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Biosand Water Filter Evaluation: Meta-Evaluation and Pilot Study of Field Use Indicators

Bethesda O'Connell
East Tennessee State Universtiy

Biosand Water Filter Evaluation: Meta-Evaluation and Pilot Study of Field Use Indicators

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by

Bethesda J. O'Connell

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Deborah Slawson, PhD, RD, LDN

Megan Quinn, DrPH, MSc

Phillip Scheuerman, PhD

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ABSTRACT

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Diarrheal diseases are a global public health burden, killing 1.8 million people annually. Diarrhea disproportionately affects children and those in poverty. Most diarrheal cases can be prevented through safe drinking water, basic hygiene and/or sanitation measures, with drinking water interventions having the most impact on reducing diarrheal disease. A meta-evaluation was completed of studies evaluating a specific household water treatment method, the biosand water filter. Results from the meta-evaluation illustrate that biosand water filters improve drinking water quality and reduce diarrheal disease. However, there is no generally agreed upon field method for determining biosand water filter effectiveness that is useable in low-resource communities. A pilot study was conducted of potential field use indicators, including the Colilert coliform Presence/ Absence test, hydrogen sulfide, alkalinity, hardness, pH, and fluorescently-labeled latex microspheres. The study included both laboratory and field testing. The Colilert Presence/ Absence test had the highest correlation to the United States Environmental Protection Agency standard method (IDEXX Quanti-trays), but more data is needed before making a recommendation. This study adds to understanding about evaluation of biosand water filters and provides preliminary data to address the need for a field use indicator for biosand water filters.

DEDICATION

This work is dedicated to vulnerable children worldwide who are susceptible to preventable death and disease.

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The Rwandan Health and Environment Project Initiative (RHEPI) is acknowledged for building the biosand water filters in the field trial and providing education to users.

The people of Cyegera, Rwanda made this work possible by opening their homes and lives to the researchers and by participating in the formation of the research question about field use indicators. Special appreciation is noted for Ernest Batera for providing room and board, translation, and transportation.

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LIST of ABBREVIATIONS

BSFs: Biosand Water Filters

CAWST: Centre for Affordable Water and Sanitation Technology

CDC: Centers for Disease Control and Prevention

CI: Confidence Interval

CFU: Colony Forming Units

DALYs: Disability Adjusted Life Years

EMB: Eosin Methylene Blue Agar

ETSU: East Tennessee State University

FUIs: Field Use Indicators

GRADE: Grading of Recommendations, Assessment, Development, and Evaluation

HWT: Household Water Treatment

IBM-WASH: Integrated Behavioral Model for Water, Sanitation, and Hygiene

KAF: Kanchan Arsenic Filter

NTU: Nephelometric Turbidity Unit

OR: Odds Ratio

PBS: Phosphate-Buffered Saline

RCF: Relative Centrifugal Force

RHEPI: Rwandese Health and Environment Project Initiative

RR: Relative Risk

RCT: Randomized Control Trial

WASH: Water, Sanitation, and Hygiene

WHO: World Health Organization

CHAPTER 1

INTRODUCTION

Description of the Problem

Water-Related Diseases

Water-related diseases include: diseases due to microorganisms and chemicals in water that people drink; diseases which have part of their lifecycle in water (such as schistosomiasis); diseases with water-related vectors (such as malaria); drowning and some injuries; and diseases carried by aerosols containing certain micro-organisms (such as *Legionella*) (WHO, 2015).

Microorganisms in drinking water can cause a host of diseases, but because they are endemic in low-resource settings, often present with similar symptoms, and often treated and prevented similarly, they are generally classified globally simply as diarrheal illness (WHO, 2012b). These illnesses are caused by bacteria, viruses, and parasites such *Cholera*, *Cryptosporidium*, *Campylobacter*, *Escherichia coli*, *Dracunculus medinensis*, *Giardia*, Norovirus, *Salmonella*, and many others (WHO, 2012b). The most common disease resulting from chemical contamination of water is arsenic poisoning, with 20-45 million people at risk globally, predominantly in Bangladesh (WHO, 2012). Mosquito-carried illnesses including malaria and dengue are of major public health concern. In 2013, there were an estimated 198 million cases of malaria, with about 584,000 deaths globally (WHO, 2014). Annually, there are an estimated 390 million cases of dengue, with about 96 million manifesting clinically, 500,000 hospitalizations, and 2.5% of cases dying (WHO, 2015b). Drowning occurs globally at a rate of 8.4 per 100,000 in the population, with many drowning cases related to alcohol use and 50% occurring in adolescent males (WHO, 2015c). Although data on aerosol-born disease is more difficult to obtain globally, Legionellosis occurs 10-15 cases per million in the populations of United States, Australia, and Europe (WHO, 2014b). Of all water-related disease, diarrhea is the leading killer globally, and therefore a research priority and the focus of this research.

Diarrhea

Diarrheal and other water-related diseases are a global public health burden, killing 1.8 million people annually (Prüss-Ustün et al., 2014). Diarrhea disproportionately affects children and those in poverty. Globally, diarrhea is the second leading cause of death of children age five and under, with approximately 760,000 young children dying annually (WHO, 2013). Diarrhea is the primary cause of childhood morbidity and mortality in sub-Saharan Africa (O'Really et al., 2012). Ninety percent of diarreal deaths occur in developing nations (Gill, Hayes, & Coates, 2012).

Diarrhea is linked to other childhood diseases including malnutrition and malaria. Diarrhea is the leading cause of malnutrition for children five years of age and younger (WHO, 2013a). Some authors consider malnutrition, diarrhea, and poverty to be syndemic and mutually perpetuating (Guerrant et al., 2002; Pena & Bacallao, 2002). Diarrhea and malnutrition are related because if a child is malnourished, they are more susceptible to diseases including diarrhea. The cycle continues because chronic diarrhea causes the child to not absorb the full nutritional value of their food (Guerrant et al., 2002). Further, it has been argued that childhood diarrhea impacts physical and cognitive development, and therefore long term consequences include reduced productivity and economic potential (Guerrant et al., 2002). Diarrhea and malaria are also strongly associated, presumably for similar reasons of immune system development and poverty (Masangwi, Ferguson, Grimason, Morse, & Kazembe, 2015). Malaria is the most prevalent vector borne disease, killing 1.2 million people annually, predominantly African children under the age of five (HELI, 2014). Because of links with childhood malnutrition, poverty, and malaria, reducing diarrhea will impact global child health beyond the morbidity and mortality immediately associated with diarrheal diseases.

Water, Sanitation, and Hygiene

Most diarrheal cases can be prevented through safe drinking water, basic hygiene and sanitation measures (WHO, 2013). Improving water, sanitation and hygiene (WASH) at the community level reduces diarrheal disease (WHO, 2011). The World Health Organization (WHO) defines WASH as "the provision of safe water for drinking, washing and domestic activities, the safe removal of waste (toilets and waste disposal) and health promotion activities to encourage protective healthy behavioral practices amongst the affected population" (WHO, 2011). Meta-analyses of WASH interventions in developing countries summarized post-intervention relative risks of diarrhea between 0.63 and 0.75, or a risk reduction of 25-37% (Engell & Lim 2013; Fewtrell, Kaufmann, Kay, Enanoria, Haller, & Colford, 2005).

Lack of improved drinking water quality is the leading cause of preventable diarrheal deaths (Prüss-Ustün et al., 2014). An estimated 502,000 diarrheal deaths across all age groups were caused by inadequate or unimproved drinking water in 2012 (Prüss-Ustün et al., 2014). The hardest hit area was sub-Saharan Africa, where approximately 229,316 diarrheal deaths are caused by poor drinking water, with an associated 17,587,000 Disability Adjusted Life Years (DALYs) (Prüss-Ustün et al., 2014). Worldwide, 780 million individuals lack access to improved drinking water, mostly people living in extreme poverty (WHO, 2013). Further, some water sources that meet "improved" standards are still unsafe for consumption, with 10% being considered high risk (containing at least 100 *Escherichia coli* per 100 ml) (Bain et al., 2014). Because illness caused by unimproved drinking water is endemic in low-resource settings, outbreak or microbe specific data is not available on a large scale.

In locations where municipal-level drinking water system implementation is lacking, point-of-use mechanisms are a valuable tool to reduce diarrhea. A meta-evaluation of multiple types of household water treatments (HWT) resulted in an overall relative risk for diarrhea of 0.56 (risk reduction of 44%) for unblinded studies and a relative risk of 0.85 (risk reduction of 15%) for blinded studies (Hunter, 2009). Another study revealed that of many types of point-of-use treatment methods, filtration was the only form that was shown to significantly reduce diarrheal morbidity (Prüss-Ustün et al., 2014).

Biosand Water Filters

One point-of-use method to improve drinking water and reduce diarrheal disease is the biosand water filter (BSF). The BSF was created by Dr. David Manz in the 1990s at the University of Calgary, Canada and is now primarily promoted by his organization, Centre for Affordable Water and Sanitation Technology (CAWST) (CAWST, 2009). It is an adaptation of the traditional slow sand filter. It was made smaller and adapted for intermittent use, for utilization in households around the world (CAWST, 2009).

The filter is composed of a concrete or plastic container and layers of sand and rock prepared using CAWST methods (CAWST, 2009). Figure 1 displays the general structure of the BSF. See Appendixes for the CAWST Material Use Policy. Versions with a plastic filter body are widely distributed by Hydraid and Samaritan's Purse organizations (Hydraid, 2014, Samaritan's Purse, 2015). It removes contaminants from water using four methods: mechanical trapping, predation, adsorption, and natural death (CAWST 2009). The mechanical trapping mechanism occurs when solids and microbes suspended in the water are trapped in the small spaces between sand grains. Predation involves pathogens being consumed by organisms contained in the biolayer that forms in the top portion of the sand layer. Adsorption is the sticking together of pathogens to each other to the sand grains and to suspended solids. Finally, pathogens in the water experience natural death due to lack of food and oxygen deep in the filter. These four mechanisms work together to improve the drinking water (CAWST 2009).

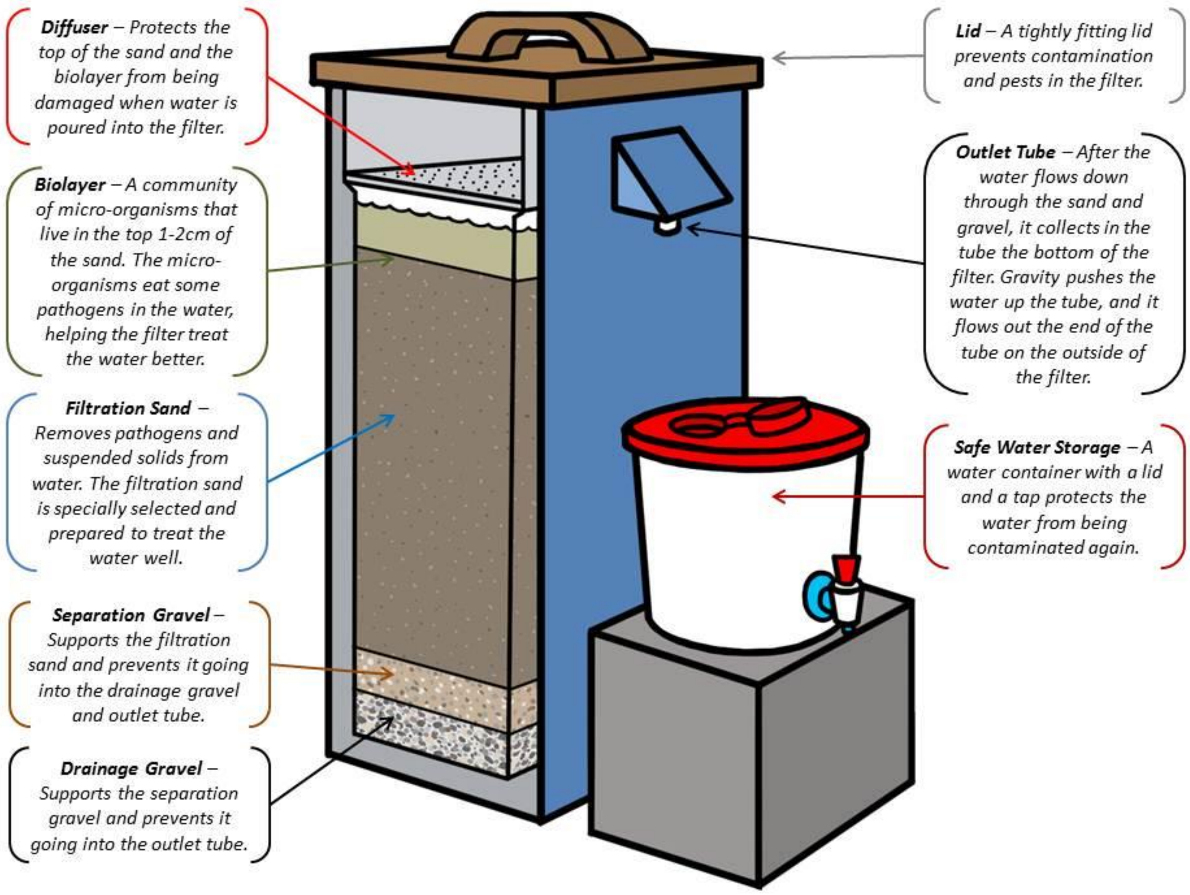

Figure 1. Biosand Water Filter Structure (CAWST, 2015)

CHAPTER 2

LITERATURE REVIEW

Diarrhea Globally

Diarrhea is an important global health issue. It is the cause of death for 1.8 million people of all ages and 760,000 children under five annually (Prüss-Ustün et al., 2014). It is the second leading cause of child death globally and primary cause of child death in sub-Saharan Africa (O'Really et al., 2012; WHO, 2013). Diarrhea is a social justice issue within global public health because it disproportionately affects young children and low-income, developing populations (Gill et al., 2012; WHO, 2013).

Diarrhea Prevalence in Study Population

The field use indicator (FUI) field trial (described further in Chapter 3: Methods) occurred in the rural community of Cyegera, Rwanda. Therefore, it was important to understand the prevalence of diarrheal disease in that population. Rwanda is located in east Africa and Cyegera is located in the Southern Province of Rwanda. It is a relatively small community with 1378 residents.

Diarrhea causes 17% of total deaths in the country of Rwanda (Prüss-Ustün et al., 2014), and Demographic and Health Surveys 2010 data shows that 13% of children under five years old were reported to have had diarrhea in the two weeks preceding the survey (DHS Program 2015). The health workers at the clinic in Cyegera, Rwanda reported that diarrhea and intestinal parasites are of major concern in the community and especially children (personal communication, July 2014). Data from the local Compassion International branch show that 2.13% of the children, ages 6-14 years, enrolled in the program had diarrhea from July 2014-June 2015 (personal communication, June 2015). This means that diarrhea was second only to malaria in causing illness in children enrolled in the program and that diarrhea continues to be a problem for older children, despite the greatest risk being in children under five. Health data specific to the community of Cyegera are not available other than through personal communication with local authorities.

WASH and Diarrhea

WASH interventions are shown to reduce diarrhea globally. A meta-analysis of 46 WASH interventions (many types) in low or middle income countries summarized post-intervention relative risks of diarrhea between 0.63 and 0.75, or a risk reduction of 25-37% (Fewtrell et al., 2005). This study further concluded that multiple interventions (combination of water, sanitation, and hygiene measures) were not more effective than interventions focused on only one change (water, sanitation, or hygiene) (Fewtrell et al., 2005). Another meta-analysis of 84 water and sanitation interventions describes significant effects for both improved water and improved sanitation relative risks: 1.34 (95% CI 1.02–1.72) and 1.33 (1.02–1.74), respectively (Engell & Lim 2013). Another study that estimated burden of disease based on attributable deaths and DALYs, projects a diarrheal disease reduction of 58% when water supply is regulated, there is full sanitation coverage, and partial sewage treatment, and hand washing is implemented (Prüss-Ustün et al., 2014). The relative risk of lack of these services is given as 2.5 (Prüss-Ustün et al., 2014).

When considering WASH and addressing the problem of diarrhea, it is helpful to consider the Integrated Behavioral Model for Water, Sanitation, and Hygiene (IBM-WASH) developed by Dreibelbis et al (2013). The model includes five levels: societal/structural, community, interpersonal/ household, individual and habitual. It further includes three set of factors that overlay with the five levels: contextual factors, psychosocial factors, and technology factors. The model represents the complex nature of WASH and WASH implementation and will be referred to in following chapters. An adapted IBM-WASH model is provided in Table 1.

Table 1.

The Integrated Behavioral Model for Water, Sanitation, and Hygiene (adapted from Dreibelbis, 2013)

Levels	**Contextual factors**	**Psychosocial factors**	**Technology factors**
Societal/Structural	Policy and regulations, climate and geography	Leadership/advocacy, cultural identity	Manufacturing, financing, and distribution of the product; current and past national policies and promotion of products
Community	Access to markets, access to resources, built and physical environment	Shared values, collective efficacy, social integration, stigma	Location, access, availability, individual vs. collective ownership/access, and maintenance of the product
Interpersonal/ Household	Roles and responsibilities, household structure, division of labor, available space	Injunctive norms, descriptive norms, aspirations, shame, nurture	Sharing of access to product, modeling /demonstration of use of product
Individual	Wealth, age, education, gender, livelihoods/employment	Self-efficacy, knowledge, disgust, perceived threat	Perceived cost, value, convenience, and other strengths and weaknesses of the product
Habitual	Favorable environment for habit formation, opportunity for and barriers to repetition of behavior	Existing water and sanitation habits, outcome expectations	Ease/Effectiveness of routine use of product

Household Water Treatment and Diarrhea

Household water treatment (HWT), a component of WASH, is of great importance to diarrheal outcomes. Forty-three percent of sub-Saharan African children lack access to drinkable water (Cho, 2013). A WASH meta-analysis concluded that water quality interventions (i.e., treatment, filtration, storage) resulted in a relative risk of 0.69 (risk reduction of 31%)

(Fewell et al., 2005). Another meta-analysis of various household water treatments resulted in an overall relative risk of 0.56 (risk reduction of 44%) for unblinded studies and a relative risk of 0.85 (risk reduction of 15%) for blinded studies (Hunter, 2009). Some interventions, all disinfection-only, were reported to have little effect after bias was accounted for, suggesting that filtration may be better (Hunter, 2009). A separate study also found that of household water treatment methods, filtration was the only type to significantly reduce diarrheal morbidity (Prüss-Ustün et al., 2014).

Biosand Water Filters

Effectiveness

BSFs have been shown to reduce water contamination. Studies have shown 27-74% reduction in incidence of diarrheal disease (Aiken, Stauber, Ortiz, & Sobsey, 2011; de Aceituno, Stauber, Walters, Sanchez, & Sobsey, 2012; Sobsey, Stauber, Casanova, Brown, & Elliott 2008; Stauber, Kominek, Liang, Osman, & Sobsey 2012; Stauber, Ortiz, Loomis, & Sobsey 2009; Stauber, Printy, McCarty, Liang, & Sobsey 2011; Tiwari, Schmidt, Darby, Kariuki, & Jenkins 2009). Variation in disease reduction is expected due to variables with other types of exposures, the specific types of organisms present in the water, and variability in the population such as ages, prevalence of other disease such as malnutrition, individual digestive system health, and individual immunity. BSFs have been shown to remove significant amounts of *E. Coli* in both laboratory and real world settings ranging from 48% to100% (Aiken et al., 2011; de Aceituno et al., 2012; Duke et al., 2006, Earwaker 200;, Elliot, DiGiano, & Sobsey, 2008; Fiore, Minnings, & Fiore, 2010; Klopfenstain, Petrasky, Winton, & Brown, 2011; Mangoua-Allali, Coulibaly, Ouattara, & Gourene, 2012; Stauber et al., 2012; Stauber et al., 2011; Stauber et al., 2009; Stauber et al., 2006). Fecal coliform removal varies from 33.7% to 96.1% (Kanda, 2013; McKenzie et al., 2013; Tiwari et al., 2009). Further, BSFs have also been shown to remove echovirus type 12 (93%) and bacteriophages (82%) (Elliot 2008).

User Uptake and Acceptability

Community uptake of BSFs is high throughout study populations. Studies indicate that long-term user acceptance ranges from 77-94% (Aiken et al., 201;, Earwaker, 2006; Fiore et al., 2010; Mangoua-Allali et al., 2012; Stauber et al., 2011).

Longevity

A longitudinal study of BSFs in rural Haiti revealed some were still functional after twelve years, although filter lifespan ranged from <1 year (Sisson et al., 2013). While some discontinued use was due to circumstances unrelated to the filters or users (i.e.- cracks in the filter body from earthquakes, moving for employment), others, such as the belief that it would not be effective in preventing cholera, could have been alleviated through robust education to the users (Sisson et al., 2013). Another study showed that after 2.5 years of use, any decrease in flow rates were remedied by cleaning out the filter (Duke et al., 2006). Cleaning out the filter would mean disruption of the biolayer, and therefore potentially lower removal rates until the biolayer is fully formed again.

Implementation and Use Considerations

The BSF's effectiveness has been shown to vary by pause time (the amount of time between uses) and how much water was being filtered (Baumgartner, Murcott, & Ezzati, 2007). In this study, BSF use with a 12-hour pause time removed more *E. coli* than with a 36-hour pause time (Baumgartner et al., 2007). Further, a 5-liter filtration volume had a higher removal rate than a 10-liter volume, which was higher still than the removal rate for a 20 liter volume (Baumgartner et al., 2007). BSF contaminant removal was not affected by the amount of contaminant in the source water (Baumgartner et al., 2007). The CAWST manual recommends a pause period of a minimum of 1 hour and a maximum of 48 hours (CAWST, 2009).

An important study that examined long-term use of BSFs concluded that in order for BSFs to be sustainably useful, educational and technical support must be provided long term, social and cultural considerations must be continually assessed, and workers should engage in collaborative work with other organizations with related interests (Sisson et al., 2013). This study further concluded that generalized distribution of BSFs may not meet the individual needs of all families and individuals and recommends individualized interaction that can be offered with smaller programs (Sisson et al., 2013). The results of this study indicated that discontinued use of BSFs occurred for the following reasons: non-compatibility with lifestyle, broken part or crack in filter, bad smell or taste, fear that it would not prevent cholera, filter clogging, inadequate resources for bucket, and an ant infestation. Many of these were traced to improper use or inadequate education at installation (Sisson et al., 2013). The authors did not indicate if other methods of HWT were used when BSFs were discontinued.

CHAPTER 3

METHODS

Specific Aims

Specific Aim 1: Conduct a meta-evaluation of published evaluation on biosand water filters.

Objective 1A: Review articles, determine inclusion criteria, and summarize the current methods and findings of biosand water filter evaluation.

Objective 1B: Describe existing gaps in the literature regarding biosand water filter evaluation.

Specific Aim 2: Select potential field use indictors of biosand water filters for further study from the pilot data available from a small laboratory and field trial.

Objective 2A: Determine correlation of selected indicators compared to the laboratory standard of IDEXX Colilert Quanti-trays.

Objective 2B: Describe water quality and usability from data collected in a field trial of the field use indicators.

Meta-Evaluation

The meta-evaluation was designed to review current literature on BSF evaluation, summarize the current methods and findings, and describe gaps in the literature regarding BSF evaluation (Specific Aim 1). Inclusion and exclusion criteria for articles are described in the next section. The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) method was used to summarize findings and gaps in the literature are described.

Inclusion and Exclusion Criteria

The evaluation was limited to peer reviewed studies, dissertations, and theses that focus on evaluation of BSFs available in full text by searching the key words "biosand water filter" and "biosand water filters" in Google Scholar, Web of Science and Pub Med search engines. Articles were excluded if they were not available in full text, not available in English, did not include the standard version of the biosand water filter, or did not include evaluation. Brief summaries of some modifications to the standard BSF and of comparison studies to other filtration mechanisms were added, but articles were not included in the meta-evaluation.

GRADE

Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) is a method of critically examining studies for purposes of systematic reviews as well as for creating guidelines. GRADE is a respected method and has been adopted by organizations such as The Cochrane Collaboration (Cochrane reviews), the World Health Organization (WHO), and Centers for Disease Control and Prevention (CDC). The methods were developed by the GRADE Working Group established in 2000 to address shortcomings in previous grading systems in health fields (GRADE Working Group, 2014). It is promoted as a systematic and transparent approach for evaluations and recommendations. The process involves assessing risk of bias, inconsistency, indirectness, imprecision, and risk of publication bias (GRADE Working Group, 2014). These assessments are conducted using definitions provided by the GRADE working group and entered into a provided Summary of Finding Table to determine overall quality of evidence and strength of recommendations (GRADE Working Group, 2014). For the purposes of this study, it will help define the overarching strength of evaluations existing on BSFs.

Laboratory Testing of Field Use Indicators

To address the gap in literature of evidence-based methods usable in a remote field setting to determine if a BSF is functioning, a pilot study was conducted of six existing potential field use indicators (FUIs): Colilert's presence/ absence, Hach's hydrogen sulfide kit, Hach's alkalinity kit, Hach's hardness kit, a Mettler Toledo EL-2 battery powered pH meter, and Sigma Aldrich fluorescently-labeled latex microspheres. Laboratory procedures were submitted to the ETSU Biosafety Committee and approved.

Description of FUIs and Standard

IDEXX Colilert Quanti-trays were used as the standard for comparison of the FUIs. The IDEXX Quanti-tray System consists of a disposable 51 well tray, the Quanti-tray sealer, and pre-prepared reagents (IDEXX, 2015). The system provides most probable number (MPN) counts for coliforms and *E. coli* (IDEXX, 2015). To use Quanti-tray for analysis, a 100 mL sample is poured into a provided bottle, a pouch of the provided reagent added and shaken (IDEXX, 2015). This mixture is then poured into the disposable well tray and so that each well has water in it

(IDEXX 2015). The tray is then sealed using the Quanti-tray sealer and incubated at 35°C for 24 hours (IDEXX 2015). The number of trays that change color to yellow for coliforms and florescent for *E. coli* are counted and the MPN table used to determine results (IDEXX, 2015).

Presence/ absence fecal coliform and *E. coli* tests have been used previously for general water sampling in field settings (O'Keefe 2012). Colilert presence/absence are also produced by IDEXX and are used similarly to the first steps of the Quanti-tray procedure (IDEXX, 2015b). The same provided bottle is filled with a 100 mL sample and the same provided reagent packet added (IDEXX, 2015b). However, instead of using the tray, the mixture is allowed to sit in the bottle. The company recommends incubating the bottle, but for purposes of this study, incubation was not done (IDEXX, 2015b). Incubation was not done so that results would be replicable in a field setting. Because incubation was not done, results (color change) were read at 12-hour increments for 48 hours, rather than only at the recommended 24-hour interval.

Use of a hydrogen sulfide test kit was considered after reading about its use for general water testing in field conditions (O'Keefe, 2012). The Hach H2S kit is used to determine the amount of hydrogen sulfide in a water sample (Hach, 2015). Hydrogen sulfide is a common metabolic byproduct of several types of bacteria, and can therefore be an indicator of contamination (Hach, 2015). This test was performed according to manufacturer standard procedures (Hach, 2015). The test is performed by adding 100 mL of sample to a provided bottle, putting provided test paper in the cap of the bottle, adding two Alka-Seltzer tablets, closing the cap, and waiting for two minutes (Hach, 2015). The color of the test paper can then be compared to the color chart that comes with the kit to determine results (Hach, 2015).

The Hach alkalinity test kit determines the total alkalinity of the water sample (Hach, 2015b). A 100 mL samples is put into a flask and a packet of the phenolphthalein reagent added and swirled to mix (Hach, 2015b). If the mixture does not change color, the alkalinity is zero (Hach, 2015b). Otherwise, the mixture will become pink in color. The digital titrator is then used to titrate the provided 1.600 N sulfuric acid until the pink color of the solution becomes clear (Hach, 2015b). The amount titrated is multiplied by the appropriate number from the digit multiplier table and the results recorded as alkalinity mg/L (Hach, 2015b).

The Hach hardness procedure was used to determine mg/L of hardness of the sample. The procedure requires that a 100 mL sample be put in a flask and 2 mL of the provided Buffer

Solution 1 added and swirled to mix (Environmental Health Science Laboratory, 2005). One of the Man Ver 2 Hardness Indicator Powder Pillows was added, then 0.800 M EDTA solution titrated using the digital titrator until the red color changes to blue (Environmental Health Science Laboratory, 2005). The amount titrated (displayed in the titrator window) is recorded as mg/L $CaCO_3$ (Environmental Health Science Laboratory, 2005).

A Mettler Toledo EL-2 battery powered digital pH meter was used to test pH of each sample. The pH meter was calibrated at two points, 4.0 and 7.0, each day of testing. To test, the sensor was placed in 100 mL of sample and the "read" button pressed. When the symbol signifying that the reading was complete appeared, the result was recorded.

While there is not an established standard operating procedure for use of microspheres in filter testing, they have been used previously in testing riverbank sand filters (Metge et al., 2011). The idea is that if microspheres the size of contaminants can break through the mechanical filtration process, microbes the same size and smaller may also be able to make it through the filter. For this study, Sigma Aldrich latex microspheres of two types were used: 2.0 µm yellow-green and 1.0 µm red. At first use, 1 mL of each size was mixed in the influent to be put in the four filters in treatment group A. At each sampling event, 100 mL was collected and filtered through black 0.2 µm Millipore Isopore Membrane filters. The florescent beads were expected to be visible against the black filter when there was breakthrough. A microscope was used to look at each filter for the microbeads. The microbeads were to be counted and compared to other indicator outcomes. This was the only proposed indicator that would go through the filtration process rather than test the effluent. The microspheres were used only in treatment group A because latex and glass microspheres or microbeads are sometimes used in filter media as a filtration aid and could therefore potentially affect the filtration process (Balsimo & Mary, 1994).

Study Design

Laboratory testing of the FUIs occurred with nine BSFs at the East Tennessee State University (ETSU) Eastman Valleybrook campus. BSFs were stored in room 113 at Valleybrook under lock and key due to the presence of microorganisms for testing. The filters were set up in three groups: four receiving microspheres in the first influent (group A), four not receiving microspheres (group B), and one control (C). The two testing groups were established to delineate if the microspheres had an effect on the other measures because they were being poured directly into the BSFs. The control BSF was used to detect any environmental fluctuations influencing the testing. Only straight tap water was used for the control. Figure 2 represents the BSF placement in the lab. *E. coli* was added to the influent so that there was a known contaminant for testing. This organism was chosen because it is a common contaminant and there was a known source for isolation.

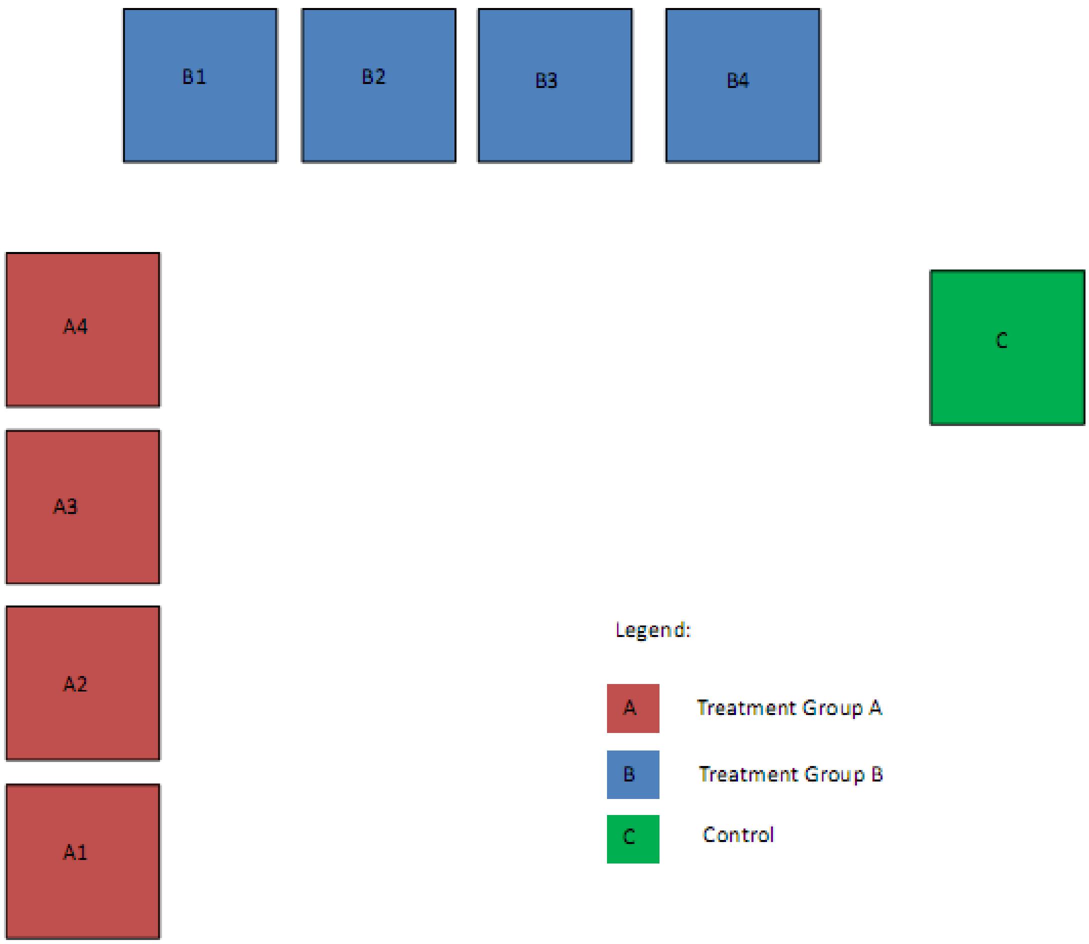

Figure 2: Biosand Water Filter Testing Groups and Physical Arrangement in the Lab

BSF Construction

The BSFs for the laboratory testing were constructed during August and September of 2014 according to instructions published by CAWST (CAWST, 2009).

E. coli Isolation, Growth, and Preparation

The *E. coli* was isolated from an environmental sample taken from Sinking Creek in Johnson City, Tennessee. The sample was initially cultured on Eosin Methylene Blue Agar (EMB) agar plates to isolate *E. coli*, and then transferred to slants of Tryptic Soy agar. It was tested using the Remel RIM Latex test for presumptive identification of *E. coli* O157:H7 (Thermo Scientific, 2015) to ensure that it was not of the O157:H7 serotype. New slants were streaked approximately monthly to maintain robust colonies. Each time new slants were made, the organisms were again cultured on EMB plates and re-isolated to ensure continued use of *E. coli* only.

To prepare *E. coli* for addition to the influent, 300 mL of tryptic soy broth was inoculated with a single loop of *E. coli* and incubated at 35 degrees Celsius for 18 hours. This broth was divided in 100 mL increments and centrifuged for ten minutes at 800 RCF (relative centrifugal force). This process produced an *E. coli* "pellet" at the base of each centrifuge container. The broth was removed from above these pellets. Two mL of phosphate-buffered saline (PBS) was then added, the mixture vortexed, and this solution was transported to the Valleybrook campus for influent seeding.

Influent Seeding, and Application

Influent was prepared by de-chlorinating 40 liters of tap water using 0.5 mg of sodium hypochlorite in two 20 liter carboys. *E. coli* suspended in 2 mL of PBS was then added to the influent (1 mL per carboy). Influent was then poured into a 1 liter graduated cylinder and poured into BSF A1 (the first BSF in the A group). One liter portions were poured in A2, A3, A4, B1, B2, B3, and B4 respectively. Then liter portions were added starting again at A1. This process continued until all the filters had received five liters. If a BSF did not yet have effluent flowing, one liter portions were added to all filters until all were flowing. Need for more than five liters per BSF only occurred when there had been a long break since the previous testing, likely because some of the water retained in the filters had been depleted over time.

Sampling and Testing

Immediately after completing the task of adding influent to all the filters, 2000 mL samples were collected from each filter. Two hundred mLs of each sample was transported to Hutcheson Hall on the ETSU main campus for the Colilert Quanti-tray test and for the microspheres. The Quanti-tray was conducted according to the manufacturer's procedures. One hundred mL was vacuum filtered to trap any microspheres that had broken through the BSFs. The Millipore black 0.2 µm filters were mounted on slides and examined under a microscope for the florescent beads. The other five FUIs were performed according to manufacturer specifications in rooms 111 and 112 at Valleybrook using the remaining sample.

Field Trial of Field Use Indicators

ETSU researchers Bethesda O'Connell (the author) and Dr. Megan Quinn travelled to Cyegera, Rwanda June 4-30, 2015 (in country June 5-29) to perform the field trial. The importance of the field trial was to test the FUIs under real world conditions to observe any problems using them and differences from laboratory data. The field trial was a cross-sectional study intended for future scale-up and repetition to become a longitudinal study. ETSU and University of Rwanda Internal Review Boards and the Rwanda National Ethics Committee did not require the FUI data collection procedures to be reviewed because it was not considered human subjects research.

Location and Population Description

The field trial took place in the village of Cyegera in the Huye district of the Southern Province of Rwanda. The study population was described in terms of the Contextual Factors of IBM-WASH (Dreibelbis et al., 2013). Much of this information is not available from external sources and was collected through personal communications and observations, not using formal methodology.

Habitual Level Contextual Factors. The community of Cyegera was prepared to accept BSF use as a habitual behavior due to previous installation of BSFs at the local secondary school (later demolished) and children's home. Community leaders and members had requested more BSFs and shown that it was a favorable environment for habitual use. In fact, this community was chosen for the field trial because of existing relationship with the author since 2009, because they requested BSFs to be installed in the community, and because the research question began through work in this community. In July 2010, five BSFs were installed in the Faith and Hope Children's Home and a school in Cyegera by the author and the Rwandese Health and Environment Project Initiative (RHEPI). During later trips, questions were posed by the community members to the author about filter use. Real world issues, such as a child pouring powdered soap into one of the filters, had occurred and the community wanted to know if the filters still worked. This was difficult to answer without being able to perform laboratory testing.

Individual Level Contextual Factors. Cyegera was home to 1378 people (692 males and 686 females) living in 335 households as of February 10, 2015 according to the census records of Anastasia Nukabashanana, the village leader (personal communication, July 2015). That included 245 children age five and under (personal communication, July 2015). Author Bethesda O'Connell has been working on public health projects in Cyegera since June 2009 and has observed that community's primary activity and source of income is agriculture and that most of the population is low income. Exact incomes are unknown, with much of the local economy involving trading and bartering, but can be observed through lack of ability of many to pay for education, adequate food, and other basic goods and services.

Interpersonal/ Household Level Contextual Factors. According to observations by O'Connell, homes in Cyegera are generally built in a rectangular structure with a sitting or living room to the front of the home, allowing optimal placing of BSFs in a corner of this common room. People of Cyegera also recognized this as a good placement because it would allow neighbors to come in and use the filters and would allow filters to be wedged in the corner, providing protection from being turned over. Because roles and responsibilities in households varies culturally (depending on presence of multiple generations and other factors), households where BSFs were being installed were asked to send the appropriate family member to the training workshop. The training workshop was conducted by RHEPI and involved discussion of the importance of safe drinking water, the opportunity of those with filters to provide their neighbors use of the filters, and how BSFs are installed and used.

Community Level Contextual Factors. O'Connell observed that Cyegera is about 2.5 hours from the capital city of Kigali, forty-five minutes from the second largest city of Butare, and about fifteen minutes from the small town of Nyanza (all by bus). There are a few stores located in the village that sell some goods and a market is held twice per week for selling of goods from the cities as well as for local agricultural products. Important to WASH, the stores and homes nearest the road were able to pay for hook up to newly placed piped water in 2013. O'Connell observed that only one shop and the children's home were able to afford to have a tap installed. The local primary school also had a tap added, but it is technically outside the village limits.

Societal/Structural Level Contextual Factors. Despite being close to the equator and within the tropical belt, Rwanda experiences temperate climate due to elevation (Rwanda Meteorology Agency, 2015). The overall average temperature in Rwanda is 20ºC or 68ºF, with higher temperatures in the dry seasons (June- August, January-February) and lower in the rainy seasons (March-May, September-December) (Rwanda Meteorology Agency, 2015). O'Connell has further observed that the terrain is extremely hilly and the wells providing water are located in the valleys, causing concern about contamination. There are no known relevant policies or regulations concerning water; however, the lack of policy around WASH issues is an important observation.

BSF Installation

For the field trial, eight new BSFs were installed in homes throughout the village near water sources and two existing BSFs in the children's home were reinstalled. The filters that were previously installed at the school were demolished when part of the school caved in. The school has since closed. One of the filters at the home was also destroyed when a child turned it over while trying to climb on it. The two remaining filters at the children's home were not working; one had a clog in the tubing and the other had developed a hard surface on the sand layer. It was said that they had worked from July 2010 to August 2014 without any maintenance. The contents of these filters was removed, rinsed, sifted, and reinstalled according to the CAWST manual. The tube was unclogged by pushing a reed in to move the built-up hardened sand causing the blockage. The process of BSF installation was described using IBM-WASH Psychosocial and Technological Factors at all levels (Dreibelbis et al., 2013).

Societal/Structural Level Psychosocial Factors. The village leader, Anastasia, and local pastor, Ernest Batera, were involved throughout the installation process. The first new BSF installed was done so at the home of the village leader and the concurrent educational workshop was conducted in her home. Further, the village leader was asked to help identify homes for the other BSFs to be installed where there were influential and community-focused individuals present who would promote use of the BSF among neighbors. The homes selected by the village leader were visited by researchers before installation to ensure that they were close to water sources so community members could use the filters conveniently, and that the household was willing to allow their neighbors to use the filter in their home.

Societal/Structural Level Technology Factors. The materials for the eight new BSFs were provided by RHEPI and financed through an ETSU Research Development Committee Major Grant. No financial "buy-in" was required of participants because of the contextual factors of low income and demonstrated eagerness to learn and accept the BSFs. The BSFs were delivered to each home by local men hired to transport the filter bodies and components of the filter media. They used bicycles to carry the heavy structures and contents to homes, sometimes over multiple hills and valleys.

Community Level Psychosocial Factors. The people of Cyegera possess a strong sense of community, shared values, and social integration. These factors made it possible to install BSFs in individual homes while ensuring community access.

Community Level Technology Factors. The BSFs were intended for community access due to budget constraints, but were installed in individual homes so that there was a sense of individual responsibility for maintenance and reporting of any problems. This method was strongly recommended by RHEPI. Although this method has not been used by RHEPI or evidenced in published studies, the concept was in line with the local culture of communal advancement. This was confirmed through observation when leaders of households selected for filters exhibited a sense of honor in the ability to serve their community.

Interpersonal/Household Level Psychosocial Factors. With guidance of the village leader, homes of influential people were chosen for BSF installation to account for norms of the local culture. New concepts and social changes are normally led by and encouraged by such leaders. Further, there is a general sense of aspiration for better lives amongst community members, so they are eager to adopt technology that allows advancement of any kind.

Interpersonal/Household Level Technology Factors. RHEPI founder James Rubakisibo provided a two-hour educational workshop at the home where the first filter was installed. Subsequently, the members of the households where the BSFs were installed were responsible to install the BSFs themselves while RHEPI and ETSU researchers observed for quality control. This ensured that they understood how the filters worked. This was followed by a one week follow-up phone call by James and two visits by researchers O'Connell and Quinn to trouble shoot any problems and answer any questions. Further, the local pastor returned to each home where a BSF was installed in July and September 2015 to ensure that there were no problems and reported back to RHEPI and O'Connell.

Individual Level Psychosocial Factors. Several individuals who received training on BSF installation and use reported a sense of honor for the opportunity to provide a service for their family and community (personal communication, June 2015). Further, the teach-back method utilized in training and being trained by a fellow Rwandan allowed increased self-efficacy and decreased perceived threat.

Individual Level Technology Factors. The BSFs were provided free of monetary cost to the community members, and they demonstrated high perceived value for the filters through many offerings of thanks, prompt attendance of the training, eager receipt of the BSFs in individual homes, and attentive teach-back and reporting of initial questions and problems.

Habitual Level Psychosocial Factors. The community was ready to use BSFs habitually due to having observed their use and having received WASH education by O'Connell through multiple formats previously.

Habitual Level Technology Factors. BSFs are relatively easy to use and maintain. To further ease use over time, the community and individuals are able to contact RHEPI with any questions or concerns at any time.

Sample Collection and FUI Procedures

Water samples were collected from each filter at installation and again on Saturday June 27, 2015. It was intended that the second set of samples would be taken two weeks after installation to allow the biolayer to fully form, but schedule delays and time spent trouble shooting the older BSFs meant that they were not two weeks old. The FUIs needed 48 hours to fully process, so samples were collected and tested on the 27^{th} to allow the researchers to leave on the 29^{th}. Samples were collected and tested from the four community water sources on June 22nd. Water was sampled and tested from the tap at the children's home on June 27^{th} (the tap only ran two days per week). FUI procedures from laboratory testing were followed in the field with one exception- the Colilert Presence/Absence test was read every six hours instead of twelve due to possible ambient air temperature differences.

Data Analysis

Laboratory data and field trial data were entered into Microsoft Excel spreadsheets. Negative or "0" results were replaced by the method detection limits as provided by the manufacturers. All data were imported into SPSS version 23.0.

Due to non-normal distributions, data were transformed. Transformations were performed on the results of each test to make the data as normally distributed as possible to meet requirements for use of statistical testing. Logarithmic, square root, and exponential transformations were performed on data from each test. Data for pH and Colilert Presence/ Absence was used without transformation. Logarithmic transformation produced the most normal data for Quanti-tray MPN and Hach Hardness tests. Square root transformation produced the most normal data for Hach Alkalinity and Hydrogen Sulfide tests. Pearson's R statistic was performed for each FUI compared to Quanti-trays to determine correlation. Field trial data were reported for the one FUI that had correlation to log Quanti-tray MPN.

CHAPTER 4

RESULTS

Meta-Evaluation

Table 2 displays the literature search results. The Google Scholar search on December 3, 2015 using the terms "Biosand Water Filter" was used as the primary search and articles found in other searches were added if they were not included in that primary search. No additional articles were found using Web of Science and PubMed search engines or search terms 'Biosand Water Filters."

Table 2.

Meta-Evaluation Literature Search Results

Search Engine	Search Terms	Date	Total Number of Results	Number Added for Meta-Evaluation
Google Scholar	Biosand Water Filter	12/3/2015	2020	19
Web of Science	Biosand Water Filter	12/15/2015	50	0
PubMed	Biosand Water Filter	12/15/2015	29	0
Google Scholar	Biosand Water Filters	12/22/2015	1099	0
Web of Science	Biosand Water Filters	12/17/2015	58	0
PubMed	Biosand Water Filters	12/18/2015	22	0

Table 3 displays the articles included in the meta-evaluation. Results were excluded if they did not include evaluation measures of biosand water filters including disease impact, water quality measures, and acceptability. Examples of results excluded are: construction manuals, reports of projects lacking filter evaluation, and studies on other methods of water purification and filtration. Further, articles about modified BSFs and comparing BSFs to other HWT methods were not included in the formal meta-evaluation with GRADE. However, select articles on modified BSFs and comparative studies were summarized. These articles were selected to represent the types of modifications and types of comparison HWT.

Table 3.

Meta-evaluation Articles

	Author(s) and year	**Title**	**Study Type**	**Water Quality Impact**	**Disease Impact**	**Other Findings**
1	Aiken, B. A., Stauber, C. E., Ortiz, G. M., & Sobsey, M. D. (2011).	An assessment of continued use and health impact of the concrete biosand filter in Bonao, Dominican Republic.	Water quality-Cross sectional; Disease outcome-Longitudinal prospective cohort	Bacterial reduction was 84-88%; 75% of filtered water had *E. coli* concentrations less than 10 MPN/ 100 mL	OR 0.39 (61% diarrhea reduction) (CI 0.23–0.68)	90% still in use at 1 year
2	de Aceituno, A. M. F., Stauber, C. E., Walters, A. R., Sanchez, R. E. M., & Sobsey, M. D. (2012).	A randomized controlled trial of the plastic-housing biosand filter and its impact on diarrheal disease in Copan, Honduras.	RCT	61% reduction of E. coli and a 38% reduction in total coliforms	Children under 5 years reduced by 45% (odds ratio = 0.55, 95% confidence interval = 0.28, 1.10); all ages 0.73 (0.48, 1.12)	n/a
3	Duke, W. F., Nordin, R. N., Baker, D., & Mazumder, A. (2006)	The use and performance of BioSand filters in the Artibonite Valley of Haiti: a field study of 107 households.	Non-random longitudinal follow-up	98.5% *E. coli* removal; 97% of samples had 0-10 cfu/ 100 mL of *E. coli;* turbidity reduction from 6.2 to 0.9 NTU	n/a	n/a

Table 3 (continued)

4	Earwaker, P. (2006).	Evaluation of Household Biosand Filters in Ethiopia.	Cross-sectional	average *E.coli* reduction rate of 87.9%; 75.7 % of filtrate samples achieving *E.coli* rates of <10cfu/100ml and 81.2% achieving turbidity values of <5TU	n/a	Continued use rates from 44-100%
5	Elliott, M. A., DiGiano, F. A., & Sobsey, M. D. (2011).	Virus attenuation by microbial mechanisms during the idle time of a household slow sand filter.	Experiment-al	Virus removal dependent on microbial layer maturation	n/a	n/a
6	Elliott, M. A., Stauber, C. E., Koksal, F., DiGiano, F. A., & Sobsey, M. D. (2008).	Reductions of E. coli, echovirus type 12 and bacteriophages in an intermittently operated household-scale slow sand filter.	Experiment-al	Reduced turbidity from a mean of 3.90 to 1.45 NTU, reduced *E. coli* at a rate of 90-98%, reduced bacteriophages at a mean rate of 82%, and reduced echovirus 12 at a mean rate of 93%	n/a	n/a
7	Fiore, M. M., Minnings, K., & Fiore, L. D. (2010).	Assessment of biosand filter performance in rural communities in southern coastal	Longitudin-al follow-up	median bacterial removal efficiency was 80%, but only 26 filters; 17% reduced E. coli to <10	n/a	77% continued use

Table 3 (continued)

		Nicaragua: an evaluation of 199 households.		CFUs/ 100 mL		
8	Jenkins, M. W., Tiwari, S. K., & Darby, J. (2011).	Bacterial, viral and turbidity removal by intermittent slow sand filtration for household use in developing countries: Experimental investigation and modeling.	Experiment-al	98.5% removal of bacteria and 88.5% removal of MS2 viruses	n/a	Smaller grain size and longer pause time produce better microbial removal
9	Kanda, A. (2013).	Performance of biosand filters in treating source water in post emergency: A case of two rural districts of northern Zimbabwe.	Longitudin-al	85.8 to 96.0% fecal coliform removal	n/a	n/a
10	Kennedy, T. J., Anderson, T. A., Hernandez, E. A., & Morse, A. N. (2013).	Assessing an intermittently operated household scale sand filter for the removal of endocrine disrupting compounds.	Experiment-al	Removal of endocrine disruptors less than 15% unless bleach was added	n/a	n/a
11	Klopfenstein, L., Petrasky, L., Winton, V., & Brown, J. (2011).	Addressing water quality issues in rural Cameroon with household biosand filters.	Longitudin-al	70-92.4% removal of *E. coli*	n/a	n/a

Table 3 (continued)

12	Mangoua-Allali, A. L. C., Coulibaly, L., Ouattara, J. M. P., & Gourene, G. (2012).	Implementation of biosand filters in rural area for drinking water production.	Longitudin-al	100% reduction of *E. coli* and *C. perfingens*	n/a	94% user acceptability
13	McKenzie, E. R., Jenkins, M. W., Tiwari, S. S. K., Darby, J., Saenyi, W., & Gichaba, C. M. (2013).	In-home performance and variability of biosand filters treating turbid surface and rain water in rural Kenya.	Longitudin-al	96.1% fecal coliform and 32.5% turbidity mean removal rates	n/a	n/a
14	Sisson, A. J., Wampler, P. J., Rediske, R. R., & Molla, A. R. (2013).	An assessment of long-term biosand filter use and sustainability in the Artibonite Valley near Deschapelles, Haiti.	Longitudin-al	n/a	n/a	Lifespan range <1 to 12 years
15	Stauber, C. E., Kominek, B., Liang, K. R., Osman, M. K., & Sobsey, M. D. (2012).	Evaluation of the impact of the plastic BioSand filter on health and drinking water quality in rural Tamale, Ghana.	RCT	97% mean reduction of *E. coli*, 67% mean reduction of turbidity; 44% of filtered samples versus 15% of the pre-filter samples contained <10 MPN *E. coli* /100 mL	all ages RR 0.40 (0.05, 0.80); age five and under RR 0.26 (0.07, 0.89)	n/a

Table 3 (continued)

16	Stauber, C. E., Printy, E. R., McCarty, F. A., Liang, K. R., & Sobsey, M. D. (2011)	Cluster randomized controlled trial of the plastic biosand water filter in Cambodia.	Cluster RCT	*E. coli* reduction 93.3- 99.3%; turbidity reduction 64% reduction	IRR 0.41 (0.24, 0.69)	89% user acceptability
17	Stauber, C. E., Ortiz, G. M., Loomis, D. P., & Sobsey, M. D. (2009)	A randomized controlled trial of the concrete biosand filter and its impact on diarrheal disease in Bonao, Dominican Republic	RCT	48% reduction of *E. coli*	0.53 IRR	n/a
18	Stauber, C. E., Elliott, M. A., Koksal, F., Ortiz, G. M., DiGiano, F. A., & Sobsey, M. D. (2006)	Characterization of the biosand filter for E. coli reductions from household drinking water under controlled laboratory and field use conditions	Longitudinal	91% -97% *E. coli* reduction in lab; 93% field *E. coli* reduction; field turbidity reduction from 8.1 to 1.3 NTU; field pH increase from 7.4 to 8.0	n/a	n/a
19	Tiwari, S. S. K., Schmidt, W. P., Darby, J., Kariuki, Z. G., & Jenkins, M. W. (2009).	Intermittent slow sand filtration for preventing diarrhea among children in Kenyan households using unimproved water sources	RCT	Reduction of fecal coliform geometric means from 89.0 CFU to 30.0 CFU/ 100 ml (33.7% reduction)	age-adjusted RR 0.46; 95 % CI = 0.22, 0.96	n/a

Summary of Articles

Plastic Hydraid BSFs placed in ninety households (532 people) in Honduras reduced diarrhea in children age five and under by 45% (odds ratio (OR) = 0.55, 95% confidence interval (CI) = 0.28, 1.10) and all ages by 27% (0.73 (0.48, 1.12)) (de Aceituno et al., 2012). While disease reduction was not statistically significant, water quality results also indicated improvement (de Aceituno et al., 2012). Water samples were taken five times before and nine times after installation of filters and tested with the IDEXX Colilert Quanti-trays system and Hach portable meters for turbidity and pH (de Aceituno et al., 2012). Despite similar water quality in sources used, intervention households had a lower geometric mean *E. coli* concentration compared with control households (23 and 45 MPN/100 mL, respectively ($P < 0.0001$)), and slightly lower turbidity (21 versus 23 NTU) (de Aceituno et al., 2012). When source water was compared to drinking water post filtration, the BSFs achieved 61% reduction of E. coli and a 38% reduction in total coliforms (de Aceituno et al., 2012). Limitations for this study include recall bias for disease reporting and lack of ability to address seasonal variations in disease with post intervention evaluation occurring only from December 2008 to February 2009 (de Aceituno et al., 2012).

A longitudinal follow-up of 107 households non-randomly selected from a previous intervention group of 2000 households in Haiti determined that at an average of 2.5 years of use, the BSFs were removing a mean of 98.5% of E. coli and 97% of samples had 0-10 cfu/ 100 mL of *E. coli* (Duke et al., 2006). Further, the BSFs reduced turbidity from a mean of 6.2 NTU in source waters to 0.9 NTU post filtration (Duke et al., 2006). The homes studied were selected based on location. The study also collected data indicating that 10 of the 71 children age six and under in these households had had diarrhea in the previous two weeks (Duke et al., 2006). There was not pre-intervention diarrheal incidence for comparison. Further information was collected on other risk factors such as sanitation, hygiene, and socioeconomic indicators, but again without comparison data.

Later follow-up of 55 of the filters in the same communities in Haiti further revealed that BSF lifespans ranged from less than one year to over twelve years (Sisson et al., 2013). Of the non-randomly selected filters visited, 45% were no longer in use (Sisson et al., 2013). Reasons for discontinued use included lifestyle incompatibility (such as traveling for work), reasons that could have been addressed through comprehensive education (such as concern that the filter would not protect from cholera), and functional problems (including clogging and broken parts) (Sisson et al., 2013). Education was a significant concern since users did not understand basics of linkage between drinking water and disease (Sisson et al., 2013). The authors recommended comprehensive education and cultivation of long-term relationships with local partners to ensure that users could contact someone with concerns and have continued education (Sisson 2013). However, the study did demonstrate that filters have the ability to function at least twelve years if used properly (Sisson et al., 2013). Limitations of this study include small sample size and non-randomization, but a major strength is the length of follow-up. The Sisson et al 2013 publication was based on Sisson's 2012 thesis (Sisson et al., 2012).

BSFs in rural Ethiopia, tested after five years of use provided an average *E.coli* reduction rate of 87.9% with 75.7 % of filtrate samples achieving *E.coli* rates of <10cfu/100ml and 81.2% achieving turbidity values of <5TU (Earwaker, 2006). Continued use rates varied widely by village, ranging from 44-100% (Earwaker, 2006). The study stated that the organization that installed the BSFs originally did not provide adequate follow-up, and that communities with the lowest rates of continued use were those who were provided the filters last, receiving the least follow-up (Earwaker, 2006).

A laboratory experimental study of BSF performance in removing seeded *E. coli*, echovirus type 12 and bacteriophages determined that filter performance increased over time, with about 30 days being full maturation (Elliot, 2008). Overall, the BSFs reduced turbidity from a mean of 3.90 to 1.45 NTU, reduced *E. coli* at a rate of 90-98%, reduced bacteriophages at a mean rate of 82%, and reduced echovirus 12 at a mean rate of 93% (Elliot, 2008). The authors recommended further investigation into the removal of viruses.

Virus attenuation was determined in continued research to occur only after biolayer maturation, and increased with further maturation (Elliot et al., 2011). This suggests that removal of viruses by BSFs may be due to microbial activity rather than mechanical methods. Further, when sodium azide was used to inhibit microbial activity, viruses were not effectively removed (Elliot et al., 2011). Virus removal occurred at 0.061- and 0.053-log per hour (Elliot et al., 2011).

A study examining the best grain size of sand and best pause time to use in BSFs determined that smaller grains and overnight pause time were best (Jenkins Tiwari, & Darby 2011). On average, the filters (including all grain sizes) removed 1.40 log fecal coliform CFU

(SD 0.40 log, *N* = 249) and 89.0 percent turbidity (SD 6.9 percent, *N* = 263) (Jenkins et al., 2011). The best performance conditions were for fine sand, 10 cm head, and long operation, overnight pause time between 20L batches (Jenkins et al., 2011). These conditions created mean 1.82 log removal of bacteria (98.5%) and mean 0.94 log removal of MS2 viruses (88.5%) were achieved (Jenkins et al., 2011).

A study in Zimbabwe concluded that BSF performance improved with time. The study included 58 filters and two phases, six and twenty-four week follow-ups (Kanda, 2013). Results included mean fecal coliform levels in twenty-eight source water samples were 43.9±11.8 (phase 1) and 34.3±14.5cfu/100m (phase 2) (Kanda, 2013). These concentrations were reduced using BSFs to mean values of 6.3±1.9 (phase 1) and 1.2±0.6cfu/100ml (phase 2), suggesting improved treatment with time of use (Kanda, 2013). Overall coliform removal was 85.8 to 96.0% (Kanda, 2013). By phase 2, 82.8% of the filters provided microbiologically safe water for human consumption by the researcher's standard of 0cfu/100ml (Kanda, 2013).

Kennedy, Hernandez, Morse, and Anderson (2013) examined the ability of the BSF to remove the endocrine disrupting compounds of estrone (E1), estriol (E3), and 17α-ethinyl estradiol (EE2). The laboratory study of twelve BSFs concluded that removal rates were only about 15%, although higher than in studies of the slow sand filter, a similar design to BSFs (Kennedy et al., 2013). The researchers then tested removal of the compounds when bleach was added to the filter effluent. The removal rates varied by 50 to 98% based on bleach concentrations (Kennedy et al., 2013).

Partnership between Engineers Without Borders and Hope College produced a small study of 25 BSFs in Cameroon (Klopfenstein et al., 2011). The study evaluated *E. coli* removal rates over a three year period under varying pause times and concluded that there were 70-92.4% removal rates of *E. coli* (Klopfenstein et al., 2011). The study also included some qualitative evaluation of use over time, generally indicating that the BSFs were used over the three years and that users felt that they benefited from the filters (Klopfenstein et al., 2011). This study's major limitation was sample size, but had a significant strength with better follow-up time than many other studies.

Longitudinal follow-up of 199 of 600 BSFs installed over the previous two years in rural Nicaragua revealed that forty-five of them were no longer in use (77% continued use) (Fiore et al., 2010). Of the 154 still in use, the median bacterial removal efficiency was 80% (Fiore et al., 2010). However, only 26 filters (17%) reduced E. coli to <10 CFUs/ 100 mL (Fiore et al., 2010). Recontamination after filtration was identified as a problem. Limitations of the study include that the sample was conveniently selected, but an important strength is that the study was funded by non-governmental organizations without competing interests.

McKenzie et al. (2013) reported on a six-month performance study of BSFs in low-income Kenyan households. A total of 115 households were included and were reported to use both rain water and river water sources (McKenzie et al., 2013). Over the six months, the BSFs removed an average of 96.1% of fecal coliforms and 32.5% of turbidity (McKenzie et al., 2013). The researchers commented that filters fed river water only performed better, but did not provide specific data (McKenzie et al., 2013). This could be due to the formation of a more robust biolayer due to consistency of influent water quality. The study limitations included short follow-up time and lack of provision of data details.

A longitudinal study of nine BSFs over 56 days in Ivory Coast had overwhelmingly positive results. The study stated that 94% of users were satisfied with the use of the filters and that they remover 100% of *E. coli* and *Clostridium perfringens* (to 0 CFU per 100 mL) from the water (Mangoua-Allali et al., 2012). This studies major limitations are sample size and follow-up time.

A randomized control trial (RCT) of plastic BSFs in Ghana included 260 households (117 intervention households or 1012 people and 143 control households or 1031 people) over seven months (Stauber et al., 2012). The results for water quality measures were 97% mean reduction of *E. coli* and 67% mean reduction of turbidity (Stauber et al., 2012). Further, 44% of filtered samples versus 15% of the pre-filter samples contained <10 MPN *E. coli* /100 mL (Stauber et al., 2012). Diarrhea risk for intervention households including all ages was 0.40 (0.05, 0.80) (Stauber et al., 2012). For children age five and under the relative risk (RR) was 0.26 (0.07, 0.89) (Stauber et al., 2012). The primary limitation of the study is short duration of follow-up.

A cluster randomized control trial of the Hydraid plastic BSF in Cambodia conducted in 2008 revealed lower incidence of diarrhea and lower *E. Coli* concentrations in sampled water in households with filters compared to control households (Stauber et al., 2011). The study included 99 households (601 participants) in 6 villages who received an intervention group that received hygiene education and the plastic BSFs. The control group was composed of 90 households (546 participants) in 7 villages who received hygiene education only. Then, over 24 weeks, households were visited biweekly and questioned about diarrheal incidence in the household. Data on other factors were also collected including the presence of soap, whether water was boiled, access to sanitation facility, type of water source, and measures of wealth. Water samples were also collected during these visits including pre-filtered water, water directly from the plastic BSF outlet tube, and BSF treated water that had been stored for drinking. The study resulted in a 0.41 (95% CI: 0.24, 0.69) incidence rate ratio (IRR) of diarrhea for the intervention group, with a 0.45 (95% CI: 0.26–0.77) IRR of diarrhea for children under the age five years, however both of these were not statistically significant at the 95% confidence level (Stauber et al., 2011). Further, diarrheal cases were shorter in the intervention group (1.9 vs 3.4 days for plastic BSF and control group, respectively, $p = 0.018$) (Stauber et al.,2011). The water sample analysis resulted in lower *E. coli* concentration in the drinking water of the intervention group of 2.9 versus 19.7 CFU/100 mL ($p < 0.001$). This was an *E. coli* reduction of geometric mean 93.3- 99.3% (Stauber et al., 2011). Turbidity was also reduced with results of 1.6 Nephelometric Turbidity Unit (NTU) in the intervention group versus 2.5 NTU in the control group ($p < 0.001$) (Stauber et al., 2011). Overall, user acceptance of the plastic BSF was 89% (Stauber et al., 2011). Study limitations include possible recall bias in the questionnaire and lack of measurement of other parameters including other water quality measures and outcome measures other than diarrheal disease. It should also be noted that the study was funded in part by Cascade Engineering who was a partner in manufacturing the Hydraid filter.

A randomized control trial in the Dominican Republic involved visiting houses up to four months before intervention to establish diarrhea rates and water quality, installation of BSFs or a control, water sampling biweekly for six months, and redetermination of diarrhea rates (Stauber et al., 2009). There were 75 households receiving BSFs and 79 control households (Stauber et al., 2009). Diarrhea rates were determined by verbal report and *E. coli* removal was determined using Colilert Quanti-trays. Relevant covariates such as rainfall, age, education, and income were controlled for. Intervention households experienced decreased diarrhea with an Incidence Rate Ratio (IRR) of 0.47 (Stauber et al., 2009). After adjustment for age, the intervention households experienced 0.53 times the amount of diarrhea as control households (Stauber et al., 2009). Intervention households had a lower mean concentration of *E. coli* in the water after filtration (11 compared to 19 MPN per 100 mL), and a mean 48% reduction of *E. coli* (Stauber et al., 2009).

An earlier study by the same research group involved laboratory and field testing to determine water quality changes pre and post biosand water filtration (Stauber et al., 2006). The laboratory testing involved using lake water seeded with *E. coli* as influent for testing in two different concentrations for about one and a half months each (Stauber et al., 2006). The laboratory results included 97% and 91% geometric mean *E. coli* reductions (Stauber et al., 2006). The field study involved sampling water pre and post filtration from fifty-five households in the Dominican Republic. The filters had been in use 4-11 months prior to testing. Field testing results included a mean of 93% *E. coli* reduction (with variation from no apparent reduction to 99.7% reduction), turbidity reduction from averages of 8.1 to 1.3 NTU, and pH increase from 7.4 to 8.0 (Stauber et al., 2006). Variation in *E. coli* removal was attributed to variations in use.

Further follow-up of the Dominican Republic filters by the same research group determined that of 328 households visited, 90% of the BSFs were still in use at one year post installation (Aiken et al., 2011). Bacterial reduction was 84-88% (Aiken et al., 2011). Further, 75% of filtered water had *E. coli* concentrations less than 10 MPN/ 100 mL compared to 10% of the pre-filtered water (Aiken et al., 2011). To determine disease reduction, 66 RCT households and 69 control households were selected for an 8-week prospective cohort study. Intervention households had a diarrhea OR of 0.39 (0.23, 0.68) compared to households without BSFs (Aiken et al., 2011). The Aiken et al 2011 article was produced from Aiken's thesis research (Aiken et al., 2008).

Tiwari Schmidt, Darby, Kariuki, & Jenkins (2009) conducted a randomized control trial of BSFs in Kenya. Thirty intervention homes and twenty-nine control homes with children and unimproved water sources were selected (Tiwari et al., 2009). For six months, homes were visited monthly for diarrheal incidence recall and water quality testing (Tiwari et al., 2009). The study concluded that intervention households had better drinking water quality than control households with fecal coliform geometric means of 30.0 CFU vs. 89.0 CFU ⁄ 100 ml (Tiwari et al., 2009). Further, intervention homes reported significantly fewer diarrhea days (86 days over 626 child-weeks) compared to controls (203 days over 558 child-weeks) among children up to 15 (age-adjusted RR 0.46; 95 % CI = 0.22, 0.96) (Tiwari et al., 2009). The results were greater for children age five and under with RR of 0.49 (0.34, 1.02), although not statistically significant (Tiwari et al., 2009). The study acknowledged limitations of small sample size and lack of control for socioeconomic factors, especially of interest since homes with unimproved water sources are more likely to be lower income and of lower educational status (Tiwari et al., 2009).

Overall, the studies included in the meta-evaluation yielded diarrheal disease reductions of 27% to 74% with BSF use. Further, the studies included *E. coli* removal rates of 48% to 100%. Variance in disease reduction is expected due to broader issues of exposures other than drinking water, variations in the types of organisms present, and variations in individual (i.e.- digestive micro biome) and population health (i.e.- prevalence of other disease that would change susceptibility). Other water quality measures were inconsistently used across studies. User acceptance rates were 77 to 94%. Sustainability of BSFs is unclear with filters functioning effectively at rates varying from less than one year to over twelve years in included studies. Studies evaluated filter function using laboratory testing not possible in many settings. It should also be noted that of the many of the studies were conducted by one group of researchers consisting of Duke, Sobsey, Stauber, Elliot, Sisson, and others. Further, companies that market BSFs were involved in funding of many of the studies. The strength of the evidence for use of BSFs to reduce diarrheal disease and improve drinking water quality are evaluated in the GRADE section of the Results chapter.

Modified BSFs. Various modifications to the standard BSF have been studied. The goals of the modifications have been to improve overall performance, and in some cases to improve removal of specific contaminants. Some of the studies of BSF modifications are summarized in this section.

The BSF has been amended with iron addition in various ways to remove arsenic as well as pathogens. One such method is to coat the sand with iron oxide. Laboratory analysis of an amended BSF with 10 cm of iron oxide-coated sand compared with the standard BSF over four months concluded that the two types removed turbidity similarly, but the modified version had a better removal rate of *E. coli* during the first month, 99.3% versus 90.0% (Ahammed & Davra 2011). Both versions had increased removal rates after biolayer maturation of approximately one month (Ahammed & Davra 2011). It should be noted that iron oxide-coating would be more difficult to source and produce in developing world or low-resource settings.

Further experimentation with several iron amendments to BSF standard media was done by BradleyStraub, Maraccini, Markazi, & Nguyen (2011). Iron-amended sand filters resulted in bacteriophage removal of $5\log_{10}$ versus $0.5 \log_{10}$ for standard BSFs (Bradley et al., 2011). BSFs with added iron particles and with steel wool both removed rotavirus at $4\log_{10}$ (Bradley et al., 2011). The study concluded that further research should investigate iron-amended BSFs.

A prominent amended BSF is the Kanchan Arsenic Filter (KAF) which includes addition of iron nails. One study piloted the KAF in Nepal (Ngai Shrestha, Dangol, Maharjan, & Murcott, 2007, Ngai & Walewijk, 2003). A pilot laboratory and field study concluded that the modified BSF was effective in removing arsenic (range = 87 to 96%, mean = 93%), total coliform (range = 0 to >99%, mean = 58%), *E. coli* (range = 0 to >99%, mean = 64%), and iron (range = >90 to >97%, mean = >93%) (Ngai & Walewijk, 2003). The full study involved provision of 1000 filters to rural Nepal. The full study had similar results with removal of 85–90% of arsenic, 90–95% of iron, 80–95% of turbidity, and 85–99% of total coliforms (Ngai et al., 2007). The design of the filter was not described in detail.

The KAF was further studied in Cambodia with three different groundwater sources with varying concentrations of arsenic (Chiew Sampson, Huch, Ken, & Bostick, 2009). The study raised concerns about the effectiveness of KAF in removing arsenic with large variation in removal by concentrations in the influent- means of 39.4, 74.9, and 45.4% (Chiew et al., 2009). Overall, the effluent was left with arsenic concentrations above drinking water standards- between 74 and 226 μg L^{-1} (Chiew et al., 2009).

A study investigated BSFs with addition of coniferous pinus bark biomass (CPBB) in various quantities: 1 cm (treatment 2), 2.5 cm (treatment 3) and 5 cm (treatment 4) (Baig Mahmood, Nawab, Shafqat, & Pervez 2011). Lab experiments resulted in the standard BSF removing means of 93% of *E. coli* and 95% of total coliforms at 15 days of trial (Baig et al., 2011). The experimental filter with the most added CPBB (5 cm) removed 100% of E. coli and total coliforms from days 30-45 of sampling (Baig et al., 2011). Mean removal rates for the four treatment groups over 75 days were 81 ± 3%, 85 ± 2%, 87 ± 2% and 93 ± 1%, respectively (Baig et al., 2011). It should be noted that CPBB may be limited in availability for some populations.

A doctoral dissertation study experimented with four BSFs with an additional diffuser basin and sand layer compared to 30 standard BSFs in Ghana (Kikkawa, 2008). The four experimental BSFs after day 13 removed 92- 95% of turbidity compared to 87% by the standard BSFs (Kikkawa, 2008). The study intended to collect data on *E. coli* and total coliforms removal as well, but inconsistent power supply interfered with the methods (Kikkawa, 2008).

A further study experimented in Ghana with dual sand layer biosand filter with a 3-7 cm deep raised upper sand layer prior to biological treatment and further filtration of the water in a

15-16 cm deep lower sand layer (Collin, 2009). Field-testing of the dual sand layer biosand filter showed this filter achieved 59% turbidity reduction, 38% higher than an unmodified control filter; and at least 85% *E. coli* and 95% total coliform reductions, comparable in performance to unmodified control filters (Collin, 2009). Laboratory testing demonstrated average reductions of 93% turbidity, 97% *E. coli* and 71% total coliform after filter maturation, comparable to unmodified control filter results (Collin, 2009).

BSF outlet tube size was examined by Kennedy Hernandez, Morse, and Anderson (2012). Three different outlet tube sizes were tested including 0.5, 0.37, and 0.25 centimeter diameters (Kennedy et al., 2012). Spiked lake water was used and pH, dissolved oxygen, fecal coliforms, turbidity, nitrate, nitrite, and ammonia examined (Kennedy et al., 2012). No significant water quality difference was observed for the different outlet tube sizes (Kennedy et al., 2012).

Comparative Studies. Rather than focus on just BSFs for evaluation, some studies compare multiple HWT mechanisms. These are important for determining the best possible mechanism for improving drinking water. Some of the comparison studies that appeared in the meta-evaluation searches are summarized in this section.

Baumgartner Murcott, and Ezzati (2007) examined the BSF and the Potters for Peace Filtron ceramic filter. These filters are produced around the globe in small factories set up by the non-profit organization and consist of a clay pot made to fit inside a bucket with a spigot (Potters for Peace 2016). Both the ceramic filters and BSFs were shown to function with significantly different removal rates under varying operating conditions. Under the best conditions, the two types of filters appeared to have similar removal rates (Baumgartner et al., 2007). This study showed that operating conditions significantly affected the amount of contaminant removed. Operating conditions included pause time (the time between uses), with 12 hours pause removing more contaminant than 36 hours pause, and volume filtered, with more contaminant removed when 20 liters were filtered than 10 liters (Baumgartner et al., 2007). The pause time variable is related to the feeding of the biolayer by pouring water in the filter. The more robust the biolayer is, the more effective the filtration. The volume filtered variable is related to the fact that there is a reserve of water in the filter and that when water is poured in, the first water out is actually what has been in the filter previously. So the more water filtered, the more diluted the reserve water (Baumgartner et al., 2007).

A laboratory comparison of the performance of the BSF versus that of the Filtron ceramic filter concluded that the ceramic filters removed more E. coli than the BSFs (Duke et al., 2006). The study showed that the BSFs reduced E. coli to 0 per 100 cc in only two of thirty-one samples (Duke et al., 2006). However, the study showed similar performance between the two filters toward the end of the study as measured by *E. coli* removal as well as total coliforms, turbidity, total organic carbon, and dissolved organic carbon (Duke et al., 2006). The study lasted for about a month, so the development of the biolayer explains the lower performance of the BSFs in the initial samplings.

A meta-regression of three disinfection methods, chlorination, combined coagulation and chlorination, and solar water disinfection (SODIS), and two filtration methods, ceramic and BSF, include 39 studies with three of BSFs (Hunter, 2009). The three studies on BSFs were included in the studies used in this meta-evaluation. It concluded that the HWT methods and studies included had a pooled RR of diarrhea of 0.56 (95% CI = 0.51−0.63), but when adjusted for lack of blinding a pooled RR of 0.71 (0.63−0.81) (Hunter 2009). The study said that BSFs were less effective than ceramic filters, with RRs of 0.65 and 0.37 respectively (Hunter, 2009). The disinfection only methods were found to be unhelpful (Hunter, 2009). However, the study recognized the limitations of their conclusions, which were based in the limitation of the studies included. The authors recommended future studies with stronger methods including blinding and long-term follow-up (Hunter, 2009).

Another meta-regression included the same HWT methods and considered microbial efficacy, health impacts, and sustainability factors: water quantity produced, application to wide range of water quality, ease of use, cost, supply chain requirements, and long-term user acceptability (Sobsey et al., 2008). Use of all of these factors in evaluating the water treatment methods illustrates the complexity of WASH issues. The study found that ceramic filters produced a higher reduction of bacteria than BSFs, with logarithmic reduction values of 4-6 versus 3-4 (Sobsey et al., 2008). BSFs reduced diarrhea by an average of 47% overall (21-64%), more than all the disinfection methods and ceramic water purifiers, but lower than ceramic filtration through candle filters (average reduction of 63%) (Sobsey et al., 2008). Sustainability factors were scored on a scale of 1 to 3, with 3 being highest. For water quantity produced, BSFs scored 3 while ceramic filters scored 2 (Sobsey et al., 2008). For application to a wide range of water quality, both BSFs and ceramic filters scored a 3 (Sobsey et al., 2008). For ease of use, both scored 2 (Sobsey et al., 2008). In cost, BSFs scored a 2 and ceramic filters scored a 3 (Sobsey et al., 2008). For supply chain requirements, BSFs scored a 3 while ceramic filters scored a 2 (Sobsey et al., 2008). The total scores for sustainability criteria concluded with BSFs at 13 and ceramic filters at 12 (Sobsey et al., 2008). Finally, BSFs were shown to have the highest sustained user acceptance and continued use at greater than 85% (Sobsey et al., 2008). The authors recommended that more studies be done with longer follow-up.

A published critical comment on this study stated that the sustainability criteria were not well enough described, were evaluated on too limited of studies, and did not include several important sustainability criteria such as consumer preference, economic considerations, cultural practices, and local water quality (Lantagne Meierhofer, Allgood, McGuigan, & Quick, 2008). Examination of five filters [(biosand filter-standard (BSF-S); biosand filter-zeolite (BSF-Z); bucket filter (BF); ceramic candle filter (CCF); and silver-impregnated porous pot (SIPP)] for their ability to improve the quality of drinking water at the household level revealed variation in flow rates from 0.05 L/h to 2.49 L/h for SIPP, 1 L/h to 4 L/h for CCF, 0.81 L/h to 6.84 L/h for BSF-S, 1.74 L/h to 19.2 L/h and 106.5 L/h to 160.5 L/h for BF (Mwabi, Mamba, & Momba 2012). Further, the turbidity of the raw water samples ranged between 2.17 and 40.4 NTU (Mwabi et al., 2012). The average turbidity obtained after filtration ranged from 0.6 to 8 NTU (BSF-S), 1 to 4 NTU (BSF-Z), 2 to 11 NTU (BF), and from 0.6 to 7 NTU (CCF) and 0.7 to 1 NTU for SIPP. The BSF-S, BSF-Z and CCF removed 2 to 4 log10 (99% to 100%) of coliform bacteria, while the BF removed 1 to 3 log (90% to 99.9%) of these bacteria (Mwabi et al., 2012). In summary, the authors viewed SIPP as the highest performer among those assessed due to its high removal of turbidity and indicator bacteria (>5 log10, 100%) (Mwabi et al., 2012).

Description of Gaps

An existing gap in evaluation of biosand water filters is a low cost method of evaluating water quality produced by BSFs that can be used in a field setting without access to a laboratory. Hammond (2015) recognized this gap and suggested a filter clogging assay that has promising correlation to total coliform measurements (0.93, $p = 6.5^{-10}$) and costs about $1.50 per test. The quality of this study cannot yet be determined as it is currently embargoed from the literature, with only an abstract available. The laboratory and field testing of FUIs included in this dissertation is intended to be a preliminary step in filling this literature gap.

Other concerns with existing evaluation of BSFs are study quality problems. As pointed out by meta-regressions (Hunter 2009, Sobsey et al., 2008), the body of literature would be improved by studies with longer follow-up times and by studies that are blinded to reduce bias. The fact that many of the studies have been conducted by the same research team suggests that more studies be independent researchers may be needed. Further, funding from companies that market of several of the studies indicates potential for conflict of interest.

GRADE

A GRADE Summary of Findings table was used to determine the strength of evidence for each evaluation measure. The Summary of Findings table provided through GRADE Pro (GRADE Pro, 2015) allows the user to enter the information and automatically calculates the overall quality per outcome and study type. The GRADE Working Group (GRADE, 2014) resources provide detailed descriptions of considerations within each category. Study designs including cohort, longitudinal, and cross-sectional were all categorized by GRADE as observational. Further, outcomes with only one study associated (such as echovirus removal) were not recommended to be included for GRADE analysis.

For this meta-evaluation, down grading reasons included publication bias for the RCT studies dominated by one research group, risk of bias in observational studies due to sample size and length of follow-up issues, indirectness for observational studies due to concerns about generalizability, and finally inconsistency for observational studies on fecal coliform reduction due to a wide range of results. All down grading were to “serious” rather than “very serious” other than “strongly suspected” for the publication bias around RCTs. Table 4 displays the GRADE Summary of Findings. Interpretation of the Summary of Findings is discussed in chapter 5.

Table 4.

GRADE Summary of Findings

Quality Assessment						**Summary of Findings**		
# of Studies	**Study Design**	**Risk of Bias**	**Inconsist-ency**	**Indirect-ness**	**Imprecision**	**Public-ation Bias**	**Effect**	**Quality**
Diarrhea reduction- all ages								
5	RCT	Not serious	Not serious	Not serious	Not serious	Strongly Suspected	0.506 (0.05, 1.12)	Moderate (3/4)
1	Observat-ional	Not serious	Not serious	Not serious	Not serious	Strongly Suspected	0.39 (0.23,0.68)	Very Low (1/4)
Diarrhea reduction- children 5 and under								
2	RCT	Not serious	Not serious	Not serious	Not serious	Strongly Suspected	0.405 (0.07, 1.10)	Moderate (3/4)
***E. coli* removal**								
4	RCT	Not serious	Not serious	Not serious	Not serious	Strongly Suspected	0.24	Moderate (3/4)
9	Observat-ional	Serious	Serious	Serious	Not Serious	Not Detected	0.09 (0, 0.7)	Very Low (1/4)
Fecal coliform reduction								
1	RCT	Not serious	Not serious	Not serious	Not serious	Not detected	0.66	High (4/4)

Table 4 (continued)

3	Observat-ional	Serious	Serious	Serious	Not Serious	Not Detected	0.27	Very Low (1/4)
Turbidity reduction								
2	RCT	Not serious	Not serious	Not serious	Not serious	Strongly Suspected	0.345	Moderate (3/4)
4	Observat-ional	Serious	Serious	Serious	Not Serious	Not Detected	0.89	Very Low (1/4)

Testing of FUIs

Laboratory Testing Results

The latex micro beads that were put into the first influent were never seen in effluent samples collected, therefore there are no results associated with latex micro beads. This may have been because samples were not collected every time there was effluent. Correlation could not be calculated for Colilert Presence/ Absence results for readings at twelve or twenty four hours because all were negative. Pearson's R correlation is provided in Table 5 below for each test compared to Quanti-tray results. Pearson's R was used versus the Spearman correlation coefficient because the Spearman coefficient leads to higher correlations, but more probability of error.

Table 5.

Pearson's R Statistic Results

Field Use Indicator	Pearson's R compared to log Quanti-tray MPN
Colilert P/A at 36 hours	0.642
Colilert P/A at 48 hours	0.503
pH meter	-0.037
Hach Hardness (log)	-0.014
Hach Alkalinity (square root)	-0.075
Hach Hydrogen Sulfide (square root)	0.151

Chi-Square results for the categorical log Quanti-tray MPN and Colilert Presence/Absence are displayed in Tables 6 and 7. Quanti-tray MPN data was categorized according to the WHO recommended acceptable *E.coli* MPN concentration in drinking water, which is <10 MPN per 100 mL (WHO 2011b). This corresponds to <1 log MPN.

Table 6.

Chi- Square Colilert P/A 36 hour

		Colilert P/A 36 hour		
		A	**P**	
Log Quanti-tray MPN Categorical	**≤ 1 log MPN/ 100 mL**	41	11	52
	> 1 log MPN/ 100 mL	3	15	18
		44	26	70

The χ^2 for Table 6 was 22.143 (p= 0.000). Because one cell had less than five in it is necessary to use Fisher's exact, which was also p = 0.000. Further, type II error was calculated at 0.068 and type I error at 0.423.

Table 7.

Chi- Square Colilert P/A 48 hour

		Colilert P/A 48 hour		
		A	**P**	
Log Quanti-tray MPN Categorical	**≤ 1 log MPN/ 100 mL**	29	23	52
	> 1 log MPN/ 100 mL	1	17	18
		30	40	70

The χ^2 for Table 7 was 13.767 (p= 0.000). Fisher's exact was also significant (p = 0.000). Further, type II error was calculated at 0.033 and type I error at 0.575.

Field Trial Results

In the field trial, none of the samples collected changed color for the Hach Alkalinity test. Further, results for Colilert Presence/ Absence readings under 36 hours could not be used because correlation to Quanti-trays could not be established from the laboratory data and results. Because correlation to Quanti-trays was low for other tests, field trial results were analyzed for

Colilert Presence/ Absence readings at 36 hours. Table 6 displays test results of samples taken from drinking water sources, from BSFs at installation, and from BSFs on June 27, 2015.

Table 8.

Field Trial Colilert P/A Results by Source

Field Use Indicator	Number of Negative Samples	Number of Positive Samples
Water Sources	0	5
Filters at Installation	2	5
Filters on June 27	0	8

CHAPTER 5

DISCUSSION

Meta-Evaluation

While the meta-evaluation of BSFs revealed that there is evidence of reduction of diarrhea disease and increase in water quality, the description of gaps and use of GRADE Summary of Findings also adds caution regarding the quality of the studies available. Publication bias around the RCTs due to four of the five being conducted by the same research group is the primary reason why many of the RCT outcomes were reduced from high to moderate quality of evidence. The observational studies outcomes were reduced further due to small sample sizes, inconsistency of findings, and concerns with generalizability. It should also be noted that GRADE methodology was originally selected as an objective means of determining strength of evidence, but after completing the table, the criteria are now understood to be rather subjective. Guidelines are provided regarding each input, but the decision is ultimately a judgment call by the researcher(s). As such, it is likely a better tool for comparing two interventions than simply to determine evidence for one intervention. Recommendations for future studies stemming from these findings are discussed in the recommendations section of this chapter.

Testing of FUIs

Laboratory Testing of FUIs

Interpretation of laboratory testing results for the FUIs should include consideration of the wide range of corresponding MPN from Quanti-trays to the results for Colilert P/A. The positive results for 36 hour readings of the P/A test corresponded to a range of log MPN values of <0 to 3.38. The negative results for 36 hour readings correlated to log MPN values ranging from <0 to 2.21. According to the WHO, acceptable *E.coli* MPN concentration in drinking water is <10 MPN per 100 mL (WHO, 2011b). This would correspond to <1 log MPN. Out of 70 testing dates, three of the negative results for Colilert Presence/ Absence corresponded to log MPN values that are above this value and six of the positive results for Colilert Presence/ Absence corresponded to log MPN values within the WHO recommendation.

Further testing and more data would potentially enhance the predictive value and reduce the type I and type II errors. Reduced correlation between Quanti-tray MPN and 48 hour readings of Colilert P/A was likely due to the fact that positive results for Colilert Presence/Absence at 48 hours corresponded to a broader range of Quanti-tray MPN. While only one negative Presence/ Absence result corresponded to an MPN value above one, positive Presence/ Absence results corresponded about half of the time to MPNs within acceptable risk. While risk of a type II error resulting in recommending use of unsafe water is reduced with the 48 hour reading of Colilert Presence/ Absence, the risk of a type I error is increased. A type II error is more dangerous in terms of preventing diarrhea, but a type I error resulting in not recommending use of safe drinking water could be detrimental in communities with limited water quantity. The precautionary principle leads us to err on the side of caution, preferring a type I error over type II. Future studies may benefit from reading the Colilert test at more time intervals between 36 and 48 hours to provide more information on the best balance of error probability.

Field Trial of FUIs

Several factors are important to note when interpreting the results of the field trial. The June 27th results were twelve days after installation of eight of the BSFs, nine days after the re-installation of another and only seven days after re-installation of the final BSF. Further, two of the homes where BSFs were installed reported having to clear some hardened sand from the top of the column because of low flow rates. While this seems to have resolved flow rate problems, it may have disturbed the formation of the biolayer. Therefore, the final testing date of June 27, 2015 was not adequate to allow full formation of the biolayer. Further, it must be noted that because the Colilert Presence/ Absence test was conducted without incubation or other temperature controls, the laboratory results and field trial results likely differ simply because of ambient temperature. Therefore, the only conclusion that can be drawn from the field trial data is that the source waters are likely not safe for consumption and that the filters were not able to amend this by the testing dates. Follow-up on the BSFs from the field trial is recommended.

Limitations

The meta-evaluation limitations included the literature searches performed. It is possible that searching other databases or with other terms may have produced articles that were not included. Further, the meta-evaluation was limited by the research available. Limitation of the studies included created overall limitations. Common limitations included sample size, use of convenience samples, lack of blinding, recall bias, and length of follow-up.

The FUI pilot study had significant limitations, as expected in a pilot study. An important limitation was failure to collect and test multiple samples per filter on testing days for purposes of reliability analysis. There were small sample sizes for both laboratory testing and the field trial. Further, summaries of field testing were based on the significant assumption that Colilert Presence/ Absence tests could be used to estimate risk in the same way that Quanti-trays could. Delays in filter installation in Cyegera resulted in inadequate testing dates that did not allow full formation of the BSF biolayers.

Recommendations

Important recommendations emerged from the meta-evaluation of BSFs. First, it is recommended that evaluation studies of BSFs occur over longer periods of time and with higher sample sizes, allowing for better evaluation of filter efficacy long term, and therefore sustainability. Second, more independent studies are needed outside of the existing major research groups who are consistently published on BSF evaluation. Third, GRADE methods would likely be best utilized if comparing methods, rather than two filter types. Alternatively, development of a WASH specific evaluation tool may be the best way to determine study strength. Such a tool should include the ability of the study to address relevant IBM WASH (Dreibelbis et al., 2013) issues as well as some criteria from GRADE. GRADE's inclusion of criteria on generalizability may not be appropriate due to the necessity of adaptation to unique needs in communities. Further, GRADE evaluation of publication bias may not be appropriate because production of many papers out of one institution or collaboration is not uncommon on specific topics such as this. However, the inputs would need to be evaluated collaboratively or by the same researcher due to the subjective nature of evaluation. Fourth, it is recommended that future study control for variables in disease prevalence external to drinking water exposures to limit variability in outcomes (i.e.- prevalence of other exposures to water related diseases, prevalence of diseases that would alter susceptibility). Finally, a method for reliably determining filter efficacy outside of standard lab conditions is needed.

Much was learned from the pilot study of testing FUIs, leading to many recommendations for future research. First, more study is needed both in laboratory and field settings. This further study should include testing of multiple samples of effluent per filter per day to be able to determine reliability of FUIs. Samples should be collected for each effluent to avoid the issue of possibly missing important data such as breakthrough of micro beads. Longer time periods between testing dates would be aided by scheduling a longer time at the study location. Use of Quanti-trays with and without incubation would allow for more information to examine when comparing to non-incubated FUI results. Further, reading results of the Colilert Presence/Absence test at more narrow time intervals could identify a more optimal predictor of risk. Finally, the Colilert Presence/Absence test should be further studied with the BSF along with several other indicator tests such as the water canary (Water Canary, 2015) and the filter clogging assay (Hammond, 2015).

Conclusions

In conclusion, BSFs are a viable solution to reduce burden of diarrheal disease by increasing drinking water quality. Much can be done to improve future evaluation of BSFs, with focus on length of follow-up and controlling for variables external to drinking water exposure. The Colilert Presence/ Absence test deserves further investigation as a FUI. Future testing of Colilert Presence/Absence and other FUIs can also be improved, most significantly through larger samples sizes, adequate length of testing time, and inclusion of other promising tests.

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VITA

BETHESDA O'CONNELL

Education: Doctor of Public Health (DrPH), Concentration: Community Health, East Tennessee State University, May 2016.

Master of Public Health, Concentration: Community Health, East Tennessee State University, May 2013.

Bachelor of Science in Public Health, Minors: Biology, Disaster Response and Preparedness, East Tennessee State University, May 2011.

Teaching Experience:

Teaching Associate, East Tennessee State University. COBH 1020: Introduction to Public Health. Aug 2014-May 2016.

Teaching Assistant, East Tennessee State University. EPID 5700: Interprofessional Perspectives on Global Health. Jul 2014.

Teaching Assistant, East Tennessee State University. COBH and HSMP 4850: Field Experience. Aug 2011- Dec 2013.

Visiting Instructor, Kiruhura Christian College in Rwanda. Biology and General Paper Classes. May-Jul 2010.

Research Experience:

Co-writer- not funded. Transforming Evaluation of Safe Water Interventions and Outcomes to Sustainably Reduce Diarrheal Disease. East Tennessee State University Research Development Committee. Mar 2015.

Co-writer and Research Assistant Ensuring safe water in communities: establishing a field-use indicator for biosand water filters. East Tennessee State University Research Development Committee. $9,992. Jul 2014- Jun 2015.

Co-writer and Research Assistant. Curriculum Internationalization of Infectious Disease Epidemiology. East Tennessee State University Honors College. May-Jun 2014.

Poster Presentations. Global Health and Innovation Conference, 2016. Appalachian Student Research Forum, 2015. Tennessee Environmental Conference, 2015. Tennessee Conference of Graduate Studies, 2015, 2013, 2012, 2011. American Public Health Association Annual Conference, 2013.

Additional Experience:

Volunteer Application Reviewer. Honors College Study Abroad Scholarship Committee. East Tennessee State University. Aug 2012- present.

Volunteer Public Health Outreach Coordinator. Hope 2.2.1. Rwanda. Jul 2009- present.

Volunteer CPR and First Aid Instructor. Public Health Student Association. Feb 2009- present.

Volunteer First Aid Coordinator. Pathfinders Youth Camp. Aug 2005- present.

Intern. Appalachia Service Project. Rural Tennessee, North Carolina, Virginia, Kentucky, and West Virginia. Jul-Dec 2015.

President. Public Health Student Council. East Tennessee State University. May 2013-Apr 2014.

Intern. Centro de Atencion a la Familia y al Nino Maltratado (CAFNIMA). Ulpan Valley, Guatemala. Jan- May 2013.

Certified Nursing Assistant. Mountain States Health Alliance Indian Path Medical Center. Oct 2007- Mar 2012.

Intern. Hope 2.2.1. Cyegera, Rwanda. May- Jul 2010.

Vice President. Public Health Student Association. East Tennessee State University. May 2009-Apr 2010.

Honors, Awards, and Scholarships:

Most Outstanding DrPH Community Health Student. Apr 2016.

ASPIRE Appalachia Scholarship. Jun 2015.

Most Outstanding MPH Community Health Student. Apr 2013.

Bruce and Amelia Goodrow Endowment Scholarship. Apr 2009 and Apr 2011.

Frist Global Health Leaders Scholarship. May 2010 and Jan 2013.

Honors Program. Northeast State Community College. Aug 2006- May 2007.