Baseline Randomized Trial to Assess Behavioral Impediments to the Implementation of Low Cost, Household-Level Water Treatment (HWT) Strategies for Reduction in Diarrheal Disease Incidence in Children in Rural and Peri-Urban Communities in Low-Development Countries

Background

Diarrheal diseases represent a significant cause of illness for children < 5 years old (y.o.) in many low- and moderate- development countries, and may be responsible for ~ 20% of deaths in this cohort (Clasen and Cairncross, 2004; Schmidt and Cairncross, 2008). Diarrheal diseases impact childhood growth and development in multiple ways and may result in malnutrition, impaired growth, limited immunity, and stunted cognitive development (Clasen and Cairncross, 2004). Diarrheal diseases in children result from a variety of factors, some of which are specifically sanitation related and include unclean household drinking water, poor personal hygiene (which may result from many factors including limitations on water supply and/or soap), and inadequate sanitation services and infrastructure.

The World Health Organization (WHO) has estimated that 80% of infectious diseases in low- to moderate- development countries result from inadequacies in hygiene and water/sanitation and that the implementation and consistent utilization of effective household-level water treatment (HWT) can result in a 20% - 40% decrease in childhood diarrheal diseases as compared to households/environments in which HWT is not consistently applied (van Wijk and Murre, 1995; Clasen and Cairncross, 2004; Schmidt and Cairncross, 2008). The World Bank (1993) has further noted that poor hygienic practices and unclean/ unsafe household environments may account for approximately 30% of the

overall disease burden in low- to moderate-development countries, and that within this category of disease causation, 75% of life years lost may be due to an inadequate supply of clean water and poor sanitation practices.

As noted by Curtis et al. (2009), the subject of habit, and specifically, the relationship between habit and the adoption of health-improving behaviors, has not been well addressed in the behavior change literature, despite the fact that as much as half of daily activity may be habit driven. Because benefits of drinking water treatment exist in multiple categories of health-related behaviors, i.e., habitual behaviors (activities that we are taught to do), motivated behaviors (activities that provide short-term benefit), and planned behaviors (activities that provide long-term benefit), these observations suggest an opportunity to study behavioral limitations on the adoption of inexpensive HWT strategies.

Fiebelkorn et al. (2012) conducted a literature review of studies assessing the effectiveness of point-of-use water treatment interventions in low- or moderate- development countries. These researchers observed that of the 1551 papers they were able to identify on this subject, only 26 (1.7%) both applied and evaluated a behavioral intervention as a component of the assessment of the intervention's effectiveness, and only 5 presented the details of the behavioral intervention. These authors conclude that based on the lack of published research in this field, the study of behavioral aspects of HWT adoption is a topic in need of greater exploration.

Of the 26 studies reviewed in Fiebelkorn et al. (2012) that met their inclusion criteria for behavioral assessment, 14 (54%) were conducted in Africa. The WHO notes that a significant majority of individuals living without access to improved drinking water sources reside in sub-Saharan Africa, where it is estimated that approximately 50% of individuals are exposed to drinking water

sources that are often or frequently contaminated with fecal matter (WHO, 2014). Moreover, in this region, WHO notes that where HWT does occur, implementation is most commonly project-based (as opposed to household-based) and occurs in response to crisis situations such as outbreaks of cholera (WHO, 2014). It is estimated that in sub-Saharan Africa, only ~ 20% of households treat drinking water before consumption (WHO, 2014).

Based on these research findings and suggestions for further study, this project proposes to conduct a behaviorally focused HWT intervention in the peri-urban and rural communities around the city of XXXX in the country of YYYY. Study design will be as a randomized trial with the specific goal to identify both method-specific and, potentially, generalizable factors that encourage or hinder the adoption of new health practices, and by association, new habits. A randomized trial design is selected here so that the research team does not intentionally or unintentionally bias the placement of participants into either the Control versus Intervention arms of the study or to the selection of applied HWT technologies. The study design, as well as options for HWT, are discussed in further detail below.

It has been suggested that the key benefits or factors that significantly influence individuals' willingness to adopt new health/hygienic practices include (1) demonstration that the practice will make life easier or better for self and/or family; (2) support and influence from other individuals regarding the adoption of the new practice; and (3) a sense of having the means and ability to carry out the practice (van Wijk and Murre, 1995). As such, the goal with this study is to create a HWT intervention that is specifically linked to health objectives, is supported by local medical staff (field nurses), and is low cost and effectible on the household level. Health data regarding incidence of diarrheal disease will also be collected as a component of this behavioral study through household questionnaires and

medical exams (discussed further below), although these data do not represent the principal focus of the study.

It is recognized here that other structural limitations to the adoption of HWT strategies also exist and include limitations on transport and supply of materials as well as consistent and relevant educational interventions to more specifically and consistently link the adoption of new behaviors to visible, desired, and achievable outcomes. While these aspects of limitation on adoption of new technologies and habits are significantly deserving of further research, they are outside of the direct scope of this baseline study. That being stated, this study specifically acknowledges that there is little point in assessing the effectiveness of an intervention if that intervention is not scale-appropriate in terms of feasibility and costs. As such, interventions chosen for this study will be chosen specifically based on confirmed ready and inexpensive availability of HWT materials in the communities in which the study is proposed to be conducted.

It should also be re-stated here that, as noted in the introduction to this proposal, not all sources of diarrheal disease infection result from contaminated drinking water and not all water treatment options are 100% effective in eliminating water-borne pathogens. Thus, it is important to recognize that while there are very few health negative outcomes associated with improving drinking water quality (i.e., the practice is overwhelmingly net beneficial for human health), error and inconsistencies exist along the chain associating practice (treating drinking water to reduce or eliminate pathogens) and effect (reducing childhood diarrheal disease incidence). From the vantage of study participants it is therefore important to discuss the benefits of water treatment (of which there are many) while limiting the scope of promises or guarantees regarding changes to diarrheal incidence in participants' children. It is expected that the potential for disconnect between the study practice's reality (i.e., that treating all consumed

water will to some degree improve infant and child health) and the participants' expected outcome (i.e., the hoped for elimination of all diarrheal disease incidence in household children) may represent a principal potential reason for attrition from the study. With the proposed focus herein on the behavioral aspects of study participation, some participant attrition is to be expected and would be considered as viable data "outcome" rather than a source of data bias. Other potential sources of data bias and misclassification are discussed further in the conclusion of this proposal.

Exposures

This study will focus on three low-cost strategies for treatment of drinking water at the household level. These strategies are:

1. Water treatment through use of chlorine disinfectant - either as liquid bleach or chlorine tablets (as dependent on local availability).
2. Water treatment through solar disinfection (i.e., SODIS)
3. Water treatment through boiling.

Specific details regarding treatment strategy (i.e., dosing rate for chlorine disinfectant, length of solar exposure for SODIS bottles, boiling time) have been covered by WHO (WHO, 2014) and will not be detailed in this proposal. Briefly, water treatment through use of chlorine disinfectant entails the addition of a defined dose of liquid bleach or defined number of chlorine tablets to a specified volume of water (commonly a 5 gal. pail or jug such as may be used to collect water from a community source). Dosed water is allowed to stand for a defined period - typically between 6 and 10 hours - to allow for disinfection. Solar disinfection (SODIS) entails the placement of 2 L clear plastic water bottles onto a strongly reflective surface (such as a galvanized metal roof) for a period of 6 to

10 hours (or typically for “one day”) to allow for UV disinfection. Boiling entails bringing drinking water to a boil for a period of 5 to 10 minutes. For both solar disinfection and boiling, water may be used warm (for cooking) or cooled (for drinking). For chlorine disinfection, water may be consumed immediately following the treatment period.

These three HWT strategies have been identified by WHO as effective in reducing or eliminating bacterial contamination of drinking water (WHO, 2014). It should be noted, however, that these strategies vary in effectiveness with respect to their ability to eliminate viral and protozoan contaminants. The selection of these three interventions/exposures is consistent with the literature review presented by Fiebelkorn et al. (2012), in which chlorination, solar disinfection (SODIS) and boiling were included, either singly or in combination, in 58% (chlorination), 31% (solar disinfection), and 15% (boiling) of interventions meeting their criteria for inclusion in the literature review.

Other HWT technologies assessed by Fiebelkhorn et al. (2012) and not included in this current study include flocculation disinfection (included in 19% of interventions assessed in their literature review) and various forms of water filtration (included, in aggregate, in 16% of interventions assessed in their literature review). Flocculation disinfection and filtration are not included in this proposed study because of costs associated with the purchase of treatment materials. While both strategies have found success (either singly or in combination with other HWT methods) in HWT, implementation likely includes either/both significant education/training and costs that would not likely be supportable without subsidies in low-development countries (Schmidt and Cairncross, 2009). For this study, materials required for HWT (i.e., bleach or chlorination tablets, 2 L transparent HDPE [SODIS] bottles, or supplemental fuel as needed) will be supplied to study participants. It is hoped that in selecting the

three most straightforward of the potential HWT technologies reviewed by WHO for inclusion in this study, that differences *between* technologies in relative difficulty in application for HWT will not create a source of challenge to study participants that might negatively impact willingness to participate in the study for any one HWT technology group versus the other groups.

All HWT methods included in this study have their strengths and weaknesses, including impacts on taste of treated water (chlorination and solar disinfection), limitations on scale-up ability (solar disinfection using recycled 2 L HDPE bottles), and potential impacts on indoor air pollution (boiling). These limitations are noted here to highlight that there is no universal optimum strategy for HWT and that it is likely that educational efforts will be required to encourage and support the implementation of any of these treatments for households not currently treating drinking water. In the context of this behavioral study, it is hypothesized that the intervention arm of the study (as detailed below) will see greater success (in terms of sustained participation) than the non-intervention arm of the study due to the technical and educational support provided as a component of the intervention.

Study Design

This baseline randomized trial will include two study groups - a Screening (control) group and a Screening + Intervention group. Placement of participants in study groups will be via a numerical algorithm with the goal of achieving an equal number of participant households in each Study Group x Treatment Option category. Because the principal goal of this study is to assess behavioral impediments to the implementation of low cost HWT, the “control” in this study is defined by the presence versus absence of a behaviorally-focused intervention, rather than by the presence versus absence of a water treatment technology. All

study participants will be assigned a water treatment option (chlorine disinfectant, SODIS or boiling).

It is hoped that between 10 - 15 households can be enrolled in each Study Group x Treatment Option category, for a total of 60 - 90 households participating in the baseline randomized trial. It is recognized that for the small likely size of each Study Group x Treatment Option category, as well as the limited scope and budget for this trial, that results will be descriptive/semi-quantitative. The value of this research, in our belief, is in beginning to address the recognized need for behaviorally-focused assessments of impediments to implementation of HWT in low- development countries.

1. Screening (Control) Group

Members of the Screening Group will receive a bi-monthly household visit from a team of community field nurses. As defined, a “bi-monthly household visit” will involve 2 home visits within 72 hours, as explained further below. Screening will include a health questionnaire for all household members focused on incidence of diarrheal diseases and medical screening for all children under the age of 5 y.o. Medical screening will focus on addressing signs of illness (including diarrhea and vomiting) potentially resulting from exposure to waterborne pathogens. Nurses will receive training in administering the questionnaire as well as the medical screening protocol.

It is recognized that conducting a study with self-reporting targets (i.e., self reporting of disease symptoms) likely creates bias in recall of frequency or severity of symptoms relative to a study in which symptoms result in the active seeking of medical care (see Cairncross et al. 2010, as example). While this bias cannot be eliminated in this study, it is hoped that through a combination of

symptom reporting, in-home screening by field nurses, titer test plate data documenting relative microbial contamination of untreated versus treated water (described further below), and selection of study participants from individuals having demonstrated a willingness to seek medical care in response to observed diarrheal disease symptoms in themselves or their family members (see further discussion below), that a combined picture of *evidence, frequency, and severity* of disease will emerge in parallel with data regarding implementation and continuation rate of HWT in participating households.

Field nurses will work in pairs, with one nurse per visit administering the questionnaire and conducting the medical exams. The second nurse in the pair will collect water samples - both treated and untreated - from each household to conduct a simple water quality test (3M™ Petrifilm™ Aerobic Count Plates).[1] This test involves a 48 hr incubation of a bile salt plate onto which a water sample has been pipetted. This technique provides rapid visual identification of bacterial contamination including, specifically, *E. coli,* an indicator organism for fecal coliform contamination of drinking water. To conduct this test, a pre-treatment water sample (if possible) is collected from the household water supply and pipetted onto a test plate (further details on the test plates provided in footnote link). Possible source of pre-HWT water can include, as examples, water stored in rain barrels or in receptacles transported from a community well. A post-HWT water sample is also collected and pipetted onto a separate bacterial test plate. The distinction of pre- versus post-HWT is important in that it is unlikely (and unnecessary) for all water retrieved for household use be treated to drinking water quality. Water sampling will be conducted in view of and with the

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[1] http://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Petrifilm-Aerobic-Count-Plates?N=5002385+8709314+8710780+8711017+8711295+8711414+8711726+8716589+8720505+3293785706&rt=rud

participation of (if possible) household members so as to provide context for sharing resultant data on the subsequent house visit (detailed below).

Following sampling in households, bacterial test plates will be returned to a community clinic or field station, incubated for the required interval (typically 48 hrs), and then enumerated and digitally photographed for confirmation bacterial counting. Following data logging, the field nurse team will return to the participating household to present visual plate results to household members and explain data (i.e., differences in bacterial counts for water samples that represent untreated [i.e., pre-HWT] and treated [i.e., post- HWT] water samples), as well as health implications of these data. Data presentation will be in a qualitative manner, and will employ terms such as “more than”, “less than”, “more bacteria” or “fewer bacteria”, so that the results are understandable to study participants.

2. Screening + Intervention Group

For the Screening + Intervention Group, the first of the paired household visits comprising a “bi-monthly household visit” will be conducted in the same manner as for the Screening Group, as detailed above. During the second visit - in which bacterial test plate data are presented - a technique-specific check in will also occur. This check in will include discussion regarding any technical aspects of the intervention that may require adjusting, including (as examples) suggestions for adjusting dosage (for chlorination treatment), replacing bottles or adding a simple pre-filtration step to address turbid water concerns (for SODIS), or limitations on fuel supply or negative impacts on indoor air quality (for boiling). The goal of the intervention is to direct conversation specifically to the HWT method so as to encourage household members to focus specifically on the “nuts and bolts” of proper water treatment as well as on the direct link between the

intervention and improvements in drinking water quality and infant and child health.

As noted earlier in this proposal, this project is focused on identifying factors that may encourage or hinder the adoption of new health-related practices and habits. Specific research targets for this study therefore include the length of time individual households continue in the study, to what extent (if any) the choice of HWT technology affects participation rate, and whether specific and direct intervention (i.e., “trouble-shooting” the results of water quality assays and HWT technologies) increases the duration of a household’s participation in the study.

For both the Control and Intervention arms of the study, the field nurses will also note the point at which participants no longer appear to be treating drinking water. This point of non-participation may be documented visually (such as no longer seeing SODIS bottles on roofs) or by admission of participants. If lack of visual evidence of participation is apparent, the field nurses will be trained in the manner to inquire as to why participants are deciding to opt-out of the study and to gather as much information as possible regarding motivations for opting out. The field nurses will also make clear that regardless of the decision to stop participating in the study, all participants will continue to receive bi-monthly health screening check-in visits for the duration of the study.

Duration of Study and Proposed Study Outcomes

This study is designed as a 24 month assessment, with assessment time allocated as follow:

Sign up period (3 mo.) in which participating households are identified, HWT strategies are randomly assigned, and households are randomly placed into the Control vs Intervention arms of the study.

Roll in period (3 mo.) in which baseline comfort with participation in the study is established. During this period, 2 paired household visits will occur (either following Control or Intervention protocol) so that participating households become comfortable with receiving nursing staff into their homes and familiar with questionnaire, screening, and water testing protocols.

Study period (16 mo.) in which 8 bi-monthly household visits will occur. Each paired visit, as described above, will include 2 visits within 72 hours, with the first visit comprised of a questionnaire, medical screening, and water sample collection, and the second visit to allow presentation of bacterial test plate water quality data (for the Screening group) or presentation of bacterial test plate water quality data + discussion of technical aspects of HWT in use (for the Screening + Implementation group). Following completion of the 16 mo. period, each household will be interviewed regarding the behavioral support aspect of the study. Of particular interest here is documenting the extent to which behavioral (as well as technical) support was sought or provided by community members other than the field nurse teams.

Data analysis period (2 mo.) in which results will be compiled and written up. Data from this study will include health questionnaires, bacterial test plate data, and narrative results from household visits as collected by field nurses. It is expected that narrative results will include discussion of participation (including, as examples, ease versus difficulty of continuing with study protocol, perceived benefits of participating, and reasons for continuing to participate [or not] in study objectives) as well as (for the Implementation group) documentation of types of

questions asked and topics discussed during presentation of bacterial test plate data and subsequent conversation about HWT concerns (if any). As previously noted, health data regarding incidence of diarrheal disease will also be collected as a component of questionnaires and medical exams. While these data do not represent the principal focus of this study, they will allow exploration of questions regarding frequency, severity, and age demographics of diarrheal disease incidence in participating households.

The study period selected for this research (16 months) is consistent with the median study period (14.5 months; range from 3 months to 5 years) presented in the Fiebelkorn et al. (2012) literature review regarding the implementation of HWT in low- to moderate- development countries.

Participation Criteria for this Study

1. At least one child under the age of 5 y.o. in the household.
2. Currently not using any drinking water treatment strategy (preferred) or willing to switch from existing water treatment strategy to a different HWT method.
3. Willing to participate in a 2 year project with bi-monthly health-focused household visits by a team of local field nurses.

Within the broad geographic region and rural/peri-urban area in which this study will be conducted, it is hoped that all participants in the study can be recruited from clinic visits. Notices will be placed in clinics with the goal of recruiting participants, particularly those who may be bringing children to the clinic for treatment of diarrheal disease symptoms. Clinic staff will also participate in the recruitment of study participants by discussing study objectives with patients and inquiring whether they may be interested in participating. Patients

interested in participating will be referred to the study team for further conversation and recruitment (if interested).

Consideration of Bias/Misclassification

Regarding bias and misclassification, it is recognized that the strategy for participant selection described above creates (1) a selection bias in favor of individuals who actively seek medical treatment, as well as (2) a subtle pressure bias to participate by incorporating clinic staff into the enrollment team. It is hoped that these biases can be exploited in a constructive way by creating a "best case roster" of individuals (households) demonstrating an initial willingness to participate in a study specifically designed to address one of the causative agents (i.e., waterborne microorganisms) of the diarrheal disease for which they'd sought medical attention.

Likewise, It is recognized that conducting a study with self-reporting targets (i.e., self reporting of disease symptoms) likely creates bias in recall of frequency or severity of symptoms relative to a study in which symptoms result in the active seeking of medical care. While this bias cannot be eliminated in this study, it is hoped that through a combination of symptom reporting, in-home screening by field nurses, bacterial test plate data, and selection of study participants from individuals having demonstrated a willingness to seek medical care in response to observed diarrheal disease symptoms in themselves or their family members, that a combined picture of *evidence, frequency, and severity* of disease will emerge in parallel with data regarding implementation and continuation rate of HWT technologies at the household level.

Regarding compliance, as detailed in the proposal, it is expected that the potential for disconnect or disillusionment between the study practice's reality

(i.e., that treating all consumed water will to some degree improve infant and child health) and the participants' expected outcome (i.e., the hoped for elimination of all diarrheal disease incidence in household children) may represent a principal potential reason for attrition from the study. With the proposed focus herein on the behavioral aspects of study participation, some participant attrition is to be expected and would be considered as viable data "outcome" rather than a source of data bias. Relatedly, as discussed above, it is noted that all methods included in this study have their strengths and weaknesses and it is hoped that by selecting the three most straightforward of the potential HWT technologies reviewed by WHO (WHO, 2014), that this study controls for bias potentially resulting from significant variability in difficulty (versus ease of use) associated with implementation of particular HWT techniques available on the market.

In terms of efforts to control for misclassification, it is important that field nurses receive careful training in the recording of information provided during household visits. In specific, it is important to document the extent to which unprompted technical questions may be asked by household members of the Screening Group during presentation of bacterial test plate data, as well as what level of technical details are provided to household members as answers. Because the ultimate goal of studies such as the one proposed here is the improvement of childhood health through HWT, all questions should be answered for all participants with a comparable level of technical focus *regardless of the arm of the study to which participants have been assigned*. To address the potential for misclassification of households between the Screening versus Intervention arms of this study, however, it is important to document the extent and content of unprompted technical support that Screening arm participants receive. This documentation is key because, as noted above, it is hypothesized that the Intervention arm of the study will see greater success (in terms of

sustained participation) than the Screening arm of the study based on the technical and educational support specifically provided as a component of the intervention.

Relatedly, because it is likely that some percentage of study participants may know other members of the study, it is important to document (as possible) to what extent participants gained insights or support regarding HWT implementation from other households in the community (including households not participating in this study). To this end, it is proposed that all participating households be interviewed at the completion of the study period to explore what sources of technical and behavioral support were accessed throughout the study period. Because the principal goal of this study is to assess behavioral impediments to the implementation of low cost HWT, discussion and support received other than that provided by field nurses should be documented (so as to allow for examination of potential misclassification of participants between Control versus Intervention arms of the study), but not discouraged.

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