation defined “basic sanitation” as the “lowest cost option for securing sustainable access to safe, hygiene, and convenient facilities and services for excreta and safe disposal that provide privacy and dignity, while at the same time ensuring a clean and healthful living environment both at home and in the neighborhood users”. The MDG definition requires low income rural area to have pit latrines (Lenton et al., 2005). Community Led Total Sanitation (CLTS) is an intervention geared towards achieving and sustaining open defecation free status (ODF) in communities. Communities facilitate their own analysis of their sanitation profile, and their open defecation practices and the consequences. “Community led total sanitation helps community members to design latrines, adopt improved hygienic practices, solid waste management, waste water disposal, care, protection, maintenance of drinking water sources, and other environmental measures” (Kar & Chambers, 2008; Mirasse, 2009; Bongartz et al., 2010; Mukherjee, 2012; Obuh, 2015). The community takes action and constructs toilets themselves from local resources. The goal of CLTS is to eliminate open defecation because it assumes that if only a few individuals continue to defecate in the open it represents a risk to the whole community. Community led total sanitation is active in over 40 countries including Africa, Asia, and Latin America, and the Middle East. It is endorsed by the World Bank, UNICEF, and NGOs (Mehta et al., 2010). The estimate cost to provide simple pit latrines for improved sanitation to the growing world’s populations is estimates to be $300 billion USD. Preventing sanitation and water-related diseases could save $7 billion per year in health system costs. Ghana and Pakistan estimate environmental condition improvements could save 8%-9% of GDP annually (Mara et al., 2010). Pour-flush latrines, ventilated improved latrines, and simple pit latrines can be constructed for an estimated $60 USD. The estimated annual cost per capita over a 5 years period is $12 USD. Intervention in Bangladesh using simple pour flush latrines costs $0.27 USD per household to construct (Skolnik, 2008). Interventions studies in Ethiopia estimated 4 days to construct a latrine at costs of 0$ to $4 USD per household (O'Loughlin et al., 2006).

K. <u>Conceptual Framework</u>

Mehta & Movik (2010) use the socio-ecological model to illustrate the dynamics of the CLTS framework. The diagram illustrates social and cultural factors that influence program implementation, ecological/environmental issues, and technological issues (See Figure 1) (Mehta & Movik, 2010).

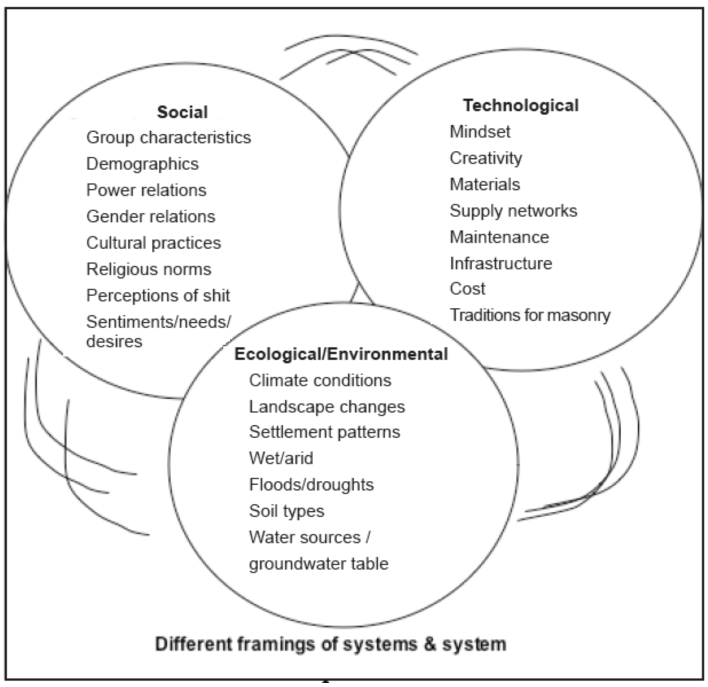

Figure 1. (Mehta & Movik, 2010)

Study methodology and health system inadequacy lead to difficulties in evaluating sanitation, hygiene, and water supply intervention programs (Cairncross et al., 1996). There is a lack of randomized control trials in excreta disposal intervention studies. Many of the studies are observational, which are subject to bias and confounding. Previous reviews did not employ the necessary rigorous methodologies and statistical methods of a typical systematic review. Language barriers, case definition variation for diarrhea morbidity are other shortcomings of current epidemiologic studies. There is little evidence regarding acceptability, scalability, and sustainability of excreta disposal interventions in rural areas (Clasen et al., 2010). Older studies (1970s-1980s) are missing measures of association values such as confidence intervals. Control selection in older case control studies was questionable. Controls groups were too similar to case groups to make adequate comparisons. Blinding was not possible in randomized control trials (RCT) because the presence of a latrine cannot be concealed. Randomization compliance in RCTs was inadequate due to low adherence to interventions, contamination in control villages, pre-knowledge of interventions in intervention villages, and larger learning curves in control villages. Initial selection of groups to receive latrine intervention could have introduced selection bias.

The studies reviewed are summarized in Table 1. The quality of studies is classified as “Good” or “Fair”, based on the following criteria: adequately defining explanatory and response variables, while maintaining internal validity, skilled study power and statistical analysis, minimizing bias and confounding, justifying public health significance, while providing a well versed manuscript. There were no studies meeting the quality definition of “Excellent”, which would have exemplified all of the above criteria at a high level with exceptional public health significance in terms of study implications. Only one of the studies reviewed provided programmatic cost estimates for latrine construction. Sixty-nine percent of latrine owners spent $0.0 on their latrine, and owners who paid spent an average of $4.0. The median cost was $0.0 and the mean was $0.80 (O’Loughlin et al., 2006). Overall, the studies found a wide range increased and decreased effects of latrines using on diarrheal health. The quality of recent studies was ranked higher than older studies. Comprehensive randomized control trials provided the most valid data, but complexities of the intervention such as adherence may have impacted the study results.

TABLE 1. STUDIES WITH LATRINES/STOOL DISPOSAL EXPOSURES OR COVARIATES AND CHILD HEALTH RELATED OUTCOMES

Reference	Year of Study	Country	Setting	Participants	Exposures/ Covariate	Outcome	Effect Size	95% CI	Study Design	Study Quality
Gascón et al.	1997	Tanzania	Rural	Children ≤5	Latrine ownership	Diarrhea	OR: 0.40	0.16, 0.94	Case control	Good
Caruso et al.	2014	Nyanza, Kenya	Rural	Primary schools	Latrine condition	School absenteeism	Proportion: 12.6%	0.10,0.15	3 arm cluster randomized trial	Good
Rahman et al.	1976-1978	Bangladesh	Rural	4 weeks to 1 year old	Latrine ownership	Post neonatal mortality	OR: 3.12	1.42, 6.86	Birth record review	Fair
Traoré et al.	1990-1991	Burkina Faso	Rural	≤ 36 months	Child stool disposal; Human stools in yards	Child diarrhea related hospital admission	OR: 1.10	0.78, 1.57	Case control	Poor
Roberts et al.	1993	Malawi	refugee camp	All Ages; Children ≤5;	Latrine; Visible feces on floor; water vessel	Diarrhea	OR: 0.86	p-value: 0.188	randomized trial	Fair

TABLE 1: STUDIES WITH LATRINE/STOOL DISPOSAL EXPOSURES OR COVARIATES AND CHILD HEALTH RELATED OUTCOMES (continued)

Reference	Year of Study	Country	Setting	Participants	Exposures/ Covariate	Outcome	Effect Size	95% CI	Study Design	Study Quality
Patil et al.	2009-2011	India	Rural	Children ≤5	Latrine ownership	Child health outcomes	7.4% v. 7.7%	Diff: -0.019, 0.013	Cluster Random Control trial	Good
O'Loughlin et al.	2004	Ethiopia	Rural and Urban	households	Latrine coverage, cost, knowledge, attitude, practice	Latrine ownership	50.2%	44-56	Cross-sectional	Good

TABLE 1: STUDIES WITH LATRINE/STOOL DISPOAL EXPOSURES OR COVARIATES AND CHILD HEALTH RELATED OUTCOMES (continued)

Reference	Year of Study	Country	Setting	Participants	Exposures/ Covariate	Outcome	Effect Size	95% CI	Study Design	Study Quality
Wanazahun et al.	2012	Ethiopia	Rural	Children ≤5	Latrine availability; Child stool disposal	Acute diarrhea	OR: 2.43; 3.35	1.19, 4.87; 1.45, 4.13	Case control	Good
Belizario et al.	2009-2011	Philippines	Rural	6-15 years; 2-5 years	Village with latrines; Village without latrines	Soil helminthes	63% +; 32% +	----	Cross-sectional	Good
Garrett et al.	2001	Nyanza, Kenya	Rural	Children ≤5	Latrine ownership	Diarrhea incidence	RR: .58	.26, .67	cohort	Good
Clasen et al.	2010-2013	India	Rural	Children ≤5	Village with latrines; Village without latrines	Diarrheal illness	PR: 0.97; 8.8% Vs. 9.1%	.83, 1.12	Cluster Random Control trial	Good
Aziz et al.	1984-1987	Bangladesh	Rural	Children ≤5	Village with latrines; Village without latrines	Diarrheal illness	0.75	---	Control trial – cross-sectional surveys	Fair
Azurin et al.	1968-1972	Philippines	Rural	All ages	Sanitation/water facilities	Cholera incidence	RR: .53	---	Prospect. cohort	Fair

TABLE 1: STUDIES WITH LATRINE/STOOL DISPOAL EXPOSURES OR COVARIATES AND CHILD HEALTH RELATED OUTCOMES (continued)

Reference	Year of Study	Country	Setting	Participants	Exposures/ Covariate	Outcome	Effect Size	95% CI	Study Design	Study Quality
Daniels et al.	1987-1988	Lesotho	Rural	Children ≤5	Latrine ownership	Diarrheal disease	OR: .76	.58-1.01	Case control	Good
Hoque et al.	1983-1987	Bangladesh	Rural	Children ≥5 and ≤5	Latrine Ownership Vs. No Latrine ownership	Diarrheal disease	RR: 2.25 vs. 1.96	P<0.0001; P=0.07	Cross-sectional	Fair
Nanan et al.	2001	Pakistan	Rural	Children ≤6	Water and sanitation intervention	Diarrheal disease	OR: 1.33	P value =.049	Case control	Good

L. Purpose

The purpose of this study was to examine the relationship between communities with 100% latrine usage (ODF) and non-usage communities (non-ODF free). Diarrheal disease prevalence calculations in children five years old and under determined the success of the latrine intervention program between communities. The study also identified risk factors for diarrheal illness within the communities. Water quality analysis acted as a possible bacterial organism exposure indicator. Water quality analysis measured water cleanliness. Anthropometric measures served as an indicator for child health.

Objectives

Aim: To examine latrine interventions as a predictor of childhood diarrheal prevalence and other covariates including water safety, water source factors, latrine usage behaviors, anthropometric indicators, dietary factors, food handling, breastfeeding, livestock proximity, demographic factors, hygiene, latrine adherence, latrine constructions and maintenance, treatment behaviors, and co-morbidities in Kisumu County, Kenya.

Hypothesis 1: Childhood diarrheal prevalence will be lower in the communities with 100% latrine usage.

Hypothesis 2: Risk factors of childhood diarrhea are water safety, water source factors, latrine usage behaviors, anthropometrics, dietary factors, breastfeeding, food handling, livestock proximity, demographic factors, hygiene, treatment behaviors, and co-morbidities.

Hypothesis 3: Fecal coliforms and turbidity measures will be lower in communities with 100% latrine usage.

IV. METHODS

A. Study Design and Procedures

The study was a condensed cohort study in Ahero district town Kisumu County, Kenya. Surveys were distributed amongst latrine usage and non usage communities to obtain diarrheal prevalence measures in children 5 years old and under. A cohort study was optimal because I selected a group of exposed individuals (non-latrine usage group) and unexposed individuals (100% latrine usage group). Our initial plan was to compare the incidence of childhood diarrheal with a recall period of 4 days prior to responding to the survey, but given the low frequency of diarrhea in the past 4 days, we compared the prevalence of childhood diarrhea with a recall period of one year prior to responding to the survey. (Gordis, 2013). Water samples were obtained from village water sources during interviews. Children were measured for height, weight, length, and MUAC to determine overall health.

Kisumu County has 5.4 million inhabitants (KCBS, 2008; Caruso et al., 2014). Nyando is located near Lake Victoria in Kisumu County, Western Kenya (Brooks, 2006). The district lies in the eastern part of the lowland surrounding the Nyando Gulf. (Nyakundi, 2012). The Nyando District is prone to flood disasters, with frequent floods, leading to epidemics of cholera and diarrhea (Tiondi, 2000). Nyando has a geographic coverage of 1,168.4km,^{2} with a population of 356,393. Nyando's ethnic group is mostly Luo speaking. The population is rural, with high poverty levels (Nyakundi, 2012). In 2008, 10.2% of individuals in Kisumu County defecated using a toilet or latrine, while 79% disposed of stools safely. Nyanza has among the lowest proportions of children fully vaccinated (62.2%), with the highest levels of both under-five and infant mortality rates in Kenya (KNBS, 2010). Roughly 56.6% of individuals attended a health facility during diarrheal episodes. Eighty-one percent increased fluid intake during episodes. No individuals reported taking zinc supplements. Kenya's Health and Demographic Survey estimates for stunting were 26.9%, wasting was 3.2%, and 13.7% were underweight in Nyando. Other endemic diseases include malaria, tuberculosis, and malnutrition (WHO, 2010).

B. Subject Enrollment

Children age 5 years old and under living in Ahero district with a parent, grandparent, or long term caregiver were present in the household to respond to the questionnaire to be eligible for entry. Children are at higher risk for dehydration due to diarrheal illness due to a greater proportion of bodily fluid compared to adults, higher metabolic rates, more febrile illness and infections. Indicators that are specific to children ≤5 are important for calculating a country's under-five mortality rate. The health of children ≤5 years old is a life expectancy and country development indicator due to a child's unique susceptibility to the negative effects of poverty, not having access to education and health services, and environmental risks including access to safe water and sanitation (UN, 2015). Parents, grandparents, and long terms caregivers were eligible to answer questions regarding child health.

Parent or caregivers who refused the participation were not included in the study. Households without a parent present were also excluded from the study because it would have been unethical to speak to children directly and many are too young to answer questions regarding their health. Close family members or long term caregivers were preferred for survey responding compared to short term caregivers or non-family members because they were more likely to be familiar with their child's health. Households without a child ≤5 years old were excluded.

OpenEpi software Version 3 was used to calculate sample size with a power of 80% and a two-sided significance level of 0.05. Using data from Kenya's most recent Demographic Health Survey, we estimated a 16.2% prevalence of diarrhea in children under age five in the exposed (non-latrine usage) group (KCBS, 2008). These parameters estimated a necessary enrollment of 396 subjects (198 children in each group) to detect a 9% absolute reduction in diarrhea prevalence in the unexposed (100% latrine usage) group (Garrett et al., 2008; Clasen et al., 2014; Patil et al., 2014). This expected difference was a mid-point estimate based on literature review of similar studies that found between a 24-64% reduction in diarrheal disease prevalence in children ≤5 (Azurin & Alvero, 1974; Aziz et al., 1990; Daniel et al., 1990; Garrett et al., 2008; Tiwari et al., 2009; Clasen et al., 2014; Patil, S. R. et al., 2014).

In Kenya, each sub-location can have 10–30 villages each, with each village having about 100 households (Ochomo et al. 2014). According to the most recent Kenyan DHS, 16.2% of rural households include children <5 years. We sought to enroll 198 subjects in each area (latrine and non-latrine using) via simple random sampling [see Sample size calculation, section 6.0]. This is justified by estimates of 850 children ≤5 in the latrine using group and 1,238 children ≤5 in the non-latrine using group. We conducted simple random sampling stratified by sub-location. The latrine using area has a total of 3 sub locations with 4, 5, or 6 villages in each of the sub-locations for a total of 15 villages. The non-latrine using community has a total of 2 sub locations with 18 villages: 4 villages in one, and 14 villages in the other. To conduct simple random sampling in the non-latrine using location, we will enroll 22% of the sub location with 4 villages, and 78% of the sub location with 14 villages. This results in 11 subjects per village in the smaller sub location and 14 subjects per village in the larger sub location. In the latrine using location, we will enroll 27% of the sub location with 4 villages, 33% of the sub location with 5 villages, and 40% of the sub location with 6 villages. This results in 14 subjects per village in each of the sub locations in the latrine using location. We visited each household to identify those with children ≤ 5 years of age. We anticipated being able to complete a maximum of 40 surveys per day. In villages with more than 100 households or many more eligible households than expected, we conducted sampling over a 2-day period. If a household member refused study entry or was ineligible, we continued to the next nearest household (Bennet et al., 1991). If there was more than one child ≤ 5 years present and resident in the household, simple random selection using a random number generator function on a calculator was used to choose one at the time of the interview.

C. Data Collection Management and Procedures

A standardized questionnaire collected data including: demographics factors, food handling, hygiene behaviors, latrine usage behaviors, diet, breastfeeding, co-morbidities, treatment, livestock proximity, diarrhea in the past year, and factors related to diarrhea illnesses. The questionnaire was available in English, Kiswahili, and Dholou. Kenya is among many Sub-Saharan African countries to appoint national community health workers (CHW) to strengthen health systems to mitigate the shortage of doctors and nurses. According to the WHO, CHWs should be members of the communities, should be available to the communities for their activities, should be supported by the health system but not necessarily a part of the organization, has short training than professional workers, and maybe specialized to specific disease or health events such as the management of childhood illnesses (Haines et al., 2007; Lehmann & Sanders, 2007). Community health workers have an important role in increasing coverage of essential interventions for child survival (Haines et al., 2007). The CHWs had a close relationship with the Ministry of Public Health and Sanitation Kenya and various other organizations that regularly require their interviewing services for studies. The CHWs are proficient in English, Dholou, and Swahilli.

Western Kenya's sources of drinking water contamination include agricultural runoff as well as human and animal waste (Grady et al., 2014). Molecular stool testing was not financially feasible, therefore water quality analysis was conducted to verify possible bacterial exposures in the children. Water samples were obtained from as many community water source locations as possible during interviews. Sampling sources included: piped connections, public taps or standpipes, tube wells, boreholes, protected dug wells, protected springs, rainwater, ponds, streams, and rivers (UN, 2012; Grady et al., 2014). We asked the interviewee where they obtain their water from during the interview and we sampled the corresponding sources. The number of samples collected depended on the financial limit of our budget and number of water sources available for testing. Minimally, we expected to test at least of 25 water sources in each area (latrine using, and non-latrine using). Sampling procedures followed the Standard Operating Procedures for Determination of Total Coliforms and *E. coli* in Water using the 24 hour Colilert methodology (APHA, 2012). Deviations from the procedure included the usage of Aquagenx Compartment Bag Tests (CBT) tests for the detection of waterborne *Escherichia coli* (Aquagenx, 2015). *E. coli* are key fecal indicator micro-organisms in water according to the WHO (Ashbolt et al. 2001). The main advantage of the CBT tests was that they were portable, simple, convenient, flexible, and informative (Aquagenx, 2015). In short, 100mL of drinking water was collected, transferred to the compartment bags, incubated for 24 hours, and then they are expected for color changes to indicate bacterial presence (Aquagenx, 2015). An electronic turbidity meter was used to measure turbidity or water cloudiness. High turbidity is an indicator of bacteria in water (WHO). Turbidity meters are very accurate and are measured in nephelometric turbidity units (NTU). Drinking water should have a turbidity of 5 NTU or less. Possible contamination is indicated in measures of 5 NTU or more (WHO). Marked increases in turbidity were the primary indicator for the presence of *Cryptosporidium* oocysts during the *Cryptosporidium* outbreak in Milwaukee, Wisconsin that sickened an estimated 403,000 people (Kenzie et al., 1994).

Weight, height/length, and middle upper arm circumference was obtained from each child upon obtaining permission from the mother and explaining the importance of these measurements. A tared scale was best for weighing children age 2 years old or under. For children ≤2 years old, the mother removed her shoes and stood on the scale. The scale was tared and the child was handed to the mother. The child's weight appeared and was recorded in kilograms. Children two years or older removed their shoes and stood on the scale on their own if they were calm and willing to stand still (WHO, 2008). Height and length of infants was determined using a measuring tape. Children under age 2 were instructed to lie down and keep still to be measured using a measuring tape from head to toe to the nearest inch. Height was measured using an accurate, non-stretchable measuring table which was securely fastened to the wall to obtain measurements of children over age 2. Older children stood straight against the wall next to the tape (Walsh et al., 2002). MUAC is predictive for child health and death in children age 6 to 60 months (Cattermole et al., 2010; Mwangome et al., 2012). Therefore, MUAC measurement was only be obtained for children 6 months and older. MUAC can be measured easily, quickly and affordably. MUAC values cut-offs of 125 mm and 115 mm are used to define moderate and severe acute malnutrition respectively (Mwangome et al., 2012). The midpoint of the arm was identified using a string between the shoulder and tip of the elbow. The MUAC tape was placed around the arm midpoint and fed thought the opening to read the measurement in the middle window. Community health workers were trained to measure height/length, weight, and MUAC according to the WHO and UN standards. A recent study in western Kenya showed that trained community health workers can accurately measure MUAC, weight, height/length measurements in children and infants (Mwangome et al., 2012).

D. Data Analysis

Univariate analysis included frequencies, descriptive statistics of continuous variables including means, medians, and standard deviations, and missing values of each exposure, outcome, and covariate variable. Contingency tables were used for ODF, water safety, drinking water, time to drinking water source, drinking water treatment, child HIV status, monthly income, hand washing, employment, highest education level, household electricity, household cluster toilet availability, young child stool disposal, currently breastfeeding, and gender categorical variables. Chi square statistics will be computed.

The outcome for analysis was diarrhea in the past year, dichotomized as yes vs. no. The primary explanatory variable was ODF location. Effect modification was determined by observing differences between stratums of covariates. Confounding was assessed by comparing crude and adjusted estimates. Anticipated confounders were: latrine usage behaviors, household hygiene behaviors, water source factors, water quality, food handling, personal hygiene, breastfeeding, co-morbidities, seasonality, treatment, hospital facility access, occupation, and livestock proximity. Anticipated effect modifiers included demographic factors such income, family size, education level, and age (Hosmer et al., 2013).

To assess hypothesis 1, the primary outcome was a prevalence rate calculation with a recall period of one year of acute diarrheal episodes. To address hypothesis 2, modified poisson regression with robust variance was used to approximate the log binomial model to calculate prevalence ratios to measure the association between latrine using communities and having diarrhea in the past year, with water safety, water source factors, latrine usage behaviors, demographic factors, hygiene, and child's HIV status. Variables with a p-value <0.10 were entered in multivariable model. Backwards selection was conducted in SAS Version 9.3 software to determine which variables will remain in the model using an alpha level of ≤0.05. Effect modification was assessed by stratifying variables from the backward selection model that increased the risk of diarrheal disease in latrine using communities. Likelihood ratio testing was used to compare the final model to the models with interactions to determine which model is the best fit. A separate model examined the association with sub location, which reflected non-ODF and ODF status as well as water safety measures (Table 4). The final model consisted of significant variables from the backwards selection procedure and stratification analyses. Confidence intervals at 95% will be estimated using robust variance estimates.

For hypothesis 3, laboratory analysis confirmed the presence of fecal coliforms and water cloudiness. Measurements were categorized according to the WHO recommendations for drinking water safety and were included as a water safety covariate in analysis.

1. *Primary Explanatory Variable*

In the primary analysis, open defecation free location status was categorized with "Yes, ODF" and "No, Non-ODF" variables, with the non-ODF group being the anticipated higher risk group due to the exposures from the potential effects of not having 100% latrine usage compared to the lower risk ODF group. In the secondary analysis, by sub-location, 5 sub locations (3 ODF, 2 non-ODF) were utilized as the primary explanatory variable. We expected to see higher rates of diarrhea in the non-ODF group, using ODF sub-location #3 as the referent because they had the lowest rates of diarrhea of all 5 sub locations.

2. *Demographic Variables*

The variable for last month's household income in Kenyan Shillings (KSH) was categorized into "None", "Less than 2,000", and "More than 2,000" due to cell sparsity across the higher valued original 8 category variable. The employment variable originally consisted of 10 groups, but the majority of respondents answered the "farmer" category due to the farming lifestyle of the Dholuo tribe, therefore the variable was grouped into "farmer" or "other" occupations. Cell sparsity of the education variable prompted the 2 category grouping of “no education” or “some education” instead of the original none, primary, or post primary education variable. Yes or no responses remained for the electricity variable. Child age in years and gender remained as 6 and 2 category variables, respectively.

3. <u>Water Safety Variables</u>

Percent unsafe, median turbidity, and percent untreated was calculated for the sampled water sources within the 5 sub locations (3 ODF, 2 non-ODF) in order to apply the ecological level results to the individual level survey data. The compartment bag test (CBT) (Aquagenx) was used to detect *E. coli* concentration according to pre-determined WHO health risk categories for water drinking safety (Aquagenx, 2015). A safe/unsafe category was created for analysis due to the sparsity of water results according to the WHO’s original 6 health risk groupings. Sampled types of water sources were categorized according to the specific type, using unprotected and protected as the WHO identifies. Sampled turbidity levels were grouped according to the WHO’s drinking water recommendation of ≤5 NTU as “low”, and >5 NTU as “high” levels.

The survey asked subjects “Where do you get your drinking water?”; responses were condensed from 11 categories into 3 categories (Natural, Tap, Well). Natural sources included: rivers, ponds, lakes, and streams. Tap sources included: taps inside the home, taps >100 meters from the home, or taps <100 meters from the home. Well sources included: protected or unprotected pump sources. The survey asked subjects the duration of time to get to the water source, and this was categorized into ≤5 minutes, 5-<10 minutes, 10-<15 minutes, and 15 minutes or longer.

4. <u>Co-Morbidities</u>

Child’s HIV status included HIV negative, HIV positive, and Don’t Know categories. The continuous MUAC variable was categorized into low or normal, with low indicating severe at risk acute malnutrition, and normal indicating well nourished. As recommended by the United Nations (UN), low corresponds ≤125 centimeters, and >125 centimeters corresponds to normal. The UN’s 3 category variable that corresponds to the MUAC's pre-grouping markers were too sparse in terms of subjects' responses, therefore low and normal categories were best for analysis.

5. *Sanitation, Hygiene, and Health Behaviors*

Subjects responded to the washing hands after last stool variable with three categorizations: "No", "Yes", and "Don't Know". Toilet availability within the household cluster area remained as "yes" or "no" responses. Child stool disposal was categorized as: "put on the ground", "throw in the latrine", "bury in the yard", and "child too old, >3 years old". The survey asked subjects "are you currently breastfeeding the child"?; subjects responded "yes" or "no". The currently breastfeeding variable was combined with the age variable to create 3 categories including: (1) yes, child is currently breastfeeding, (2) child is <3 years old and was not breastfeeding, and (3) child is >3 years old. This categorization helped to analyzed breastfeeding data by age. Subjects responded to the breastfeeding duration variable on a 12 month scale. The scale was collinear with the age in months scale, therefore the currently breastfeeding and age combined variable was best for analysis. Drinking water treatment remained as a yes/no variable.

V. RESULTS

From June 23, 2015 to July 7, 2015, 426 households were surveyed via parents (87.0%) or caregivers (13%) of children ≤5 years old; 210 were located in the open defecation free location (Kochogo) and 216 were located in the non-open defecation free location (Kanyagwal). The participation rate was nearly 100%, with one subject declining participation due to compensation expectations. Latrines were located within 10 minutes walk of household clusters for 97% of ODF households, and 76% of non-ODF households ($p<0.001$). Overall, respondents were 13.9% HIV positive, 79.1% with primary school educational attainment, 79.0% reporting <2000 KSH per month household income, and 39.5% employed as farmers. The population of respondent's children ≤5 years old was 51.6% female and 48.4% male, with a median age of 36 months, and 4.9% HIV positive.

A. <u>Factors Associated with Diarrhea</u>

Overall, survey respondents reported that 27.9% of children ≤ 5 had diarrhea of at least 3 days duration in the past year (Table 2). The occurrence of diarrhea did not differ by location (ODF = 25% vs. non-ODF = 31%, $p=0.171$). The mean age of children was 3 years, and did not differ by diarrhea status (Diarrhea 3 years vs. No Diarrhea 3 years; $p=0.936$). The distribution of gender did not differ by diarrhea status ($p=0.582$, Table 2). In the context of water sources and access, a greater proportion of subjects reporting diarrhea collected water from natural sources (51.0%), compared to tap (13.7%), and wells (24.2%) ($p<0.001$). A greater proportion of subjects who traveled 10-15 minutes to water sources reported diarrhea (34.3%) compared to individuals who traveled <10 minutes (27.9%) ($p=0.140$). The prevalence of diarrhea was higher among HIV positive (66.7%) than HIV negative (27%) subjects ($p <0.001$). Diarrhea was higher among subjects with lower income (No income=56.3%) compared to subjects with higher income (More than 2,000 KSH=27.6%) ($p<0.001$). Diarrhea was higher among subjects who reported "no education" (44.4%) compared to subjects with some education (26.2%) ($p=0.010$). A greater proportion of diarrhea was reported in 45.2% of subjects who reported not washing hands after their last stool compared with 25.9% of subjects who reported washing their hands ($p=0.053$). Subjects without toilets available had a greater proportion of diarrhea (56.9%) compared to subjects with toilets (23.4%) (p<0.001). Twenty-two percent of subjects who reported throwing stools of children ≤3 years old in the latrine reported diarrhea compared to 50.0% who reported putting child's stools on the ground, and 47.1% who reported burying stools in the yard (p<0.001).

TABLE 2. CHARACTERSTICS OF SUBJECTS BY DIARRHEA STATUS

Variables	'Yes' Diarrhea Past Year, N=118 % (n)	'No' Diarrhea Past Year, N=304 % (n)	P –value
Open Defection Free			0.136
No (non-ODF)	30.9 (67)	69.1 (148)	
Yes (ODF)	24.9 (51)	75.1 (156)	
Water Safety by Sub Location			0.043
Sub Location 5, Non-ODF: Percent Unsafe (42.9), Median Turbidity (2.2), Percent Untreated (0.0)	42.4 (28)	57.6 (38)	
Sub Location 4, Non-ODF: Percent Unsafe (66.7), Median Turbidity (2.0), Percent Treated (5.6)	26.0 (39)	74.0 (111)	
Sub Location 3, ODF: Percent Unsafe (70.0), Median Turbidity (3.7), Percent Treated (10.0)	19.4 (13)	80.6 (54)	
Sub Location 2, ODF: Percent Unsafe (75.0), Median Turbidity (1.7), Percent Treated (16.7)	25.0 (14)	75.0 (42)	
Sub Location 1, ODF: Percent Unsafe (87.5), Median Turbidity (17.5), Percent Treated (12.5)	28.9 (24)	71.1 (59)	
Where do you get your drinking water?			<0.001
Natural	51.0 (50)	49.0 (48)	
Tap	13.7 (13)	86.3 (82)	
Well	24.2 (55)	75.8 (172)	
Time to drinking water source from household			0.140
>15 minutes	29.1 (23)	70.9 (56)	
10<-15 minutes	34.3 (34)	65.7 (65)	
5<-10 minutes	27.9 (46)	72.1 (119)	
<5 minutes	18.4 (14)	81.6 (62)	
Do you treat your drinking water?			0.756
No	29.5 (18)	70.5 (43)	
Yes	27.6 (99)	72.4 (260)	

TABLE 2. CHARACTERSTICS OF SUBJECTS BY DIARRHEA STATUS (continued)

Variables	'Yes' Diarrhea Past Year, N=118 % (n)	'No' Diarrhea Past Year, N=304 % (n)	P –value
Child HIV Status			<0.001
HIV Negative	27.1 (81)	72.9 (218)	
HIV Positive	66.7 (14)	33.3 (7)	
Don't Know	22.6 (23)	77.5 (79)	
Last Month Income (KSH)			<0.001
None	56.3 (40)	43.7 (31)	
Less than 2,000	21.0 (54)	79.0 (203)	
More than 2,000	27.6 (24)	72.4 (63)	
Wash Hands After Last Stool			0.053
No	45.2 (14)	54.8 (17)	
Yes	25.9 (91)	74.2 (261)	
Don't Know	33.3 (13)	66.7 (26)	
Employment			0.133
Farmer	23.3 (38)	76.7 (125)	
Other	30.1 (74)	69.9 (172)	
Highest Education Level Obtained			0.010
No Education	44.4 (20)	55.6 (25)	
Some Education	26.2 (96)	73.8 (271)	
Electricity in household			0.973
No	26.7 (100)	73.3 (274)	
Yes	26.5 (9)	73.5 (25)	
Toilet Availability (≤10 mins from household cluster location)			<0.001
No	56.9 (33)	43.1 (25)	
Yes	23.4 (85)	76.7 (279)	
Young Child Stool Disposal (≤3 years)			<0.001
Bury in Yard	47.1 (33)	52.9 (37)	
Put on the Ground	50.0 (18)	50.0 (18)	
Throw in the Latrine	22.0 (54)	77.9 (191)	
Child >3 years old	11.8 (2)	88.2 (15)	
Don't Know	20.4 (11)	79.7 (43)	
Currently Breastfeeding			0.397
Yes, currently breastfeeding	26.5 (31)	73.9 (88)	
No, child <3 years old	25.2 (35)	74.8 (104)	
No, child >3 years old	31.7 (51)	68.3 (110)	
Child Age (Years)			0.407
<1 Year	13.0 (3)	86.9 (20)	
1 Year	31.2 (19)	68.9 (42)	
2 Years	31.5 (34)	68.5 (74)	
3 Years	29.3 (34)	70.7 (82)	
4 Years	28.1 (23)	71.9 (59)	
5 Years	16.7 (4)	83.3 (20)	

TABLE 2. CHARACTERSTICS OF SUBJECTS BY DIARRHEA STATUS (continued)

Variables	'Yes' Diarrhea Past Year, N=118 % (n)	'No' Diarrhea Past Year, N=304 % (n)	P –value
Gender of Child			0.582
Male	26.4 (52)	71.2 (148)	
Female	28.9 (60)	73.6 (145)	
Middle Upper Arm Circumference			0.127
Low MUAC (severe-at risk acute malnutrition)	38.9 (14)	61.1 (22)	
Normal MUAC (Well Nourished)	26.9 (104)	73.1 (282)	

B. Water Safety by Location, Safety, Turbidity, and Water Source Type

Fifty-five water samples were collected from the ODF (N=30) and non-ODF locations (N=25) (Table 3a-3f). Overall, the ODF location had a higher proportion of unsafe water (67%) compared to the non-ODF location (60%), though this was not statistically significant (p=0.187; Table 3a). Turbidity levels (high vs. low) also did not differ by location (ODF = 58.3%, non-ODF = 41.7%, p=0.623). However, the ODF community had a higher proportion of unprotected water pumps (56.7%) compared to the non-ODF (24.0%) community (p=0.009). One hundred percent of unprotected water sources were unsafe compared to 39.1% of safe protected pumps (p<0.001). Unprotected pumps had higher turbidity in samples compared to protected pumps (High: 75.0% vs. 8.7%; p<0.001). In general, higher turbidity levels corresponded with unsafe water, while lower turbidity levels corresponded with safe water, which aids in validated the CBT water test for *E. coli* concentration levels (p=0.002). Higher turbidity in the unsafe samples and lower turbidity in safe samples confirms the validity of the CBT tests. Additionally, there were differences by sub-location. Within the ODF there were 2 sub-locations, and 3 within the non-ODF. When assessing water samples by percent unsafe by *E. coli* concentration, median turbidity levels, and percent treated by sub-location, the non-ODF sub locations had higher proportions of lower risk water compared to the ODF sub locations (non-ODF: 66.7% and 42.9% vs. ODF: 87.5%, 75%, and 70%; p-value <0.001) (Table 4).

TABLE 3a. CHARACTERSTICS OF LOCATIONS AND WATER SAFETY

Water Safety Based on *E. coli* Concentration			
Open Defection Free	**Safe (*E. coli* ≤0 MPN/100ml) % (n)**	**Unsafe (*E. coli* ≥1 MPN/100ml) % (n)**	**P-value**
No (non-ODF)	40.0 (10)	60.0 (15)	0.187
Yes (ODF)	23.3 (7)	76.7 (23)	

TABLE b. CHARACTERSTICS OF LOCATIONS AND WATER SOURCE TYPE

Type of Water Source					
Open Defection Free	**Natural % (n)**	**Unprotected Pump % (n)**	**Protected Pump % (n)**	**Treated % (n)**	**P-value**
No (non-ODF)	16.0 (4)	24.0 (6)	56.0 (14)	4.0 (1)	0.009
Yes (ODF)	0.0 (0)	56.7 (17)	30.0 (9)	13.3 (4)	

TABLE c. CHARACTERSTICS OF LOCATIONS AND TURBIDITY LEVELS

Turbidity			
Open Defection Free	**Low (≤5 NTU) % (n)**	**High (>5 NTU) % (n)**	**P-value**
No (non-ODF)	60.0 (15)	40.0 (10)	0.623
Yes (ODF)	53.3 (16)	46.7 (14)	

TABLE d. CHARACTERSTICS OF WATER SOURCE TYPE AND WATER SAFETY

Water Safety Based on *E. coli* Concentration			
Type of Water Source	**Safe (*E. coli* ≤0 MPN/100ml) % (n)**	**Unsafe (*E. coli* ≥1 MPN/100ml) % (n)**	**P-value**
Natural	0.0 (0)	100.0 (4)	<0.001
Unprotected Pump	0.0 (0)	100.0 (23)	
Protected Pump	60.9 (14)	39.1 (9)	
Treated	60.0 (3)	40.0 (2)	

TABLE e. CHARACTERSTICS OF WATER SOURCE TYPE AND TURBIDITY LEVELS

Turbidity			
Type of Water Source	**Low (≤5 NTU) % (n)**	**High (>5 NTU) % (n)**	**P-value**
Natural	0.0 (0)	100.0 (4)	<0.001
Unprotected Pump	21.7 (5)	78.3 (18)	
Protected Pump	91.3 (21)	8.7 (2)	
Treated	100.0 (5)	0.0 (0)	

TABLE f. CHARACTERSTICS OF TURBIDITY LEVELS AND WATER SAFETY

	Water Safety Based on *E. coli* Concentration		
Turbidity	**Safe (*E. coli* ≤0 MPN/100ml) % (n)**	**Unsafe (*E. coli* ≥1 MPN/100ml) % (n)**	**P-value**
High (>5 NTU)	8.3 (2)	91.7 (22)	0.002
Low (≤5 NTU)	48.4 (15)	51.6 (16)	

C. <u>Characteristics of Non-ODF vs. ODF Respondents</u>

Compared to the ODF residents, respondents from the non-ODF community had lower monthly income (69.3% vs. 54.4%, <2,000 KSH), less education (14.5% vs. 7.9%, No education), and less electricity (98.5% vs. 84.5% no electricity) ($p<0.05$, each; Table 4). Respondents in the non-ODF location were more likely to be HIV positive compared to the ODF location (non-ODF: 7.9% vs. ODF: 1.9%; $p=0.013$). The majority of respondents retrieved water from well sources for both locations, though this was higher among non-ODF participants (ODF: 48.9% vs. non-ODF: 59.1%; $p=0.012$, Table 4). Respondents from the non-ODF community reported less hand washing (No=10.2%) compared to the ODF community (No=4.3%) ($p=0.041$). A greater proportion of respondents in the non-ODF community reported burying children's stools in the yard (20.8%) and putting children's stools on the ground (10.2%) compared to the ODF (yard=11.9%; ground=6.7%) ($p=0.017$). A higher proportion of respondents in the non-ODF location reported not having a toilet available (23.6%) compared to the ODF location (3.3%) ($p<0.001$).

Table 4. Characteristics of Subjects by Location

Variables	Kochogo (ODF), N=209 % (n)	Kanyagwal (non-ODF), N=216 % (n)	P –value
Water Safety by Sub Location			<0.001
Sub Location 5, Non-ODF: Percent Unsafe (42.9), Median Turbidity (2.2), Percent Untreated (0.0)	0.0 (0)	30.6 (66)	
Sub Location 4, Non-ODF: Percent Unsafe (66.7), Median Turbidity (2.0), Percent Treated (5.6)	0.0 (0)	69.4 (150)	
Sub Location 3, ODF: Percent Unsafe (70.0), Median Turbidity (3.7), Percent Treated (10.0)	32.9 (69)	0.0 (0)	
Sub Location 2, ODF: Percent Unsafe (75.0), Median Turbidity (1.7), Percent Treated (16.7)	26.7 (56)	0.0 (0)	
Sub Location 1, ODF: Percent Unsafe (87.5), Median Turbidity (17.5), Percent Treated (12.5)	40.0 (84)	0.0 (0)	
Where do you get your drinking water?			0.012
Natural	22.5 (47)	24.2 (52)	
Tap	28.7 (60)	16.7 (36)	
Well	48.9 (102)	59.1 (127)	
Time to drinking water source from household			0.371
>15 minutes	19.7 (41)	18.7 (40)	
10<-15 minutes	20.6 (43)	26.2 (56)	
5<-10 minutes	43.1 (90)	35.9 (77)	
<5 minutes	16.8 (35)	19.2 (41)	
Do you treat your drinking water?			0.567
No	13.4 (28)	15.4 (33)	
Yes	86.7 (181)	84.7 (33)	
Child HIV Status			0.013
HIV Negative	74.3 (156)	66.7 (144)	
HIV Positive	1.9 (4)	7.9 (17)	
Don't Know	23.8 (50)	25.5 (55)	
Last Month Income (KSH)			0.005
None	19.2 (39)	14.9 (32)	
Less than 2,000	54.4 (111)	69.3 (149)	
More than 2,000	26.5 (54)	15.8 (34)	
Wash Hands After Last Stool			0.041
No	4.3 (9)	10.2 (2)	
Yes	87.6 (184)	79.6 (172)	
Don't Know	8.1 (17)	10.2 (22)	

Table 4. Characteristics of Subjects by Location (continued)

Variables	Kochogo (ODF), N=209 % (n)	Kanyagwal (non-ODF), N=216 % (n)	P –value
Employment			0.112
Farmer	35.8 (73)	43.3 (90)	
Other	64.4 (132)	56.7 (118)	
Highest Education Level Obtained			0.035
No Education	7.9 (16)	14.5 (31)	
Some Education	92.1 (186)	85.5 (183)	
Electricity in Household			<0.001
No	84.5 (174)	98.5 (203)	
Yes	15.6 (32)	1.5 (3)	
Toilet Availability (≤10 mins from household cluster location)			<0.001
No	3.3 (7)	23.6 (51)	
Yes	96.7 (203)	76.4 (165)	
Young Child Stool Disposal (≤3 years)			0.017
Bury in Yard	11.9 (25)	20.8 (45)	
Put on the Ground	6.7 (14)	10.2 (22)	
Throw in the Latrine	60.5 (127)	55.6 (120)	
Child >3 years old	6.2 (13)	2.3 (5)	
Don't Know	14.8 (31)	11.1 (24)	
Currently Breastfeeding			<0.001
Yes, currently breastfeeding	19.6 (42)	37.3 (78)	
No, child <3 years old	64.3 (90)	23.9 (50)	
No, child >3 years old	38.3 (82)	38.8 (81)	
Child Age (Years)			0.404
<1 Year	4.6 (10)	6.1 (13)	
1 Year	16.0 (33)	13.7 (29)	
2 Years	24.8 (51)	27.9 (57)	
3 Years	29.6 (61)	26.4 (56)	
4 Years	17.0 (35)	22.6 (48)	
5 Years	7.8 (16)	4.3 (9)	
Gender of Child			0.125
Male	45.9 (91)	54.0 (107)	
Female	53.6 (113)	46.5 (98)	
Middle Upper Arm Circumference			0.098
Low MUAC (severe-at risk acute malnutrition)	6.2 (13)	10.65 (23)	
Normal MUAC (Well Nourished)	93.8 (197)	89.4 (193)	

D. Results of Multivariable Analysis: Factors Associated With Diarrhea

Non open defecation free location was the primary exposure in the model; in addition the following covariates with p-value<0.10 in bivariate analysis were also examined: child's HIV status, hand washing after last stool, highest education level obtained, household cluster toilet ownership, disposal of child's stool, last month's household income, and drinking water obtainment location. In the crude analysis, children were at higher risk for diarrhea if they lived in the non-ODF location compared to the ODF [PRR=1.26; 95% CI: 0.87, 1.95], reported HIV positive status, had less educated parents, did not have a toilet available within 10 minutes of their household cluster, parents disposed of young child stools by burying in the yard or putting on the ground, had lower monthly household income, parents obtained drinking water from natural or well water sources, or had no latrine or soap present at their households (Table 5).

Results for the final model indicate that after adjusting for child's HIV status, stool disposal, and household income, the non-ODF community had a non-significant 16% higher risk of diarrhea compared to the ODF community (adjusted PRR=1.16, 95% CI: 0.91, 1.49). Additionally, HIV positive children had a 2.29 [95% CI: 2.07, 2.53] increased risk of diarrhea compared to HIV negative children. Subjects who reported burying children's stools in yards or putting stools on the ground had a 92% [95% CI: 1.74, 2.12] and 56% [95% CI: 1.13, 2.17] increased risk of diarrhea, respectively, compared to subjects who throw children's stools in latrines. Households with no income had a 93% [95% CI: 1.46, 2.56] increased risk of diarrhea compared to households with income of more than 2,000 KSH per month (Table 5). The toilet availability variable was removed from the model due to colinearity concerns with the ODF variable, although households without toilets available in their cluster location had an increased risk of diarrhea compared to those without toilets available in their household cluster.

TABLE 5. MULTIVARIABLE ANALYSIS OF VARIABLES ASSOCIATED WITH DIARRHEA STATUS

	Crude PRR [95% CI]	Adjusted PRR* [95% CI] N=415
Open Defecation Free		
Yes	Ref	Ref
No	1.26 [0.87, 1.95]	1.16 [0.91, 1.49]
Child HIV Status		
HIV Negative	Ref	Ref
HIV Positive	2.46 [2.12, 2.86]	2.29 [2.07, 2.53]
Don't Know	0.83 [0.46, 1.49]	0.93 [0.55, 1.58]
Wash hands after last stool		
Yes	Ref	NA, not in final model
No	1.75 [1.31, 2.33]	
Don't Know	1.29 [0.96, 1.73]	
Highest Education Level Obtained		
Some Education	Ref	NA, not in final model
No Education	1.70 [1.10, 2.62]	
Toilet Availability (≤10 mins from household cluster location)		
Yes	Ref	NA, not in final model
No	2.44 [2.10, 2.83]	
Young Child Stool Disposal (≤3 Years)		
Throw in Latrine	Ref	Ref
Bury in Yard	2.13 [1.59, 2.89]	1.92 [1.74, 2.12]
Put on the Ground	2.27 [1.66, 3.10]	1.56 [1.13, 2.16]
Child >3 Years Old	0.53 [0.22, 1.29]	0.51 [0.26, 1.00]
Don't Know	0.92 [0.53, 1.61]	0.80 [0.47, 1.37]
Last Month Income (KSH)		
More than 2,000	Ref	Ref
None	2.04 [1.58, 2.64]	1.93 [1.46, 2.56]
Less than 2,000	0.76 [0.57, 1.02]	0.67 [0.56, 0.82]
Where do you get your drinking water?		
Tap	Ref	NA, not in final model
Natural	3.73 [1.62, 8.60]	
Well	1.77 [0.70, 4.48]	
Is there soap present outside of the household latrine?		
Yes Latrine, No Soap Present	Ref	NA, not in final model
No Latrine, No Soap Present	2.49 (2.17, 2.85)	

PRR = Prevalence Rate Ratio, CI = Confidence Interval
* adjusting for ODF as primary explanatory variable and covariates

Interaction was examined between ODF and surveyed water sources; significant Breslow day test indicated that natural or well water sources might significantly modify their effect to diarrhea status (Table 6).The interaction model reflected a higher risk of diarrhea for the ODF group compared to the non-ODF when water is obtained from natural (PRR= 10.56, 95% CI: 3.54, 31.45) or well (PRR=12.03, 95% CI: 3.93, 36.86) sources after adjusting for all variables in the final model (Table 7). A significant Breslow day test for ODF and education indicated that highest education level obtained might modify the effect of diarrhea status. The interaction model resulted in a higher risk of diarrhea for the ODF group compared to the non-ODF when the parent reported having no education (PRR=2.15; 95% CI: 1.08, 4.27) after adjusting for all variables in the final model (Table 8). Following likelihood ratio testing, the model with the ODF and surveyed water source interaction did not explain the model better than the reduced final model ($689.23_{reduced}-691.81_{full}= -2.58; -2.58< X_2^4\ 0.711$). Due to lack of fit, the ODF and surveyed water source interaction was not retained in the final model. The ODF and education level interaction did explain the model better than the reduced final model ($689.23_{reduced}-688.81_{full}= 0.42; 0.42> X_2^2\ 0.103$). The ODF and education interaction was not retained in the final model because of the nearly non-significant 95% CI estimate for the PRR between ODF and non-ODF.

TABLE 6. SINGLE FACTOR STRATIFIED ANALYSIS FOR RELATIONSHIP BETWEEN ODF AND DIARRHEA STATUS, ADJUSTED FOR COVARIATES

	Adjusted PRR [95% CI]	**Breslow Day P-value**
Non-ODF and Diarrhea Crude: 1.26 [0.87, 1.95]		
Child HIV Status		
HIV Negative	1.31 [0.91, 1.91]	0.223
HIV Positive	1.41 [0.51, 3.94]	
Don’t Know	0.68 [0.33, 1.41]	
Wash hands after last stool		
No	1.02 [0.43, 2.42]	0.692
Yes	1.16 [0.81, 1.65]	
Don’t Know	1.74 [0.64, 4.69]	

TABLE 6. SINGLE FACTOR STRATIFIED ANALYSIS FOR RELATIONSHIP BETWEEN ODF AND DIARRHEA STATUS, ADJUSTED FOR COVARIATES (continued)

Highest Education Level Obtained		
No Education	2.83 [0.98, 8.17]	0.039
Some Education	1.07 [0.76. 1.51]	
Toilet Availability (≤10 mins from household cluster location)		
No	1.37 [0.57, 3.33]	0.371
Yes	0.92 [0.63, 1.34]	
Young Child Stool Disposal (≤3 Years)		
Bury in Yard	0.81 [0.49, 1.32]	
Put on the Ground	1.65 [0.76, 3.62]	0.116
Throw in Latrine	0.89 [0.56, 1.44]	
Child >3 Years Old	2.40 [0.18, 31.29]	
Don't Know	3.33 [0.99, 11.22]	
Last Month Income (KSH)		
None	1.22 [0.81, 1.83]	0.448
Less than 2,000	1.69 [0.99, 2.87]	
More than 2,000	0.94 [0.46, 1.89]	
Where do you get your drinking water?		
Tap	0.14 [0.02, 1.01]	0.011
Natural	1.28 [0.85, 1.89]	
Well	1.56 [0.95, 2.57]	
Is there soap present outside of the household latrine?		
No Latrine, No Soap Present	1.41 (0.58, 3.42)	0.361
Yes Latrine, No Soap Present	0.95 (0.66, 1.29)	

TABLE 7. SURVEY WATER SOURCE EFFECT MODIFIER RESULTS STRATIFIED BY ODF STATUS

	Non-ODF PRR (95% CI)	ODF PRR (95% CI)
Surveyed Water Source Variable, N=413		
Natural vs. Tap	1.31 [1.18, 1.45]	10.56 [3.54, 31.45]
Well vs. Tap	1.49 [1.02, 2.17]	12.03 [3.92, 36.86]

PRR = Prevalence Rate Ratio, CI = Confidence Interval
*adjusted for child HIV result, household toilet ownership, stool disposal, income

TABLE 8. EDUCATION EFFECT MODIFIER RESULTS STRATIFIED BY ODF STATUS

	Non-ODF PRR (95% CI)	ODF PRR (95% CI)
Education Variable, N=406		
No Education vs. Some Education	1.52 [1.30, 1.77]	2.15 [1.08, 4.27]

PRR = Prevalence Rate Ratio, CI = Confidence Interval
*adjusted for child HIV result, household toilet ownership, stool disposal, income

In the analysis using sub-location, after adjusting for child's HIV status, child's stool disposal, and household income, non-ODF sub location #5 (PRR=1.56; 95% CI: 1.48, 1.65) and ODF sub location #2 had a 55% [95% CI: 1.37, 1.76] increased risk of diarrhea compared to ODF sub location #3, which was the lowest risk group when assessing diarrhea risk by sub location (Table 9). Similar to the ODF vs. non-ODF model, HIV positive children, lower income, and unsafe disposal of children's stools were associated with increased risk of diarrhea.

TABLE 9. MULTIVARIABLE ANALYSIS OF VARIABLES ASSOCIATED WITH DIARRHEA STATUS

	Crude PRR [95% CI]	**Adjusted PRR* [95% CI] N=391**
Sub Location		
Sub Location 3, ODF	Ref	Ref
Sub Location 5, Non-ODF	2.19 [2.19, 2.19]	1.56 [1.48, 1.65]
Sub Location 4, Non-ODF	1.34 [1.34, 1.34]	1.24 [1.20, 1.28]
Sub Location 2, ODF	1.29 [1.29, 1.29]	1.55 [1.37, 1.76]
Sub Location 1, ODF	1.49 [1.49, 1.49]	1.14 [1.05, 1.23]
Child HIV Status		
HIV Negative	Ref	Ref
HIV Positive	2.46 [2.12, 2.86]	2.30 [2.04, 2.59]
Don't Know	0.83 [0.46, 1.49]	0.91 [0.52, 1.59]

Wash hands after last stool		
Yes	Ref	NA, not in final model
No	1.75 [1.31, 2.33]	
Don't Know	1.29 [0.96, 1.73]	
Highest Education Level Obtained		
Some Education	Ref	NA, not in final model
No Education	1.70 [1.10, 2.62]	
Toilet Availability (≤10 mins from household cluster location)		
Yes	Ref	NA, not in final model
No	2.44 [2.10, 2.83]	
Young Child Stool Disposal (≤3 Years)		
Throw in Latrine	Ref	Ref
Bury in Yard	2.13 [1.59, 2.89]	1.89 [1.64, 2.16]
Put on the Ground	2.27 [1.66, 3.10]	1.55 [1.13, 2.18]
Child >3 Years Old	0.53 [0.22, 1.29]	0.46 [0.24, 0.90]
Don't Know	0.92 [0.53, 1.61]	0.77 [0.44, 1.33]
Last Month Income (KSH)		
More than 2,000	Ref	Ref
None	2.04 [1.58, 2.64]	1.95 [1.48, 2.57]
Less than 2,000	0.76 [0.57, 1.02]	0.69 [0.57, 0.82]
Where do you get your drinking water?		
Tap	Ref	NA, not in final model
Natural	3.73 [1.62, 8.60]	
Well	1.77 [0.70, 4.48]	
Is there soap present outside of the household latrine?		
Yes Latrine, No Soap Present	Ref	NA, not in final model
No Latrine, No Soap Present	2.49 (2.17, 2.85)	

PRR = Prevalence Rate Ratio, CI = Confidence Interval, * adjusting for Sub Location and covariates

VI. DISCUSSION

Unexpectedly, there was no association between living in an open defecation free community and childhood diarrhea status. Our findings suggest that water safety offset the relationship between ODF status and diarrheal status due to a higher likelihood of unsafe water consumption in the ODF community. Children's HIV positivity, parents safely disposing of young children's stools, and low household income were positively were all risks for diarrhea. In the context of modifiability, improved water treatment, and safe stool disposal practices may reduce the risk of childhood diarrhea in the non-ODF community. Safe water treatment practices may improve the CLTS intervention in ODF communities.

A. <u>Comparison to the Literature</u>

Our null findings are similar to a previous study of total sanitation in India. Caregiver self-reported childhood diarrheal illness was measured via cluster-randomized control trial by rolling out a total sanitation campaign in India from 2009-2011 to 80 rural villages. The intervention group did not show improved child health outcomes including diarrhea after visiting households after the rollout of the latrine intervention to reduce open defecation and various adverse health behaviors including water quality (7.4% intervention vs. 7.7% control; p-value=0.687) (Patil et al., 2014). In contrast to our study's findings, reports of correct feces disposal increased as a result of the intervention (27% intervention vs. 18% control; p-value<0.001) (Patil et al., 2014). Authors attribute intervention failure to variability in household latrine coverage (5% to 79% coverage) and variability in reported daily open defecation in the intervention group (32% to 97% in men; 34% to 97% in women). An improved latrine intervention was examined as a predictor of diarrheal incidence among children under 5 in Nyanza Province, Kenya in 2008 in randomly selected intervention and comparison villages. Caregivers self-reported childhood diarrheal episodes over an 8 week period. Chlorinated stored water (RR=0.44; 95% CI: 0.28-0.69), latrine presence (RR=0.71; 95% CI: 0.54-0.92), rainwater use (RR=0.70; 95% CI: 0.52-0.95), and living in an intervention village (RR=0.31; 95% CI: 0.23-0.41) were associated with lower childhood diarrhea risk (Garrett et al., 2008). A 33% higher odds ratio was estimated in children not living in participation villages via case control study of water and sanitation participation and non-participation groups in Pakistan in 2003 (Nanan et al., 2003). These studies demonstrate the variability when examining the effects of latrine intervention on childhood diarrheal health. Many studies assessing latrine intervention and child diarrheal health are self-reported. The variability in study designs and use of subjective measures highlight the need for effective randomized control trials to reduce bias and confounding.

B. Strength and Limitations

We achieved the desired sample size of the study and we were adequately powered to detect modest differences in diarrhea by non-ODF vs. ODF location. Water quality testing acted as a biological measure and environmental indicator for contamination between communities and helped explain why the diarrheal rates observed were similar by community. The WHO has recommended levels of *E. coli* concentration and turbidity for drinking water, which acted as a proxy in variable categorization in the data. The survey was detailed and included many factors that may have confounded the relationship between ODF status and childhood diarrhea.

Water data was collected on at the ecological level due to limited funding. The majority of households in rural Nyando district, Kenya do not have private water source access. Many households share public water sources with community members, therefore collecting individual level water data was not an option.

Self-reporting may have caused bias in the data collected. Health behavior survey questions related to hand washing, stool disposal, water treatment, and latrine usage may be particular subject to self-reporting bias. This may have been exacerbated by the association of the study with the MOPHS. Self-reporting can also be susceptible to recall limitations. Some responses in the survey required the observation from the interviewer (e.g. latrine presence), which was intended to reduce bias due to self-reporting, but still may have been subject to some interviewer bias. Including more observation questions from the interviewer in lieu of questions towards the respondent may have also reduced bias self-reporting bias.

Although the sample size was optimal, missing data existed throughout variables in the study as a result of data collection errors. Continuous variables such as age or breastfeeding duration were limited to discreet values such as 1 years, 2 year, 3 year etc. as a result of parents/caregivers' uncertainty of the age of children or duration of breastfeeding. Failing to include a question regarding the number of children ≤ 5 per household limits the study's ability to assess household crowding and possibly person to person disease transmission.

Selection bias may have occurred in the way ODF and non-ODF village were selected for the study due to jurisdiction restriction of the MOPHS. These restrictions resulted in a higher prevalence of latrine coverage in the non-ODF group than desired for community selection (76% non-ODF vs. 97% ODF). Lower latrine coverage in the non-ODF community may have resulted in a larger effect size when comparing the risk of diarrhea disease in the non-ODF vs. the ODF. This might have aided in assessing covariates further. Selection bias may have also occurred in how the villages were selected initially for the intervention. Due to difficult weather circumstances during the long rain season in western Kenya, flooding in certain locations made it difficult to access homes during data collection. This may have introduced unintentional selection bias if the inaccessible households had higher rates of diarrhea compared to the households we were able to access in the field. Additionally, our interviewing process occurred from 10am-4pm during the week. This time frame may have caused us to miss children while they were in school during the day, which may have skewed our sample to children ≤3 who are too young to go to school. Older children who were home during the day and not in school may have belonged to lower income families who are unable to afford school fees. Our interviewing time frame may have also caused us to interview households who were unemployed. Bias may be introduced if households who were not home have different characteristics such as income compared to households who were present at the home and not at work during the day.

Recall limitation may have occurred in terms of reporting the outcome variable. The initial outcome variable of "past 4 day diarrhea" was intended to reduce recall limitation, but the incidence of past 4 day diarrhea was too low for analysis. Therefore, "past year diarrhea" variable became the primary outcome. Parents or caregivers may not have remembered if the child had diarrhea in the past year or how many episodes the child had within the past year, which can result in underestimation of the diarrheal rate. An underestimation of the diarrhea rate would be evidence of non-differential misclassification by ODF area because both locations are subject to under-reporting the diarrhea in their children.

Recall bias may have occurred if respondents were more likely to report their child's diarrhea status due to the child having frequent morbidities. For example, the prevalence of diarrhea was higher in HIV positive children (66.7%) compared to HIV negative children (33.3%) ($p<0.001$). Respondents of HIV positive children may have been more likely to report diarrhea compared to HIV negative children because of constant morbidities in the HIV positive child.

The cross-sectional natural of the study may produce temporal bias in terms of the study outcome of past year diarrhea; current water sources may have changed over time. Diarrhea may be due to other conditions or coincidences. It is difficult to know if the child's diarrhea episodes were due to the ODF exposures or other reasons when only one household visit to interview was conducted for the study.

C. Future Directions and Public Health Implications

The data produced by this study will be utilized by the Ministry of Public Health and Sanitation. Based on the study's findings, public health officers should promote home based water treatment interventions in the ODF community. Of the respondents who treat their drinking water, 76.5% report using chlorine and 7.6% report boiling. Public health officers should conduct education sessions to ensure that community members are using proper methods to chlorinate or boil water. Introducing alternative methods for water treatment may be another option to be sure that water is sanitized effectively. Despite finding no difference in diarrheal rate by intervention location, latrine construction should still be supported in the non-ODF location considering that households within 10 minutes of toilet had a reduced risk of diarrhea. Ideally, the combination of latrines and proper water treatment should reduce the risk of diarrhea in ODF communities. Public health officers should also emphasize safe disposal of children's feces as a component of the intervention. Interventions should be specially implemented for children with HIV. The WHO (2015) recommends "exclusive breastfeeding of infants up to 6 months of age and complementary foods with continued breastfeeding up to 2 years of age and older". For HIV-exposed infants, the WHO (2010) still recommends continued breastfeeding.

VII. CONCLUSION

In conclusion, we confirmed preliminary data showing that diarrheal disease rates in children ≤ 5 in Nyando district of western Kenya did not differ by whether a latrine intervention was implemented. However, we observe that this was likely due to water safety and recommend water treatment intervention in the ODF district. Lastly, we identified modifiable factors that can be addressed in both districts to reduce rates of diarrheal disease among children ≤ 5.

VIII. REFERENCES

Alam, N. H. & Ashraf, H. (2003). Treatment of infectious diarrhea in children. *Pediatric Drug, 5*(3): 151-165.

Allen, S. J et al. (2013). Lactobacilli and bifidobacteria in the prevention of antibiotic-associated diarrhoea and Clostridium difficile diarrhea in older inpatients (PLACIDE): a randomized, double-blind, placebo-controlled, multicentre trial. *The Lancet, 382*(9900): 1249-1257.

Aquagenx. (2015). *Safe Water for Anyone, Anywhere, Anytime*.

Arvelo, W. et al. (2010). Case-control study to determine risk factors for diarrhea among children during a large outbreak in a country with a high prevalence of HIV infection. *International Journal of Infectious Diseases*, *14*(1002-1007).

Ashbolt, N. J., Grabow, W. O. K., & Snozzi, M. (2001). Indicators of microbial water quality. *IWA Publishing*,, 289-316.

Aziz, K. M. A., Hoque, B. A., Hasan, K. Z., Patwary, M. Y., Huttly, S. R., Rahaman, M. M., & Feachem, R. G. (1990). Reduction in diarrhoeal diseases in children in rural Bangladesh by environmental and behavioural modifications. *Transactions of the Royal Society of Tropical Medicine and Hygiene, 84*(3), 433-438.

Azurin, J. C., & Alvero, M. (1974). Field evaluation of environmental sanitation measures against cholera. *Bulletin of the World Health Organization, 51*(1), 19.

Baltazar, J.C. & Solon, F.S. (1989). Disposal of faeces of children under two years old diarrhea incidence: a case-control. *International journal of epidemiology*, *18*(2): S16-S19.

Baqui, A H. et al. (2002). Effecgt of zinc supplementation started during diarrhea on morbidity and mortality in Bangladeshi children: community randomized trial. *BMJ*, *325*(7372): 1059.

Barrell, R. A. E. & Rowland, M. G. M. (1979). Infant foods as a potential source of diarrheal illness in West Africa. *Transaction of Royal Society of Tropical Medicine and Hygiene*, *73*(1): 85-90.

Barreto, M. L., Genser, B., Strina, A., Assis, A. M. O., Rego, R. F., Teles, C. A., ... & Teixeira, M. G. (2007). Effect of city-wide sanitation programme on reduction in rate of childhood diarrhoea in northeast Brazil: assessment by two cohort studies. *The Lancet*, *370*(9599), 1622-1628.

Bain, R., Cronk, R., Wright, J., Yang, H., Slaymaker, T., & Bartram, J. (2014). Fecal contamination of drinking-water in low-and middle-income countries: a systematic review and meta-analysis.

Baum, R., Luh, J., & Bartram, J. (2013). Sanitation: a global estimate of sewerage connections without treatment and the resulting impact on MDG progress. *Environmental science & technology*, *47*(4), 1994-2000.

Baum, R. et al. (2014). Assessing the Microbial Quality of Improved Drinking Water Sources: Results from the Dominican Republic. *The American journal of tropical medicine and hygiene*, *90*(1): 121-123.

Belizario, V.Y. et al. (2015). Parasitological and nutritional status of school-age and preschool-age child in four villages in Southern Leyte, Philippines: Lessons for monitoring the outcome of Community-Led Total Sanitation. *Acta tropica*, *141*:16-24.

Bennett, S., Woods, T., Liyanage, W. M., & Smith, D. L. (1991). A simplified general method for cluster-sample surveys of health in developing countries. World Health Stat Q, 44(3), 98-106.

Bhandari, N. et al. (2002). Substantial reduction in severe diarrheal morbidity by daily zinc supplementation in young north Indian children. *Pediatrics*, *109*(6): e86-e86.

Bhatnagar, S. et al. (2004). Zinc with oral rehydration therapy reduces stool output and duration of diarrhea in hospitalized children: a randomized controlled trial. *Journal of pediatric gastroenterology and nutrition*, *38*(1): 34-40.

Binder, H. J. et al. (2014). Oral Rehydration Therapy in the Second Decade of the Twenty-first Century. *Current gastroenterology*, *16*(3): 1-8.

Black, R. E. (1984). Diarrheal diseases and child morbidity and mortality. *Populations and Development Review*, 141-161.

Black R. E. et al. (1987). Prevention of shigellosis by a *Salmonella typhi-Shigella sonnei* bivalent vaccine. *Journal of Infectious Diseases*, *155*: 1260-1265.

Bloss, E., Wainaina, F., & Bailey, R. C. (2004). Prevalence and predictors of underweight, stunting, and wasting among children aged 5 and under in western Kenya. *Journal of tropical pediatrics*, *50*(5), 260-270.

Bongartz, P. et al. (2010). Tales of shit: Community-Led Total Sanitation in African-an overview. *Participatory learning and action* , *61*(1): 27-50.

Boschi-Pinto, C., Velebit, L., & Shibuya, K. (2008). Estimating child mortality due to diarrhoea in developing countries. *Bulletin of the World Health Organization*, *86*(9), 710-717.

Boudraa, G. et al. (2001). Effect of feeding yogurt versus milk in children with acute diarrhea and carbohydrate malabsorption. *Journal of pediatric gastroenterology and nutrition*, *33*(3): 307-313.

Brooks, J. T., Ochieng, J. B., Kumar, L., Okoth, G., Shapiro, R. L., Wells, J. G., ... & Slutsker, L. (2006). Surveillance for bacterial diarrhea and antimicrobial resistance in rural western Kenya, 1997–2003. *Clinical infectious diseases*, *43*(4), 393-401.

Cairncross, S. et al. (1996). The public and domestic domains in the transmission of disease. *Tropical Medicine & International Health*, *1*(1): 27-34.

Cairncross, S., Hunt, C., Boisson, S., Bostoen, K., Curtis, V., Fung, I. C., & Schmidt, W. P. (2010). Water, sanitation and hygiene for the prevention of diarrhoea. *International journal of Epidemiology*, *39*(suppl 1), i193-i205.

Caruso, B. A., Freeman, M. C., Garn, J. V., Dreibelbis, R., Saboori, S., Muga, R., & Rheingans, R. (2014). Assessing the impact of a school-based latrine cleaning and handwashing program on pupil absence in Nyanza Province, Kenya: a cluster-randomized trial. *Tropical Medicine & International Health*, *19*(10), 1185-1197.

Cattermole, G. N., Leung, P. Y. M., Mak, P. S. K., Graham, C. A., & Rainer, T. H. (2010). Mid-arm circumference can be used to estimate children's weights. *Resuscitation*, *81*(9), 1105-1110.

Chai, N. (2009). Sustainability Balanced Scorecard of SPES. In *Sustainability Performance Evaluation System in Government* (pp. 81-117). Springer Netherlands.

Chandra, R. K. (1991). Trace elements in nutrition of children-2. In *Nestle Nutrition Workshop Series* (Vol. 23). Raven Press.

Cheng, A. C et al. (2005). Infectious diarrhea in developed and developing countries. *Journal of clinical gastroenterology*, *39*(9): 757-773.

Child Health Epidemiology Reference Group (CHERG). (2015). *Breastfeeding and the Risk for Diarrhea Morbidity and Mortality*. Retrieved December 8, 2015, from http://cherg.org/projects/List-summaries/breastfeeding.html.

CCMimpact Annual Report: 1 October 2011 to 30 September 2012, Canadian International Development Agency, Population Services International:41.

Clasen, T. F. et al. (2010). Interventions to improve disposal of human excreta for preventing diarrhea. *Cochrane Database System Review*, *6*.

Clasen, T., Boisson, S., Routray, P., Torondel, B., Bell, M., Cumming, O., ... & Schmidt, W. P. (2014). Effectiveness of a rural sanitation programme on diarrhoea, soil-transmitted helminth infection, and child malnutrition in Odisha, India: a cluster-randomised trial. *The Lancet Global Health*, *2*(11), e645-e653.

Coles, C. L. et al. (2009). Risk factors for the initial symptomatic Giardia infection in a cohort of young Arab-Bedouin children. *Annals of Tropical Pediatrics: International Child Health*, *29*(4): 291-300.

Cumming, O., Elliott, M., Overbo, A., & Bartram, J. (2014). Does global progress on sanitation really lag behind water? An analysis of global progress on community-and household-level access to safe water and sanitation. *PloS one*, *9*(12), e114699.

Curtis, V. et al. (2000). Review: Domestic hygiene and diarrhoea-pinpointing the problem. *Tropical medicine & international health*, *5*(1): 22-32.

Daniels, D. L., Cousens, S. N., Makoae, L. N., & Feachem, R. G. (1990). A case-control study of the impact of improved sanitation on diarrhoea morbidity in Lesotho. *Bulletin of the World Health Organization*, *68*(4), 455.

Darrow, D. C. et al. (1949). Disturbances of water and electrolytes in infantile diarrhea. *Pediatrics*, *3*(2).

Dewy, K. (2003). On Guiding principles for complementary feeding of the breastfed child.

Dickinson, B. & Surawicz, C.M. (2014). Infectious diarrhea: an overview. *Current gastroenterology reports*, *16*(8): 1-6.

Dupont, H. L. (2009). Bacterial diarrhea. *New England Journal of Medicine*, *361*(16): 1560-1569.

Echeverria, P. et al. (1983). Flies as a source of enteric pathogens in a rural village in Thailand. *Applied and environmental microbiology*, *46*(1): 32-36.

Elhag, W. I., & Saeed, H. A. Sudan University of Science & Technology College of Graduate Studies.

Eschete, W. B. (2009). A stepwise regression analysis on under-five diarrheal morbidity prevelance in Nekemte town, western Ethiopia: maternal care giving and hygiene behavioral determinants. *East African Journal of Public Health*, *5*(3): 193-198.

Esrey, S. A., Feachem, R. G., & Hughes, J. M. (1985). Interventions for the control of diarrhoeal diseases among young children: improving water supplies and excreta disposal facilities. *Bulletin of the World Health organization*, *63*(4), 757.

Feachem, R., Mara, D. D., & Bradley, D. J. (1983). *Sanitation and disease*. John Wiley & Sons.

Gadewar, S. & Fasano, A. (2005). Current concepts in the evaluation, diagnosis and management of acute infectious diarrhea. *Current opinion in pharmacology*, *5*(6): 559-565.

Galan, D. I., Kim, S. S., & Graham, J. P. (2013). Exploring changes in open defecation prevalence in sub-Saharan Africa based on national level indices. *BMC public health*, *13*(1), 527.

Garrett, V., Ogutu, P., Mabonga, P., Ombeki, S., Mwaki, A., Aluoch, G., ... & Quick, R. E. (2008). Diarrhoea prevention in a high-risk rural Kenyan population through point-of-use chlorination, safe water storage, sanitation, and rainwater harvesting. *Epidemiology and infection*, *136*(11), 1463.

Gascon, J. G. et al. (2000). Diarrhea in Children under 5 Years of Age From Ifakara, Tanzania: a Case-Control Study. *Journal of Microbiology*, *38*(12), pgs. 4459-4462.

Glass, R. I. et al. (1999). First rotavirus vaccine licensed: is there really a need? *Acta Paediatrica*, *88*(s426): 2-8.

Godana, W. et al. (2013). Environmental factors associated with acute diarrhea among children under five years of age in derashe district, South Ethiopia. *Sci. J. Public Health*, *1*(3): 119-124.

Gordis, L. (2013). *Epidemiology*. Baltimore, Maryland: Saunders.

Gorter, A. C. et al. (1998). Hygiene behavior in rural Nicaragua in relation to diarrhea. *International journal of epidemiology*, *27*(6): 1090-1100.

Graczyk, T. K. et al. (2001). The role of non-biting flies in the epidemiology of human infectious diseases. *Microbes and Infection 3*(3): 231-235.

Grady, C. A., Kipkorir, E., Nguyen, K., & Blatchley III, E. R. (2014). Microbial quality of improved drinking water sources: evidence from western Kenya and southern Vietnam.

Green, S. T., Small, M. J., & Casman, E. A. (2009). Determinants of national diarrheal disease burden. *Environmental science & technology*, *43*(4), 993-999.

Graves, P. et al. (2001). Vaccines for preventing cholera. *Cochrane Database System*, *4*.

Guerrant, R. L., Kosek, M., Moore, S., Lorntz, B., Brantley, R., & Lima, A. A. (2002). Magnitude and impact of diarrheal diseases. *Archives of medical research*, *33*(4), 351-355.

Guerrant, R. L., Kosek, M., Lima, A. A., Lorntz, B., & Guyatt, H. L. (2002). Updating the DALYs for diarrhoeal disease. *Trends in parasitology*, *18*(5), 191-193.

Gwatkin, D. R., Guillot, M., & Heuveline, P. (1999). The burden of disease among the global poor. *The Lancet*, *354*(9178), 586-589.

Haines, A., Sanders, D., Lehmann, U., Rowe, A. K., Lawn, J. E., Jan, S., ... & Bhutta, Z. (2007). Achieving child survival goals: potential contribution of community health workers. *The Lancet*, *369*(9579), 2121-2131.

Harrison, H. E. (1989). Dehydration in infancy: hospital treatment. *Pediatrics in Review, 11*(5): 139-143.

Health and Environment: Environment Strategy Background Paper. 2000. Washington, DC : World Bank.

Helmy, Y. A. et al. (2014). Frequencies and spatial distribution of Cryptosporidium in livestock animals and childen in the Ismailia province of Egypt. *Epidemiology and Infection,* 1-11.

Hosmer Jr, D. W., Lemeshow, S., & Sturdivant, R. X. (2013). *Applied logistic regression* (Vol. 398). John Wiley & Sons.

Ichihara, M. Y. et al. (2014). Effectiveness of rotavirus vaccine against hospitalized rotavirus diarrhea: A case control study. *Vaccine*, *32*(23): 2740-2747.

Irish, S., Aiemjoy, K., Torondel, B., Abdelahi, F., & Ensink, J. H. (2013). Characteristics of Latrines in Central Tanzania and Their Relation to Fly Catches. *PloS one*, *8*(7), e67951.

Jamison, D. T., Breman, J. G., Measham, A. R., Alleyne, G., Claeson, M., Evans, D. B., ... & Laxminarayan, R. (2006). Diarrheal Diseases.

Jamison, D. T., Breman, J. G., Measham, A. R., Alleyne, G., Claeson, M., Evans, D. B., ... & Musgrove, P. (Eds.). (2006). *Disease control priorities in developing countries*. World Bank Publications.

Jenkins, M. W., & Curtis, V. (2005). Achieving the ‘good life’: Why some people want latrines in rural Benin. *Social science & medicine*, *61*(11), 2446-2459.

Johnston, B. C. et al. (2012). Probiotics for the Prevention of Clostridium difficile-Associated Diarrhea: A Systematic Review and Meta-analysis. *Annals of internal medicine*, *157*(12): 878-888.

Joint Monitoring Program (JMP). (2013). *Progress on Sanitation and Drinking-Water Update*. World Health Organization, Geneva, Switzerland. [http://www.wssinfo.org/definitions-methods/watsan-categories/]

Joint Monitoring Programme for Water Supply and Sanitation (JMP). (2015). *Improved and unimproved water and sanitation facilities*.

Kahabuka, C. et al. (2009). Factors associated with severe disease from malaria, pneumonia and diarrhea among children in rural Tanzania – A hospital-based cross-sectional study. *BMC Infectious Disease, 12*(219), pgs 1-9.

Kamm, K. B. et al. (2014). Associations between presence of handwashing stations and soap in the home and diarrhea and respiratory illness, in children less than five years old in rural western Kenya. *Topical Medicine International Health*, *19*(4): 398-406.

Kar, K., & Chambers, R. (2008). *Handbook on community-led total sanitation*. London: Plan UK.

Kayser, G. L., Moriarty, P., Fonseca, C., & Bartram, J. (2013). Domestic water service delivery indicators and frameworks for monitoring, evaluation, policy and planning: a review. *International journal of environmental research and public health*, *10*(10), 4812-4835.

Kelsey et al. (2015). OpenEpi, Version 3: Sample Size Calculator.

Kenya. Central Bureau of Statistics, Kenya. Ministry of Health, ORC Macro, & ORC Macro. MEASURE/DHS+ (Programme). (2008). *Kenya: demographic and health survey 2008*. Central Bureau of Statistics (KCBS).

Kenya National Bureau of Statistics (KNBS). (2008). *Kenya Demographic and Health Survey: 2008-2009*.

Keush, G. T. et al. (2006). *Disease Control Priorities in Developing Countries: Chapter 19: Diarrheal Diseases* (2nd ed.). Washington, DC: World Bank.

Khatib, A. M. et al. (2012). Effectiveness of an oral cholera vaccine in Zanzibar: findings from a mass vaccination campaign and observational cohort study. *The Lancet infectious diseases*, *12*(11): 837-844.

Koletzko, S. & Osterrider, S. (2009). Acute infectious diarrhea in children. *Dtsch Arztebl Int*, *106*(33): 539-547.

Kothary, M. H. & Uma, S. B. (2001). Infective dose of foodborne pathogens in volunteers: a review. *Journal of food safety, 21*(1): 49-68.

Kosec, K. (2014). The child health implications of privatizing Africa's urban water supply. *Journal of health economics*, *35*, 1-19.

Kotloff, K. L. et al. (1995). Evaluation of the saftery, immunogenicity, and efficacy in healthy adults of four doses of live oral hybrid *Escherichia coli-Shigella flexneri* 2a vaccine strain EcSf2a-2. *Vaccine*, *13*(5): 495-502.

Kotloff, K. L. et al. (1999). Global burden of *Shigel*la infections: implications for vaccine development and implementation of control strategies. *Bulletin of the World Health Organization*, *77*(8): 651-666.

Kunii, O. et al. (2002). The impact on health and risk factors of diarrhea epidemics in the 1998 Bangladesh floods. *Public Health*, *116*: 68-72.

Lamberti, L. M. et al. (2011). Breastfeeding and the risk for diarrhea morbidity and mortality. *BMC public health*, *11*(3): S15.

Langergraber, G., & Muellegger, E. (2005). Ecological Sanitation—a way to solve global sanitation problems?. *Environment international*, *31*(3), 433-444.

The Lancet. (2014). *Countdown to 2015 Maternal, Newborn & Child Survival: Fulfilling the Health Agenda for Women and Children: The 2014 Report*.

Lehmann, U., & Sanders, D. (2007). Community health workers: what do we know about them. *World Health Organization, Geneva*, *34*.

Levels and trends in child mortality: Report. United Nations Children's Fund., 2014.

Levine, M. M. et al. (1973). Pathogenesis of Shigella dysenteriae 1 (Shiga dysentery). *Journal of infectious diseases*, *12*(3): 261-270.

Levine, M. M. et al. (1977). Studies with a new generation of oral attenuated Shigella vaccine: Escherichia coli bearing surface antigens of Shigella flexneri. *Journal of infectious diseases*, *136*(4): 577-582.

Lopez, A. D., & Murray, C. C. (1998). The global burden of disease. *Nat Med*, *4*(11), 1241-1243.
Lenton, R. L., Wright, A. M., & Lewis, K. (Eds.). (2005). *Health, Dignity and Development: What Will it Take?*. Earthscan.

Lijima, A. Y. et al. (2004). Improvement in the detection rate of diarrhoeagenic bacteria in human stool specimens by a rapid real-time PCR. *Journal of medical microbiology*, *53*(7): 617-622.

Liu, L. et al. (2012). Global, regional, national causes of child mortality: an updated systematic analysis for 2010 with time trends since 2000. *Lancet*, *379*(9832): 2151-2161.

Luby, S. P. et al. (2004). Effect of intensive handwashing promotion on childhood diarrhea in high-risk communities in Pakistan: a randomized controlled trial. *Jama*, *291*(21): 2547-2554.

Mac Kenzie, W. R., Hoxie, N. J., Proctor, M. E., Gradus, M. S., Blair, K. A., Peterson, D. E., ... & Davis, J. P. (1994). A massive outbreak in Milwaukee of Cryptosporidium infection transmitted through the public water supply. *New England journal of medicine*, *331*(3), 161-167.

Mackowiak, P. A. et al. (1992). An analysis of the quantitative relationship between oral temperature and severity of illness in experimental shigellosis. *Journal of infectious diseases*, *166*(5): 1181-1184.

Mara D. L. et al. (2010). Sanitation and Health. *PLos Med*, *7*(11), 1-7.

McClarren, R. L. et al. (2011). Acute infectious diarrhea. *Primary Care: Clinics in Office Practice*, *38*(3): 539-564.

McCullough, N. B. & Eisele, C. W. (1951). Experimental Human Salmonellosis II: Immunity Studies Following Experimental Illness with Salmonella Meleagridis and Salmonella Anatum. *The Journal of Immunology*, *66*(5): 595-608.

Mehta, L. et al. (2010). The dynamics and sustainability of Community-Led Total Sanitation (CLTS). *Mapping challenges and pathways*.
Microbiology Laboratories (ML). (2015). *Coliscan Easygel*.
Millennium Development Goals. United Nations. (2015).

Milojevic, A. et al. (2012). Health effects of flooding in rural Bangladesh. *Epidemiology*, *23*(1): 107-115.

MIRASSE, A. (2009). COMPARING RURAL SANITATION CAMPAIGNS IN MOZAMBIQUE: LESSONS AND CONSIDERATIONS FOR ACHIEVING SUSTAINABLE RESULTS.

Mukherjee, N., Robiarto, A., Saputra, E., & Wartono, D. (2012). Achieving and Sustaining Open Defecation Free Communities: Learning from East Java. *Water and Sanitation Program*.

Mundial, B. (2001). Making sustainable commitments: an environment strategy for the World Bank. In *Making sustainable commitments: an environment strategy for the World Bank*. Banco Mundial.

Munoz, C. et al. (1995). Characteristics of Shigella sonnei infection of volunteers: signs, symptoms, immune responses, changes in selected cytokines and acute-phase substances. *The American journal of tropical medicine and hygiene*, *53*(1): 47-54.

Mwangome, M. K., Fegan, G., Fulford, T., Prentice, A. M., & Berkley, J. A. (2012). Mid-upper arm circumference at age of routine infant vaccination to identify infants at elevated risk of death: a retrospective cohort study in the Gambia. *Bulletin of the World Health Organization*, *90*(12), 887-894.

Myo, H.A. & Moe, K. (1990). Household faecal contamination and diarrhea risk. *The Journal of tropical medicine hygiene*, *93*(5): 333-336.

Navaneethan, U. & Giannella, R. A. (2008). Mechanisms of infectious disarrhea. *Nature clinical practice Gastroenterology & hepatology*, *5*(11): 637-647.

Nanan, D., White, F., Azam, I., Afsar, H., & Hozhabri, S. (2003). Evaluation of a water, sanitation, and hygiene education intervention on diarrhoea in northern Pakistan. *Bulletin of the World Health Organization*, *81*(3), 160-165.

Nation Master (NM). (2015). *Country vs. Country: Canada and China compared: People stats*. Retrieved December 8, 2015, from http://www.nationmaster.com/country-info/compare/Canada/China/People.

Nichols, G. L. (2010). Disease transmission by non-biting hlies. *Environmental Medicine. London: Hodder Arnold*, 434-46.

Njume, C. & Goduka, N. I. (2012). Treatment of diarrhoea in rural African Communities: an overview of measures to maximize the medicinal potentials of indigenous plants. *International journal of environmental research and public health*, *9*(11): 3911-3933.

Nyakundi, H., Mogere, S., Mwanzo, I., & Yitambe, A. (2010). Community perceptions and response to flood risks in Nyando District, Western Kenya. *Jàmbá: Journal of Disaster Risk Studies*, *3*(1), 346-366.

Nykiforuk, C. I., & Flaman, L. M. (2008). *Exploring the utilization of geographic information systems in health promotion and public health*. Centre for Health Promotion Studies, School of Public Health, University of Alberta.

Nykiforuk, C. I., & Flaman, L. M. (2009). Geographic information systems (GIS) for health promotion and public health: a review. *Health promotion practice*.

Obuh, P. (2015, November 4). Unemployed health officers decry neglect. Retrieved from http://tsaftarmuhalli.blogspot.co.uk/.

OECD/WHO. (2003). *Assessing Microbial Safety of Drinking Water: Improving Approaches and Methods*. Geneva: World Health Organization.

Ochoa, T. J. et al. (2004). Management of child with infection-associated persistent diarrhea. In *Seminars in pediatric infectious diseases*, *15*(4): 229-236.

Ochomo, E., Bayoh, N. M., Kamau, L., Atieli, F., Vulule, J., Ouma, C., & Mbogo, C. (2014). Pyrethroid susceptibility of malaria vectors in four Districts of western Kenya. *Parasites & vectors*, *7*(1), 310.

O’Loughlin, R. et al. (2006). Follow-up of a low cost latrine promotion programme in one district of Amhara, Ethiopia: characteristics of early adopters and non-adopters . *Tropical Medicine & International Health*, *11*(9): 1406-1415.

Ombui, J.N. et al. (2001). Foodborne diseases in Kenya. *East African medical journal*, *78*(1): 40-44.

ON, P. (2013). SANITATION AND DRINKING-WATER.

O’Reilly, C. et al. (2012). Risk Factors for Death among Children Less than 5 Years Old Hospitalized with Diarrhea in Rural Western Kenya, 2005-2007: A Cohort Study. *PLos Medicine*, *9*(7), pgs 1-13.

O'Ryan, M., Prado, V., & Pickering, L. K. (2005, April). A millennium update on pediatric diarrheal illness in the developing world. In *Seminars in pediatric infectious diseases* (Vol. 16, No. 2, pp. 125-136). WB Saunders.

Parashar, U. D. et al. (2003). Global illness and deaths caused by rotavirus disease in children. *Emerging infectious diseases*, *9*(5): 565.

Parker, D. J. (2000). Floods in Africa: vulnerability, impacts and mitigation. *Floods. London: Routledge*, 288-203.

Patil, S. R. et al. (2014). The Effect of India's Total Sanitation Campaign on Defecation Behaviors and Child Health in Rural Madhya Pradesh: A Cluster Randomized Controlled Trial. *PLos Medicine*, *11*(8), pgs 1-17.

Pawlowski, S. W. et al. (2009). Diagnosis and treatment of acute or persistent diarrhea. *Gastroenterology*, *136*(6): 1874-1886.

Peter, G. & Nkambule, S. E. (2012). Factors affecting sustainability of rural water schemes in Swaziland. *Physics and Chemistry of the Earth*, *50*(52), pgs. 196-204.

Rahman, M. et al. (1985). Impact of environmental sanitation and crowding on infant mortality in rural Bangladesh. *The Lancet*, *326*(8445): 28-30.

Rego, R. F., Moraes, L. R. S., & Dourado, I. (2005). Diarrhoea and garbage disposal in Salvador, Brazil. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, *99*(1), 48-54.

Rhiney, K. (2014). Urban Water Governance. GEOG3333: Urban & Regional Planning.

Roberts, L., Chartier, Y., Chartier, O., Malenga, G., Toole, M., & Rodka, H. (2001). Keeping clean water clean in a Malawi refugee camp: a randomized intervention trial. *Bulletin of the World Health Organization*, *79*(4), 280-287.

Robins, M. L. (2011). *A study of the acceptability and use of alcohol based waterless hand sanitizer among street food vendors in Pilani, India*. State University of New York at Buffalo.

Rollins, N.C. et al. (2013). Exclusive breastfeeding, diarrheal morbidity and all cause mortality in infants of HIV-infected and HIV uninfected mothers: an intervention cohort study in JwaZulu Natal, South Africa. *PloS one*, *8*(12): e81307.

Ryan, E. T. & Calderwood, S. B. (2000). Cholera vaccines. *Clinical infectious diseases*, *31*(2): 561-565.

Salminen, S. et al. (1998). Functional food science and gastrointestinal physiology and function. *British Journal of Nutrition*, *80*(S1): S147-S171.

Schäfer, A. I., Hughes, G., & Richards, B. S. (2014). Renewable energy powered membrane technology: A leapfrog approach to rural water treatment in developing countries?. *Renewable and Sustainable Energy Reviews*, *40*, 542-556.

Scott, L. (2006). Chronic poverty and the environment: A vulnerability perspective. *Chronic Poverty Research Centre Working Paper*, (62).

Seguin, M., & Niño-Zarazúa, M. (2013). What do we know about non-clinical interventions for preventable and treatable childhood diseases in developing countries?.

Shaheed, A., Orgill, J., Ratana, C., Montgomery, M. A., Jeuland, M. A., & Brown, J. (2014). Water quality risks of 'improved'water sources: evidence from Cambodia. *Tropical Medicine & International Health*, *19*(2), 186-194.

Shapiro, R. L., Kumar, L., Phillips-Howard, P., Wells, J. G., Adcock, P., Brooks, J., ... & Slutsker, L. (2001). Antimicrobial-resistant bacterial diarrhea in rural western Kenya. *Journal of Infectious Diseases*, *183*(11), 1701-1704.

Skolnik, R. (2008). *Essentials of global health*. Jones & Bartlett Publishers.

Shyamsundar, P. (2002). *Poverty--environment Indicators*. Environment Department, World Bank.

Snow, J. (1855). *On the mode of communication of cholera*. John Churchill.

Someswara, K. R. et al. (1959). Protein and Malnutrition in South India. *Bulletin of the World Health Organization*, *20*(603-639).

Standard methods for the examination of water and wastewater. Washington, DC: American Public Health Association (APHA), 2012.

Stanton, B. F. & Clemens, J. D. (1987). An education intervention for altering water-sanitation behaviors to reduce childhood diarrhea in urban Bangladesh II: A randomized trial to assess the impact of the intervention on hygienic behaviors and rates of diarrhea. *American journal of epidemiology 125*(2): 292-301.

Steyn, N. P. et al. (2006). Food variety and dietary diversity scores in children: are they good indicators of dietary adequacy. *Public health nutrition*, *9*(05): 644-650.

Strand, T. A. et al. (2002). Effectiveness and efficacy of zinc for the treatment of acute diarrhea in young children. *Pediatrics*, *109*(5): 898-903.

Strand, T. A. et al. (2012). Risk Factors for Extended Duration of Acute Diarrhea in Young Children. *Plos One*, *7*(5).

Sustainable Sanitation and Water Management (SSWM). (2015). *Glossay*. Retrieved December, 8, 2015, from http://www.sswm.info/glossary.

Tetteh, S. O. L. O. M. O. N. (2013). *Sanitation and Diarrhoeal Disease among Children under Five Years in Ghana* (Doctoral dissertation, University of Ghana).

Thapar, N. & Sanderson, I. R. (2004). Diarrhoea in children: an interface between developing and developed countries. *The Lancet*, *363*(9409): 641-653.
UNICEF Annual Report 2012 for Kenya. United Nations, 2012.

Tiondi, E. (2000). On Women, Environmental and Development: A Sub-Saharan African and Latin American. *University of South Florida*.

Tiwari, S. S. K., Schmidt, W. P., Darby, J., Kariuki, Z. G., & Jenkins, M. W. (2009). Intermittent slow sand filtration for preventing diarrhoea among children in Kenyan households using unimproved water sources: randomized controlled trial. *Tropical Medicine & International Health*, *14*(11), 1374-1382.

Traore, E. et al. (1994). Child defecation behavior stool disposal practices, and childhood diarrhea in Burkina Faso: results from a case-control study. *Journal of epidemiology and community health*, *48*(3): 270-275.

Tucker A. W. et al. (1998). Cost-effectiveness analysis of a rotavirus immunization program for the United States. *Jama*, *279*(17): 1371-1376.

UNICEF/WHO. (2010). *Diarrhoea: why child are still dying and what can be done*.

UNICEF: Eastern and Southern Africa Regional Office (UNICEF: ESARO). (2012). *UNICEF Annual Report 2012 for Kenya, ESARO*.

UniCeF. (2008). Progress on drinking water and sanitation: Special focus on sanitation. In *Progress on Drinking Water and Sanitation: Special Focus on Sanitation*. WHO/JMP.

UNICEF. (2013). *Committing to Child Survival: A Promise Renewed: Progress Report 2013*.

UNICEF. (2014). *Committing to Child Survival: A Promise Renewed: Progress Report 2014*.

UNICEF (UN). (2015). *Nutrition in Emergencies: Lessons List: Measuring MUAC*. http://www.unicef.org/nutrition/training/3.1.3/1.html

UN. Under-Five Mortality Rate.

United Nations (UN). (2012). *Indicators for Monitoring the Millennium Development Goals: Definitions, Rationale, Concepts and Sources*.

Waddington, H., & Snilstveit, B. (2009). Effectiveness and sustainability of water, sanitation, and hygiene interventions in combating diarrhoea. *Journal of development effectiveness*, *1*(3), 295-335.

Wagner, E. G., & Lanoix, J. N. (1958). Excreta disposal for rural areas and small communities. *Excreta Disposal for Rural Areas and Small Communities.*

Walker, C. L et al. (2012). Diarrhea incidence in low- and middle-income countries in 1990 and 2010: a systematic review. *BMC Public Health*, *12*(220).

Walker, C. L. et al. (2013). Global burden of childhood pneumonia and diarrhea. *The Lancet*, *38*(9875): 1405-1416.

Whitehead, F.J. et al. (1996). Dehydration deaths in infants and young children. *The American journal of forensic medicine and pathology*, *17*(1): 73-78.

Action Project: Ugandan Water Project. (2013). In GeneseoWiki.Retrieved December 8, 2015, from https://wiki.geneseo.edu/display/cultural/Action+Project:+Ugandan+Water+Project.

Wolf, J. et al. (2014). Assessing the impact of drinking water and sanitation on diarrheal disease in low- and middle-income settings: systematic review and meta-regression. *Tropical Medicine & International Health*, *19*(8): 928-942.

World Gastroenterology Organisation (WGO). (2012, February). *Global Guidelines: Acute diarrhea in adults and children: a global perspective*.

World Health Organization (WHO). (2001, March). *Report of the expert consultation of the optimal duration of exclusive breastfeeding*, Geneva, Switzerland.

World Health Organization: Department of Child and Adolescent Health and Development (WHO). (2005). *The Treatmet of Diarrhoea: A manual for physicians and other senior health workers*.

The World Health Organization (WHO). (2005). *The Treatment of Diarrhea: A Manual for physician and other senior health workers*.

World Health Organization. (2014). *Progression on sanitation and drinking water-2014 update.* Geneva, Switzerland: WHO Press.

World Health Organization (WHO). (2015). *Exclusive Breastfeeding*.
World Health Organization (WHO). (2010). Guidelines on HIV and infant feeding 2010. *Principles and recommendations for infant feeding in the context of HIV and a summary of evidence*.

World Health Organization: Joint Monitoring Programme (WHO: JMP). (May 2014). *A Snapshot of Drinking Water and Sanitation in South-eastern Asia and the Pacific*.

World Health Organization: Joint Monitoring Programme (WHO: JMP). (May 2014). *Progress on drinking water and sanitation*.

Wagner, E. G., & Lanoix, J. N. (1958). Excreta disposal for rural areas and small communities. *Excreta Disposal for Rural Areas and Small Communities.*

Walker, C. L. F., Rudan, I., Liu, L., Nair, H., Theodoratou, E., Bhutta, Z. A., ... & Black, R. E. (2013). Global burden of childhood pneumonia and diarrhoea. *The Lancet*, *381*(9875), 1405-1416.

Walsh, C. M., Dannhauser, A., & Joubert, G. (2002). The impact of a nutrition education programme on the anthropometric nutritional status of low-income children in South Africa. *Public Health Nutrition*, *5*(01), 3-9.

World Health Organization: Department of Child and Adolescent Health and Development

(WHO). (2005). *The Treatment of Diarrhoea: A manual for physicians and other senior health workers*.

World Health Organization (WHO). (2006). *Training Course on Child Growth Assessment:*

WHO Child Growth Standards: WHO Growth Standards: Boys Growth Record.

World Health Organization (WHO). (2006). *Training Course on Child Growth Assessment:*

WHO Child Growth Standards: WHO Growth Standards: Girls Growth Record.

World Health Organization (WHO). (2008). *Training Course on Child Growth Assessment:*

WHO Child Growth Standards: Interpreting Growth Indicators.

World Health Organization (WHO). (2008). *Training Course on Child Growth Assessment:*

WHO Child Growth Standards: Measuring a Child's Growth.

World Health Organization (WHO). *Fact Sheet 2.33: Turbidity measurement*.

World Health Organization (WHO). (2010). *Kenya: Health Statistics Profile 2010*.

Yusof, A. et al. (1991). 1988 floods in Bangladesh: a pattern of illness and causes of death. *Journal of diarrhea diseases research*: 310-314.

APPENDICES

APPENDIX A

TABLE 6a. SINGLE FACTOR STRATIFIED ANALYSIS FOR RELATIONSHIP BETWEEN SUB LOCATION 1 (ODF) VS. SUB LOCATION 3 (ODF) AND DIARRHEA STATUS, ADJUSTED FOR COVARIATES

	Adjusted PRR [95% CI]	Breslow Day P-value
Sub-location 1 (ODF) vs. 3 (ODF) and Diarrhea Crude: 1.49 [0.82, 2.70]		
Child HIV Status		0.439
HIV Negative	1.79 [0.84, 3.84]	
HIV Positive	--------	
Don't Know	1.03 [0.39, 2.66]	
Wash hands after last stool		0.682
No	--------	
Yes	0.88 [0.73, 1.05]	
Don't Know	0.61 [0.15, 2.51]	
Highest Education Level Obtained		0.478
No Education	3.00 [0.39, 23.07]	
Some Education	1.50 [0.79, 2.86]	
Toilet Availability (≤10 mins from household cluster location)		0.084
No	---------	
Yes	1.31 [0.71, 2.40]	
Young Child Stool Disposal (≤3 Years)		0.467
Bury in Yard	2.25 [0.92, 5.50]	
Put on the Ground	2.40 [0.29, 19.33]	
Throw in Latrine	1.29 [0.60, 2.76]	
Child >3 Years Old	--------	
Don't Know	--------	
Last Month Income (KSH)		0.213
None	2.00 [0.59, 6.74]	
Less than 2,000	0.59 [0.17, 2.12]	
More than 2,000	0.62 [0.20, 1.91]	
Where do you get your drinking water?		0.257
Tap	0.30 [0.07, 1.40]	
Natural	0.73 [0.31, 1.73]	
Well	1.39 [0.44, 4.43]	
Is there soap present outside of the household latrine?		
No Latrine, No Soap Present	--------	0.132
Yes Latrine, No Soap Present	1.31 (0.71, 2.40)	

-------- = missing data, zero cells cannot compute PRR
PRR = Prevalence Rate Ratio, CI = Confidence Interval

TABLE b. SINGLE FACTOR STRATIFIED ANALYSIS FOR RELATIONSHIP BETWEEN SUB LOCATION 2 (ODF) VS. SUB LOCATION 3 (ODF) AND DIARRHEA STATUS, ADJUSTED FOR COVARIATES

	Adjusted PRR [95% CI]	Breslow Day P-value
Sub-location 2 (ODF) vs. 3 (ODF) and Diarrhea Crude: 1.28 [0.66, 2.51]		
Child HIV Status		0.015
HIV Negative	2.22 [0.99, 4.97]	
HIV Positive	--------	
Don't Know	0.24 [0.05, 1.09]	
Wash hands after last stool		0.608
No	0.50 [0.07, 3.55]	
Yes	1.44 [0.67, 3.12]	
Don't Know	1.38 [0.17, 11.34]	
Highest Education Level Obtained		0.232
No Education	--------	
Some Education	0.88 [0.71, 1.09]	
Toilet Availability (≤10 mins from household cluster location)		--------
No	--------	
Yes	1.23 [0.63, 2.39]	
Young Child Stool Disposal (≤3 Years)		0.427
Bury in Yard	2.25 [0.84, 5.99]	
Put on the Ground	4.00 [0.56, 28.40]	
Throw in Latrine	1.00 [0.41, 2.48]	
Child >3 Years Old	0.83 [0.58, 1.19]	
Don't Know	--------	
Last Month Income (KSH)		0.838
None	1.75 [0.38, 8.06]	
Less than 2,000	1.08 [0.40, 2.93]	
More than 2,000	1.06 [0.38, 2.96]	
Where do you get your drinking water?		0.137
Tap	1.27 [0.45, 3.58]	
Natural	0.21 [0.03, 1.56]	
Well	0.89 [0.71, 1.10]	
Is there soap present outside of the household latrine?		
No Latrine, No Soap Present	--------	0.067
Yes Latrine, No Soap Present	1.16 (0.59, 2.29)	

-------- = missing data, zero cells cannot compute PRR

PRR = Prevalence Rate Ratio, CI = Confidence Interval

TABLE c. SINGLE FACTOR STRATIFIED ANALYSIS FOR RELATIONSHP BETWEEN SUB LOCATION 4 (NON-ODF) VS. SUB LOCATION 3 (ODF) AND DIARRHEA STATUS, ADJUSTED FOR COVARIATES

	Adjusted PRR [95% CI]	Breslow Day P-value
Sub-location 4 (Non-ODF) vs. 3 (ODF) and Diarrhea Crude: 1.34 [0.77, 2.34]		
Child HIV Status		0.151
HIV Negative	1.72 [0.83, 3.54]	
HIV Positive	1.20 [0.27, 5.25]	
Don't Know	0.50 [0.19, 1.33]	
Wash hands after last stool		0.653
No	0.71 [0.22, 2.28]	
Yes	1.41 [0.72, 2.76]	
Don't Know	1.57 [0.35, 7.06]	
Highest Education Level Obtained		0.505
No Education	2.40 [0.36, 15.94]	
Some Education	1.33 [0.72, 2.45]	
Toilet Availability (≤10 mins from household cluster location)		0.118
No	--------	
Yes	1.03 [0.57, 1.87]	
Young Child Stool Disposal (≤3 Years)		0.282
Bury in Yard	0.93 [0.35, 2.45]	
Put on the Ground	3.27 [0.51, 21.21]	
Throw in Latrine	0.99 [0.47, 2.07]	
Child >3 Years Old	--------	
Don't Know	--------	
Last Month Income (KSH)		0.409
None	1.75 [0.49, 6.16]	
Less than 2,000	1.41 [0.66, 3.04]	
More than 2,000	0.67 [0.23, 1.94]	
Where do you get your drinking water?		0.014
Tap	0.15 [0.19, 1.19]	
Natural	0.71 [0.27, 1.82]	
Well	2.06 [0.92, 4.59]	
Is there soap present outside of the household latrine?		
No Latrine, No Soap Present	--------	0.106
Yes Latrine, No Soap Present	1.03 (0.57, 1.87)	

-------- = missing data, zero cells cannot compute PRR
PRR = Prevalence Rate Ratio, CI = Confidence Interval

TABLE d. SINGLE FACTOR STRATIFIED ANALYSIS FOR RELATIONSHIP BETWEEN SUB LOCATION 5 (NON-ODF) VS. SUB LOCATION 3 (ODF) AND DIARRHEA STATUS, ADJUSTED FOR COVARIATES

	Adjusted PRR [95% CI]	Breslow Day P-value
Sub-location 5 (Non-ODF) vs. 3 (ODF) and Diarrhea Crude: 2.19 [1.25, 3.84]		
Child HIV Status		0.015
HIV Negative	3.06 [1.49, 6.27]	
HIV Positive	1.71 [0.42, 7.08]	
Don't Know	0.36 [0.08, 1.59]	
Wash hands after last stool		0.664
No	1.60 [0.55, 4.68]	
Yes	2.07 [1.03, 4.15]	
Don't Know	3.44 [0.88, 13.44]	
Highest Education Level Obtained		0.146
No Education	4.40 [0.72, 27.02]	
Some Education	1.79 [0.92, 3.46]	
Toilet Availability (≤10 mins from household cluster location)		0.069
No	--------	
Yes	1.32 [0.66, 2.66]	
Young Child Stool Disposal (≤3 Years)		0.172
Bury in Yard	1.94 [0.81, 4.65]	
Put on the Ground	3.82 [0.60, 24.14]	
Throw in Latrine	1.13 [0.46, 2.79]	
Child >3 Years Old	--------	
Don't Know	--------	
Last Month Income (KSH)		0.401
None	2.75 [0.83, 9.16]	
Less than 2,000	1.91 [0.85, 4.28]	
More than 2,000	1.28 [0.40, 4.15]	
Where do you get your drinking water?		0.038
Tap	1.36 [1.04, 1.78]	
Natural	0.93 [0.40, 2.15]	
Well	2.44 [0.94, 6.37]	
Is there soap present outside of the household latrine?		
No Latrine, No Soap Present	--------	0.072
Yes Latrine, No Soap Present	1.41 (0.71, 2.87)	

-------- = missing data, zero cells cannot compute PRR

PRR = Prevalence Rate Ratio, CI = Confidence Interval

TABLE 10. ASSESSING CONFOUDING BETWEEN ODF AND DIARRHEA STATUS ADJUSTED FOR COVARIATES

	Adjusted PRR (CMH) 95% CI	**Relative Effect**
Non-ODF and Diarrhea Crude: 1.26 [0.87, 1.95]		
Child HIV Status	1.15 [0.84, 1.58]	0.087
Wash hands after last stool	1.19 [0.87, 1.63]	0.056
Highest Education Level Obtained	1.21 [0.87, 1.67]	0.039
Toilet Availability (≤10 mins from household cluster location)	0.96 [0.69, 1.37]	0.238
Young Child Stool Disposal (≤3 Years)	1.09 [0.80, 1.47]	0.135
Last Month Income (KSH)	1.33 [0.98, 1.81]	-0.056
Where do you get your drinking water?	1.19 [0.87, 1.62]	0.316
Is there soap present outside of the household latrine?	1.00 [0.71, 1.41]	0.206

PRR = Prevalence Rate Ratio, CI = Confidence Interval, CMH = Cochran Mantel Haenszel
Relative Effect = (Crude PRR – Adjusted PRR) / (Crude PRR), assessing for >10% difference

APPENDIX B

Community Health Survey

1) **Interviewer** ________________

2) **Date** |__||__|/|__|__|/|__||__| Day/Month/Year

3) **Record Time** __ __ : __ __ (24 hour clock)

4) **Location** _____________

5) **Sub Location** __________________

6) ***Interviewer* Open Defecation Free:** ☐$_1$ Yes ☐$_0$ No ☐$_{97}$ Don't Know

7) ***Interviewer* Record Current Temperature** ________˚C OR ________˚F

8) ***Interviewer* When was the last Rain?**

   ☐$_1$ Today ☐$_2$ Yesterday ☐$_3$ Two Days Ago ☐$_4$ Three-Four Days Ago
   ☐$_5$ Five- Seven Days Ago ☐$_6$ More Than One Week Ago ☐$_{97}$ Don't Know

Part 1. Household

9) ***Interviewer OBSERVE:* Type of Home**
   ☐$_1$ Mud home ☐$_2$ Straw Home ☐$_3$ Brick Home ☐$_{97}$ Don't know

10) **Which of the following, if any, do you own?**
   - **a.** Electricity ☐$_1$Yes ☐$_0$No ☐$_{97}$Don't Know
   - **b.** Television ☐$_1$Yes ☐$_0$No ☐$_{97}$ Don't Know
   - **c.** Bicycle ☐$_1$Yes ☐$_0$No ☐$_{97}$ Don't Know
   - **d.** Bed ☐$_1$Yes ☐$_0$No ☐$_{97}$ Don't Know
   - **e.** Soap ☐$_1$Yes ☐$_0$No ☐$_{97}$ Don't Know
   - **f.** Radio ☐$_1$Yes ☐$_0$No ☐$_{97}$ Don't Know
   - **g.** Refrigerator ☐$_1$Yes ☐$_0$No ☐$_{97}$ Don't Know

11) **How many rooms are inside of your house?**
   ☐$_1$ One Room ☐$_2$ Two Rooms ☐$_3$ Three Rooms ☐$_4$ Four Rooms
   ☐$_5$ Five Rooms or More

Part 2. Demographics *[PERTAINS TO INTERVIEWEE]*

12) **Relationship to Child**
   ☐$_1$ Mother ☐$_2$ Father ☐$_3$ Grandparent ☐$_4$ Long term caretaker

13) **In the last month, approximately how many shillings have you earned?**
   ☐$_0$ None ☐$_1$ less than 2,000 ☐$_2$ 2,000 – 4,000 ☐$_3$ 5,000 – 9,999
   ☐$_4$ 10,000 – 25,000 ☐$_5$ More than 25,000 ☐$_{97}$ Don't Know ☐$_{98}$ Refused

14) **What is the highest level of school you attended?**
   ☐$_0$ No formal Education ☐$_1$ Primary Education ☐$_2$ Post-Primary Education

15) **How many people live in your household at least 3 nights per week for the past one month?**
   ☐$_1$ One ☐$_2$ Two ☐$_3$ Three- Four ☐$_4$ Five – Six ☐$_5$ Six – Seven ☐$_6$ Eight or more

16) How many children under the age of 13 live in your household?

☐$_{1}$ One ☐$_{2}$ Two ☐$_{3}$ Three ☐$_{4}$ Four ☐$_{5}$ Five ☐$_{6}$ Six or More

17) What do you do for a living? [Read list and check all that apply]

☐$_{1}$ Farmer ☐$_{2}$ Fisherman/woman ☐$_{3}$ Skilled Laborer ☐$_{4}$ Shop Keeper
☐$_{5}$ Artisan ☐$_{6}$ Homemaker ☐$_{7}$ Student ☐$_{8}$ Unemployed
☐$_{9}$ Looking for work ☐$_{10}$ Other: Specify______________________

18) Which of the following modes of transportation do you use to get to the nearest health facility?
[read list and check all that apply]

☐$_{1}$ Walk ☐$_{2}$ Boda Boda ☐$_{3}$ Tuk Tuk ☐$_{4}$ Matatu ☐$_{5}$ Car

19) Approximately how long does it take you to get to the nearest health facility using the mode of transportation you selected above?

☐$_{1}$ 15 minutes or less ☐$_{2}$ 30 minutes ☐$_{3}$ 45 minutes ☐$_{4}$ 60 minutes
☐$_{5}$ More than 60 minutes

Part 3. Water Source

20) Where do you get your drinking water? *[read list and check all]*

☐$_{1}$Tap inside home ☐$_{2}$Tap outside home (Less than 100 meters)
☐$_{3}$Tap outside home (More than 100 meters) ☐$_{4}$ Borehole
☐$_{5}$ Well water ☐$_{6}$ Rainwater
☐$_{7}$ River ☐$_{8}$ Lake
☐$_{9}$ Pond ☐$_{10}$ Stream
☐$_{11}$ Bottled water ☐$_{12}$ Purchased in a jerry can
☐$_{13}$ Other, specify ________________ ☐$_{97}$ Don't Know

21) Which of the following modes of transportation do you use to get to the drinking water source you identified previously?

☐$_{1}$ Walk ☐$_{2}$ Boda Boda ☐$_{3}$ Tuk Tuk ☐$_{4}$ Matatu ☐$_{5}$ Car

22) Approximately how long does it take you to get to the drinking water source you identified previously using the mode of transportation you selected above?

☐$_{1}$ <5 minutes ☐$_{2}$ 5-<10 minutes ☐$_{3}$ 10-<15 minutes ☐$_{4}$ 15-<20 minutes
☐$_{5}$ 20-<30 minutes ☐$_{6}$ 30 minutes or More

23) How often do you go to the drinking water source in one week?

☐$_{1}$ Less than 1 time per week ☐$_{2}$ 1-3 times per week ☐$_{3}$ 4-6 times per week
☐$_{4}$ 1 time per day ☐$_{5}$ 2-3 times per day ☐$_{6}$ 4 or more times per day
☐$_{97}$ Don't know

24) Where do you store your household drinking water? *[check all that apply]*

☐$_{1}$ Bucket ☐$_{2}$ Jerry can
☐$_{3}$ Collapsible bucket ☐$_{4}$ Gallon jug
☐$_{5}$ Bucket with tap ☐$_{6}$ Ceramic/Clay pot
☐$_{7}$ Large drum
☐$_{8}$Other, specify: ____________

a. ***OBSERVE:*** **Is the container covered or closed?** ☐1 Yes ☐0 No *[go to 25]*

i. ***OBSERVE:*** **If so, how is the container covered or closed?** *[check all that apply]*
☐1 Small opening with a lid ☐2 Tap/spigot for filling
☐3 Other, specify: _________________

25) Do you do anything to make your drinking water safer to drink?
☐1 Yes ☐0 No *[go to 26]* ☐97 Don't know

a. How do you make your drinking water safer to drink? *[check all that apply]*
☐1 Boiling ☐2 Liquid chlorine ☐3 Chlorine tablets ☐4 Coagulant/flocculant ☐5 Solar disinfect ☐6 Ceramic filter ☐7 Biosand filter ☐8 Membrane filter
☐9 Cloth filter ☐10 Settling ☐11 Other: ____________
☐97 Don't Know

Part 4. Sanitation

26) Do you have a toilet in your household cluster area? (10 minutes away or less by walking)?
☐1 Yes ☐0 No

i. If they have a latrine, ***ASK:*** **Do you use your latrine?** ☐1 Yes *[go to 27iii]* ☐0 No

ii. If no, why don't you use your latrine? *[Check all that apply]*
☐1 Latrine is too far away ☐2 Latrine is unsafe
☐3 Latrine is not clean ☐4 Latrine is too full to use
☐5 Latrine requires a lot of maintenance
☐6 Other, specify__________________
☐97 Don't know

iii. If they have a latrine, ***ASK:*** **How many times a day do you use your toilet?**
☐1 Once a day ☐2 Multiple times per day
☐3 Once a Week ☐98 Refused

27) Do children under the age 10 that live in your household use the toilet facility?
☐1 Yes *[go to 28]* ☐0 No ☐97 Don't know

a. If the child does not use the toilet facility, why do you think they do not use the toilet facility? [Read list and check all that apply]
☐1 Afraid of the darkness ☐2 Afraid of falling inside the toilet
☐3 Too short to squat over toilet ☐4 Do not want to share with opposite gender
☐5 Too young to use toilet ☐6 Other, specify__________________
☐97 Don't know

Part 5. Hygiene

28) Did you wash your hands after your last stool? ☐1 Yes ☐0 No ☐97 Don't know

29) What did you do with your child's last stool (for children who are too young to use the latrine on their own, ≤3 years old)? *[CHECK ONE]*

☐$_1$ Leave on the ground ☐$_2$ Throw outside in the yard
☐$_3$ Throw in the latrine ☐$_4$ Bury in the yard
☐$_5$ Other, specify _____________
☐$_{97}$ Don't Know ☐$_{99}$ NA, child >3 years

30) When do you wash your hands…? [Read response list and check one]

a.	**After using the toilet**	☐$_0$ Yes	☐$_1$ No	☐$_{97}$ Don't know
b.	**Before eating**	☐$_0$ Yes	☐$_1$ No	☐$_{97}$ Don't know
c.	**After eating**	☐$_0$ Yes	☐$_1$ No	☐$_{97}$ Don't know
d.	**Before feeding children**	☐$_0$ Yes	☐$_1$ No	☐$_{97}$ Don't know
e.	**After feeding children**	☐$_0$ Yes	☐$_1$ No	☐$_{97}$ Don't know
f.	**After tending to animals**	☐$_0$ Yes	☐$_1$ No	☐$_{97}$ Don't know
g.	**After tending to crops**	☐$_0$ Yes	☐$_1$ No	☐$_{97}$ Don't know
h.	**Before cooking**	☐$_0$ Yes	☐$_1$ No	☐$_{97}$ Don't know

31) Do you keep the following foods in your household? *[CHECK ALL THAT APPLY]*

☐$_1$ Meat ☐$_2$ Vegetables ☐$_3$ Milk ☐$_4$ Fruit
☐$_5$ Fats or oils ☐$_6$ None *[go to 32]*

a. Can you show me where you store your meat and your vegetables?

i. Packaging *[Interviewer observe and CHOOSE ONE]*

A. For meat:

☐$_1$ In a concealed package ☐$_2$ Not in a concealed package ☐$_{99}$ NA, No meat

B. For vegetables/fruit:

☐$_1$ In a concealed package ☐$_2$ Not in a concealed package ☐$_{99}$ NA,No vegetables/fruit

ii. Separation *[CHOOSE ONE]*

A. For meat and vegetables/fruit:

☐$_1$ Meat is packaged separately from vegetables/fruit
☐$_2$ Meat is not packaged separately from vegetables/fruit
☐$_{99}$ NA, No meat or vegetables/fruit

C. Flies *[CHOOSE ONE]*

A. For meat and vegetables/fruit:

☐$_1$ There are flies on meat, vegetables, or fruit
☐$_2$ There are no flies on meat, vegetables, or fruit
☐$_{99}$ NA, No meat or vegetables/fruit

Part 6. Animal ownership

32) Do you own cats or dogs? ☐$_1$ Yes ☐$_0$ No *[go to 33]*

a. Do they stay inside your house or in the yard near your house?
☐$_1$ Yes ☐$_0$ No *[Go to 33]*

b. Do you clean up their stools when you see them inside the house or in the yard near your house?
☐$_1$ Yes ☐$_0$ No ☐$_2$ They do not make stool inside the house or yard near house

33) Do you own farm animals including chickens, cattle, bull, donkey, horse, goat, and sheep?
☐$_1$ Yes ☐$_0$ No *[go to 34]*

a. If yes, where are the farm animals kept in relation to the house?
☐$_1$ Less than 30 meters away ☐$_2$ More than 30 meters away *[go to 34]*

b. Do you clean up the farm animals stools if they are less than 30 meters away from the house?
☐$_1$ Yes ☐$_0$ No

Part 7: Caregiver's Health Status

34) How would you describe your personal health?
☐$_1$ Excellent ☐$_2$ Very Good ☐$_3$ Good ☐$_4$ Fair ☐$_5$ Poor

35) Did you have any diarrheal episodes with 3 or more loose/watery stools within a 24 hour period in the past year?
☐$_1$ Yes ☐$_0$ No *[go to 36]* ☐$_{98}$ Refused

a. If yes, how many times did you have diarrhea in the past year?

________________ diarrheal episodes in the past year ☐$_{97}$Don't Know
☐$_{98}$ Refused

36) Have you had diarrhea with 3 or more loose/watery stools within 24 hour period in the past 4 days?
☐$_1$ Yes ☐$_0$ No *[go to 37]* ☐$_{98}$ Refused

a. If yes, approximately how many times did you have diarrhea each day during your illness?
____________ loose/watery stools each day ☐$_{97}$ Don't Know ☐$_{98}$ Refused

37) Have you ever been tested for HIV?
☐$_1$ Yes ☐$_0$ No *[go to 38]* ☐$_{98}$ Refused

a. If yes, what were the results of your HIV test?
☐$_1$ HIV positive ☐$_2$ HIV negative ☐$_{97}$ Don't Know ☐$_{98}$ Refused

Part 8. Child Health (Age 5 and Under) *(chosen through random # calculator)*Now I am going to ask you some questions about your child.

38) Child's a. Age in ______________ Years *and/or* b. Months |__|__|

c. Year of birth |__||__||__||__|

39) Child's Gender ☐1 Male ☐2 Female

40) Are you currently breastfeeding the child? ☐1 Yes *[go to 41]* ☐0 No

a. If no, how many months did you breastfeed the child?
☐0 Did not breastfeed
______________ months (prompt with milestones or calendar dates as needed)
☐97 Don't Know

41) Has the child had any diarrheal episodes with 3 or more loose/watery stools within a 24 hour period in the past year?
☐1 Yes ☐0 No *[go to 42]* ☐97 Don't Know ☐98 Refused

a. If yes, how many times did the child have diarrhea in the past year?
__________ diarrheal episodes in the past year ☐97 Don't Know ☐98 Refused

42) Has the child had diarrhea with 3 or more loose/watery stools within a 24 hour period in the past 4 days?
☐1 Yes ☐0 No *[Go to 43]* ☐98 Refused

a. If the child had diarrhea in the past 4 days, approximately how many times did he/she have diarrhea each day during their illness?

__________ loose/watery stools each day ☐97 Don't Know ☐98 Refused

b. If the child had diarrhea in the past 4 days, did the child have vomiting while they had diarrhea?
☐1 Yes ☐0 No ☐97 Don't Know ☐96 Refused

c. If the child had diarrhea in the past 4 days, did the child have fever while they had diarrhea?
☐1 Yes ☐0 No ☐97 Don't Know ☐98 Refused

d. If the child had diarrhea in the past 4 days, did you notice blood in the child's stools?
☐1 Yes ☐0 No ☐97 Don't Know ☐98 Refused

e. If the child had diarrhea in the past 4 days, did you to take the child to a health facility during their illness?
☐1 Yes ☐0 No *[Go to 42f.]*

i. Did your child stay overnight at the hospital?
☐1 Yes ☐0 No *[go to 42f.]* ☐97 Don't Know

ii. How many days did your child stay overnight at the hospital?
________ days ☐97 Don't Know

f. If the child had diarrhea in the past 4 days, what treatment did you give the child for their diarrhea? [Read list and check ALL THAT APPLY]

- **i.** medicine from the health facility ☐1 Yes ☐0 No
- **ii.** medicine from the kiosk/pharmacy ☐1 Yes ☐0 No
- **iii.** Oral rehydration salts ☐1 Yes ☐0 No
- **iv.** Water ☐1 Yes ☐0 No
- **v.** Zinc/Iron pills ☐1 Yes ☐0 No
- **vi.** Vitamin A ☐1 Yes ☐0 No
- **vii.** Bed rest ☐1 Yes ☐0 No
- **viii.** Herbs/herbal tea ☐1 Yes ☐0 No
- **ix.** Multivitamins ☐1 Yes ☐0 No
- **x.** Other ________________________

g. If the child had diarrhea in the past 4 days, did you continue to breastfeed your child while they had diarrhea?

☐1 Yes ☐0 No ☐97 Don't Know ☐99 Not applicable, child not breastfeeding

h. If the child had diarrhea in the past 4 days, is your child's health?

☐1 Getting worse ☐2 The same ☐3 Getting better ☐97 Don't Know

43) Has your child ever been tested for HIV?

☐1 Yes ☐0 No *[go to 44]* ☐98 Refused

i. If yes, what were the results of your child's HIV test?

☐1 HIV positive ☐2 HIV negative ☐97 Don't Know ☐98 Refuse

44) Has your child been given any vaccines?

☐1 Yes ☐0 No ☐97 Don't Know

45) Weigh child.

i. _________ kg

ii. Did not weigh child, parent reported weight: ______kg

iii. Reason weight not taken: ______________________

46) Measure child.

i._________ cm *or* _________inches

ii. Did not measure child, parent reported height ________cm *or* _________inches

iii. Reason height not taken: ____________________________

47) Measure Child's Middle Upper Arm Circumference (for children 6 months or older)

i._________mm

ii. Reason middle upper arm circumference not taken: ______________

Part 9. Latrine Observations

48) *OBSERVE:* If they have a latrine, type of latrine

☐1 Flush toilet ☐2 Piped sewer system
☐3 Septic tank ☐4 Flush/pour to flush pit latrine
☐5 Ventilated improved pit latrine ☐6 Pit latrine with slab
☐7 Composting toilet ☐8 Bucket
☐9 Hanging toilet or hanging latrine ☐10 No facilities; use bush or field

a. *OBSERVE:* If they have a latrine, is there a structure around their latrine for privacy during use?
☐1 Yes ☐0 No

b. *OBSERVE:* Is there a water container for hand washing outside of the latrine?
☐1 Yes ☐0 No

c. *OBSERVE:* Is there soap outside of the latrine? ☐1 Yes ☐0 No

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Approval Notice

Initial Review (Response to Modifications)

June 5, 2015

Courtney Babb, BS

Epidemiology and Biostatistics

1446 W. Polk Street

Unit 2F, M/C 923

Chicago, IL 60607

Phone: (862) 452-1290

RE: Protocol # 2015-0461

"Evaluation of the Effectiveness of a Latrine Intervention on Childhood Diarrheal Disease in Nyanza Province, Kenya"

Dear Ms. Babb:

Your Initial Review (Response to Modifications) was reviewed and approved by the Expedited review process on June 5, 2015. You may now begin your research. Please note the following information about your approved research protocol:

<u>Protocol Approval Period:</u> June 5, 2015 - June 4, 2016

Approved Subject Enrollment #: 396

Performance Sites: UIC; Ministry of Public Health and Sanitation, Kenya (lead performance site)

Sponsor: None

Research Protocol:

a) Evaluation of the Effectiveness of a Latrine Intervention on Childhood Diarrheal Disease in Nyanza Province, Kenya; Version 2, 5.28.2015

Recruitment Material:

a) Subject recruitment will occur in accordance with the procedures approved by the Maseno University IRB.

Informed Consent:

a) Subject enrollment will occur in accordance with the procedures approved by the Maseno University IRB.

Note: **No research may be conducted without IRB approval for the lead performance site; documentation of Maseno University IRB approval for the Ministry of Public Health and Sanitation must be forwarded to UIC OPRS upon availability. All recruitment and consent procedures/waivers/documents must be used in accordance with that IRB approval.**

Additional Determinations for Research Involving Minors:

The Board determined that this research satisfies 45 CFR 46.404, research not involving greater than minimal risk. Parental permission will be obtained in accordance with local requirements for the lead performance site (Ministry of Public Health and Sanitation, Nyanza Province, Kenya), under IRB approval from Maseno University.

Your research meets the criteria for expedited review as defined in 45 CFR 46.110(b)(1) under the following specific categories:

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

(7) Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
04/20/2015	Initial Review	Expedited	05/21/2015	Modifications Required
06/01/2015	Response To Modifications	Expedited	06/05/2015	Approved

Please remember to:

→ Use your **research protocol number** (#2015-0461) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure,

"UIC Investigator Responsibilities, Protection of Human Research Subjects"
(http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0924.pdf)

Please note that the UIC IRB has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact OPRS at (312) 996-1711 or me at (312) 413-3202. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Teresa D. Johnston, B.S., C.I.P.

Assistant Director

Office for the Protection of Research Subjects

Enclosure:

1. UIC Investigator Responsibilities, Protection of Human Research Subjects

cc: Ronald C. Hershow, Epidemiology and Biostatistics, M/C 923
Supriya Mehta, Faculty Sponsor, Epidemiology and Biostatistics, M/C 923

IX. VITA

NAME	Courtney M. Babb
EDUCATION	B.S., Biobehavioral Health; Minor, Biology, Pennsylvania State University, 2012
HONORS	Outstanding Poster Presentation, Urban Global Health Celebration Conference, University of Illinois at Chicago, 2013
	Douglas Passaro International Scholarship Award Recipient, University of Illinois at Chicago, 2015
CONFERENCE PRESENTATIONS	Babb, C. (2013, October). *Surveillance of demographics, symptoms, treatment for the incidence of diarrheal illness in children under five in Nyando, District, Kenya*. Poster presented at the Urban Global Health Celebration Conference, Chicago, Illinois