Evaluation and Regulation of Household Water Treatment Technologies in Developing Countries

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Abstract

Household water treatment (HWT) technologies are used to improve microbiological water quality and reduce diarrheal disease among users without access to safe drinking water. There is ongoing interest in developing new HWT technologies, which are typically evaluated by controlled laboratory microbiological efficacy testing, followed by diarrheal disease reduction through randomized controlled trials. In households, technologies should be both microbiologically effective and consistently used to achieve maximum health gains, yet industry standard metrics to evaluate household use are lacking. HWT technology regulation is limited both globally and nationally; few regulation frameworks exist, and most existing performance standards focus on efficacy.

Given the state of rapid HWT technology development, lack of industry standard metrics, and weak regulation frameworks, this dissertation aimed to investigate methodologies of evaluating HWT technology performance for both technology improvement and regulatory decision-making. Six research projects spanning laboratory, field, and policy domains were conducted: two evaluations of field laboratory methods for analyzing water quality indicators; three field evaluations of existing and prototype HWT technologies, including investigations of use, performance, and failure mechanisms in realistic household settings; and one demonstration of a national HWT regulation framework considering technology efficacy, toxicity, manufacturing consistency, and usability.

Results confirmed field water quality test methods, recommended standard HWT evaluation metrics and evaluations in realistic settings, and demonstrated a simple national HWT regulation framework. Overall, six main themes emerged: 1) evaluations in realistic settings are important, particularly to identify design flaws and establish technological limitations before widely distributing technologies; 2) there is a need to refine HWT field evaluation methods and regularly report consistent use and effectiveness alongside disease reduction; 3) determining HWT "success" remains difficult in disparate field study settings; 4) HWT regulation must begin with basic parameters; 5) technology is important, but behavior change cannot be ignored if health gains are to be achieved; and finally, 6) HWT is a complex public health intervention depending on many actors. HWT technologies are a viable solution, but it is critical that technologies be evaluated and regulated to ensure they are effective for those who need it most.

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Table of Contents

List of Tables

List of Figures

Evaluation and Regulation of Household Water Treatment Technologies in Developing Countries

1 Introduction

1.1 Water, sanitation, and hygiene and the global burden of diarrheal disease

Globally, diarrheal disease is a leading cause of death, and is responsible for an estimated 1.31 million annual deaths (Troeger et al., 2017). Inadequate access to water, sanitation, and hygiene (WASH) access accounts for 842,000 annual diarrheal disease deaths in low and middle income countries, which represents 58% of all diarrheal disease deaths from the year of that estimation, and 1.5% of the total disease burden (Prüss-Ustün et al., 2014a). Individuals are often exposed through contaminated food, drinking water, and poor sanitation and hygiene, and the most severe threat of diarrheal disease is death due to dehydration (WHO, 2013). An estimated 502,000 diarrheal disease deaths can be attributed to inadequate drinking water supply alone (Prüss-Ustün et al., 2014a).

Children under 5 years are particularly at risk of diarrheal disease. Overall, diarrheal disease accounts for 11% of all deaths in children under 5 (equal to 0.8 million diarrheal disease deaths per year) (Liu et al., 2012). Most diarrhea cases in children are attributable to bacteria, viruses, or protozoan cysts; specifically Rotavirus, *Cryptosporidium*, and enterotoxigenic *E. coli* (Kotloff et al., 2013), some of which could be prevented by adequate drinking water treatment, sanitation, and hygiene access.

In addition to diarrheal disease, poor WASH access is associated with other health problems in developing countries, including undernutrition (Black et al., 2013;

Dangour et al., 2013) and stunting due to environmental enteropathy (Mbuya & Humphrey, 2016), as well as neglected tropical diseases such as soil-transmitted helminth infections (Ziegelbauer et al., 2012) and schistosomiasis (Grimes et al., 2014).

1.2 Global access to safe drinking water

The UN Millennium Development Goals were established in 2000 with eight goals and associated targets to help alleviate poverty (United Nations, 2006). The drinking water and sanitation target, "to halve, by 2015, the proportion of the population without sustainable access to safe drinking water and basic sanitation," was achieved in 2010 for drinking water (WHO/UNICEF, 2015). Between 1990 and 2015, 2.6 billion people gained access to improved drinking water sources, and as of 2015, over 90% of the world's population had access to improved drinking water sources. However, there are still disparities in rural and urban populations, and the countries with lowest levels of access are concentrated in sub-Saharan Africa and Oceana (WHO/UNICEF, 2015).

Improved drinking water sources include sources such as piped water systems, protected springs, protected wells, and rainwater harvesting, which were assumed to be of good quality because the sources are protected from microbiological contamination. However, many improved water sources are still contaminated with fecal indicator bacteria (Bain, Cronk, Wright, et al., 2014), and an estimated 1.8 billion people globally are dependent on water sources – both improved and unimproved – that are fecally contaminated (Bain, Cronk, Hossain, et al., 2014;

Onda, LoBuglio, & Bartram, 2012). Additionally, water quality at the point of use is often worse than the point of collection, due to contamination during collection, transport and storage (Wright, Gundry, & Conroy, 2004).

In the post-2015 era, the Millennium Development Goals have been replaced by an expanded set of 17 Sustainable Development Goals and targets (United Nations, 2016). The new Sustainable Development Goal for drinking water is to "by 2030, achieve universal and equitable access to safe and affordable drinking water for all" (WHO/UNICEF, 2017). This new target promotes access to reliable, contaminant-free, improved water sources located on premises, and evidence suggests this high level of sustainable service yields optimal health gains (Overbo, Williams, Evans, Hunter, & Bartram, 2016).

While this remains the goal, World Health Organization (WHO) and United Nations Children's Fund (UNICEF) recognize that a third of countries are not currently on track to achieve universal coverage of improved sources on premises by 2030 (WHO/UNICEF, 2017). For those without access to safe drinking water, WHO also supports incremental water supply improvements, such as household water treatment (HWT) and safe storage, to provide heath gains associated with safer drinking water until more permanent supply or treatment solutions are available (WHO, 2011b).

1.3 Household water treatment and safe storage

HWT is a point-of-use (POU) intervention. A growing body of evidence demonstrates that HWT use improves the microbiological quality of household water and reduces the burden of diarrheal disease (T. F. Clasen et al., 2015; Thomas Clasen, Schmidt, Rabie, Roberts, & Cairncross, 2007; Fewtrell et al., 2005; Waddington, Snilstveit, White, & Fewtrell, 2009; Wolf et al., 2014). However, there is debate over the magnitude of disease reduction as a result of methodological concerns (Hunter, 2009; Wolf-Peter Schmidt & Cairncross, 2009). Despite this uncertainty, there is largely agreement that HWT use will reduce diarrheal disease when technologies are microbiologically effective, accessible to the population at risk, and used correctly, consistently, and continually (Thomas Clasen, 2015).

1.3.1 Household water treatment methods

HWT methods range from traditional methods like boiling, to use of manufactured products like polymer membrane filters. HWT methods largely follow similar processes to those used in municipal water treatment plants, but are modified to be performed by users within the home. HWT methods can be broadly categorized according to mechanism of action within five categories as: 1) coagulation, flocculation, and sedimentation; 2) physical separation (filtration); 3) chemical disinfection; 4) disinfection by heat, ultraviolet radiation, or solar radiation; and 5) combined methods. HWT methods in each of these categories are described in the following sections.

Coagulation, flocculation, and sedimentation

Coagulation, flocculation, and sedimentation are treatment processes performed in series to clarify turbid water. Natural materials like moringa seed or chemicals like alum are examples of coagulants (Preston, Lantagne, Kotlarz, & Jellison, 2010). When water is agitated, coagulants bind together suspended solids into flocs, which then settle out. Coagulation, flocculation, and sedimentation is efficacious at removing turbidity, as well as large protozoan cysts, and some bacteria (Asrafuzzaman, Fakhruddin, & Hossain, 2011; Ghebremichael, Gunaratna, Henriksson, Brumer, & Dalhammar, 2005).

Filtration

HWT filter technologies are most often either ceramic, biosand, or hollow fiber polymer membrane filters. Each filter type is described below.

Ceramic filters

Ceramic filters consist of a membrane made from clay and a burnout material, which creates a pore structure for physically trapping pathogens through processes such as mechanical screening, sedimentation, and adsorption (Van Halem, Heijman, Soppe, Van Dijk, & Amy, 2007). Ceramic filters take many shapes, but membranes are usually housed within a receptacle that also serves as a safe storage container for filtered water. Common ceramic filter membranes are "pot" shaped membranes suspended within a receptacle, which are locally produced with technical assistance provided by Potters for Peace, and "candle" filters, which are typically industrially manufactured cylinders or disks inserted between two receptacles. HWT candle filters are manufactured globally by many manufacturers and may operate by gravity or siphon action. Ceramic filters are most efficacious at reducing bacteria and protozoan cysts, and are less efficacious at reducing viruses because of their small physical size (Bielefeldt et al., 2010; Joe Brown & Sobsey, 2010; D. Lantagne et al., 2010; Van Halem et al., 2007).

Biosand filters

Biosand filters (BSFs) are intermittently-operated slow sand filters (CAWST, 2012). They typically consist of layers of sand and gravel housed in approximately 1 m tall concrete or plastic casings for household use. Technical assistance for locally constructed concrete BSFs is provided by the Center for Affordable Water and Sanitation Technology (CAWST, Calgary, Canada). The most common plastic BSF is the Hydraid® filter (Native Energy, Burlington, VT), although other designs have been produced around the world. BSFs are efficacious at reducing bacteria and protozoan cysts, but are less efficacious at virus reduction. Pathogen removal is accomplished by a combination of interaction with a biological layer (or *schmutzdecke*), as well as mechanical trapping, adsorption, and natural death as water is filtered through the sand (M. A. Elliott, Stauber, Koksal, DiGiano, & Sobsey, 2008; M. Elliott, Stauber, DiGiano, de Aceituno, & Sobsey, 2015; Napotnik, 2014; C.E. Stauber et al., 2006).

Hollow fiber membrane filters

Hollow fiber membrane filters consist of bundles of polymer membrane “tubes” housed within a plastic cartridge. Hollow fiber membrane filters have pore sizes typically 0.1µm or 0.02µm. Those with 0.1µm pores are efficacious at removing bacteria and protozoan cysts from water, and filters with 0.02 µm pore size are efficacious at removing bacteria, viruses, and protozoan cysts (Thomas Clasen, Naranjo, Frauchiger, & Gerba, 2009; Erikson et al., 2013; Hydreion, 2005a, 2005b; WHO, 2016). Commercially-available hollow fiber membrane filters include LifeStraw® (Vestergaard Frandsen, Lausanne, Switzerland), which are available for personal, family, or community use and have a 0.02µm pore size; and Sawyer PointONE™ or Point ZeroTwo (Sawyer Products, Safety Harbor, FL), which are available in both pore sizes and can be fitted to a plastic bucket for household use, among others (CAWST, 2017a).

Chemical disinfection

The most common chemical disinfectant is chlorine, which may be in liquid solution or solid tablet form. One of the most common chlorine HWT products is dilute sodium hypochlorite solution (NaClO). This was promoted as a HWT method known as the Safe Water System by the Centers of Disease Control and Prevention and Pan American Health Organization beginning in the 1990s, and locally-produced sodium hypochlorite products are marketed in many countries by Population Services International (PSI, Washington, DC) (CDC, 2000). Sodium dichloroisocyanurate (NaDCC) tablets, like Aquatabs® (Medentech Ltd, Wexford, Ireland) or Oasis Water Purification Tablets (Hydrachem Ltd, Billingshurst, UK) are also commonly used. HWT with chlorine-based technologies has been widely studied (Arnold & Colford, 2007; T. F. Clasen et al., 2015).

In addition to chlorine, other chemical disinfectants are sometimes promoted for HWT, including halogens like bromine and iodine, or metals like silver, copper, and zinc (Armstrong, Sobsey, & Casanova, 2016; K. S. Enger, Leak, Aw, Coulliette, & Rose, 2016; Gerba & Maxwell, 2012; Pyle, Broadaway, & McFeters, 1992). These are often found in liquid solution form, or tablets in the case of iodine.

Chemical disinfection is most efficacious at reducing bacteria and viruses, and is generally less efficacious at reducing protozoan cysts (Sobsey, 1989).

Disinfection by heat, ultraviolet, or solar radiation

Boiling

Boiling is the most commonly reported HWT method used globally (Rosa & Clasen, 2010). When treating water by boiling, it is recommended to heat the water until it reaches a rolling boil (100ºC), allow it to cool naturally, and store the water in a covered container to protect against recontamination. Boiling is efficacious at inactivating bacteria, viruses, and protozoan cysts (WHO, 2015).

Solar pasteurization

Solar pasteurization, like boiling, is a method of heating water to an elevated temperature to inactivate bacteria, viruses, and protozoan cysts. It requires exposure to a lower temperature (65-75ºC) for a longer time (Burch & Thomas, 1998; Ciochetti & Metcalf, 1984). This may be accomplished by using a locally-produced or industrially-manufactured solar pasteurizer or solar cooker which concentrates the sun's energy to one location with reflective surfaces and dark colors (CAWST, 2009).

Solar disinfection

Solar disinfection, or SODIS, is a method of treating water in the sun. Water is placed in a clear, polyethylene terephthalate bottle, shaken to oxygenate the water, and placed in the sun for six hours in direct sunlight, or two days if cloudy. Through a combination of thermal inactivation and UV-A radiation, SODIS is most efficacious at inactivating bacteria, and viruses, but less efficacious at inactivating protozoan cysts. (Luzi, Tobler, Suter, & Meierhofer, 2016).

Ultraviolet disinfection

Ultraviolet (UV) disinfection is a method that uses an electric UV-C germicidal bulb to inactivate bacteria, viruses, and protozoa in water. The bulb emits light at primarily 254 nm wavelength, which damages pathogen cell DNA, rendering cells unable to replicate. Commercial household systems are available, but are typically expensive; however, low-cost designs have also been developed for HWT in developing countries (Brownell et al., 2008; Reygadas, Gruber, Ray, & Nelson, 2015).

Combined HWT methods

Some HWT methods utilize combined treatment processes, such as coagulation, flocculation, and disinfection. P&G™ Purifier of Water (Proctor & Gamble, Cincinnati, OH) is one such technology, although similar locally-produced versions are also available, such as Pureit sachets® (Hinustan Unilever, Mumbai, India), Bishan Gari (Bishan Gari Purification Industries PLC, Addis Ababa, Ethiopia), and Water Maker™ (Control Chemicals, Ltd, Johannesburg, South Africa). P&G™ Purifier of Water sachets consist of powdered ferric sulfate, a coagulant, and calcium hypochlorite, a disinfectant. Suspended material is coagulated and allowed to settle out, and then water is strained and further protected by residual chlorine. Coagulants and disinfectant technologies are efficacious at reducing bacteria, viruses, and protozoan cysts, as well as reducing turbidity (J A Crump et al., 2004; John A Crump et al., 2005; Marois-Fiset, Shaheed, Brown, & Dorea, 2016; Reller et al., 2003; Souter et al., 2003).

Other combined treatment methods include ceramic or hollow membrane fiber filters that also introduce a disinfectant such as silver or iodine to work in combination with physical separation.

Novel HWT technologies

In recent years, entrepreneurs, inventors, academics, and corporate foundations have focused on developing innovative HWT technologies to address health concerns in developing country community and emergency settings. Motivations are often to produce technologies that are microbiologically efficacious, easy to use, cost-effective, easy to transport, and sustainable, with the goal of scaling up distributions among populations with diarrheal disease risk (CAWST, 2017a). As a testament to this, from 2014-2016, over 60 HWT products were submitted for laboratory testing under a WHO Scheme to evaluate HWT technologies (Majuru, 2017).

1.3.2 Global estimates of HWT use

An estimated 1.8 billion people in low and middle income countries (0.7 billion of these in China alone) reportedly practice HWT (Rosa & Clasen, 2010; Yang, Wright, & Gundry, 2012).

Common HWT methods typically vary by region (Figure 1-1). Boiling is the most commonly reported HWT method used globally, particularly in the Western Pacific region. Filtration is most common in Southeast Asia, and chlorination is most commonly used in Latin America and the Caribbean. Reported HWT use in Africa and the Eastern Mediterranean is low overall (Rosa & Clasen, 2010).

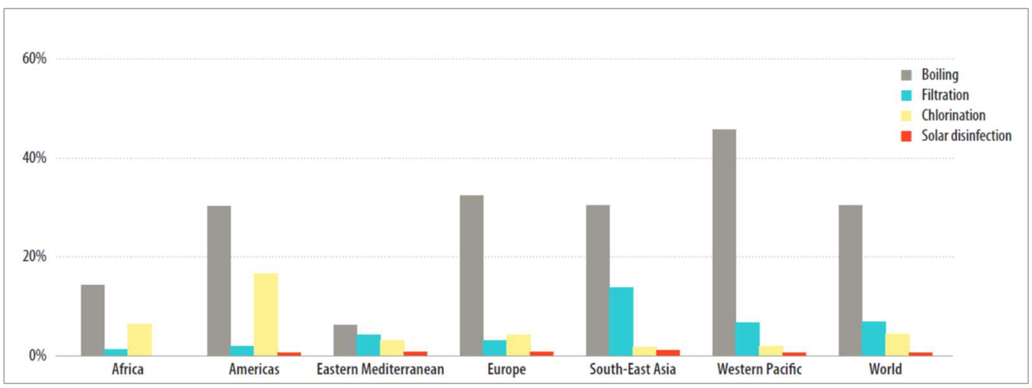

Figure 1-1: Percentage of population reporting household water treatment by WHO region. Figure reprinted from (WHO, 2014a) *with data from Rosa & Clasen, 2010.*

1.3.3 Advantages and challenges of HWT

Advantages of household water treatment practice are that it can be effective at reducing diarrheal disease for those without access to safe drinking water disease (T. F. Clasen et al., 2015; Thomas Clasen et al., 2007; Fewtrell et al., 2005; Waddington et al., 2009; Wolf et al., 2014), it can be rapidly deployed and adopted quickly, particularly in emergency settings (Daniele S Lantagne & Clasen, 2012; Yates, Allen, Leandre Joseph, & Lantagne, 2017), and it can be a cost effective intervention (Daniele S Lantagne, Quick, & Mintz, 2006).

Some challenges of household water treatment practice are that it requires sustained behavior change and places the treatment burden on users (Hulland, Martin, Dreibelbis, DeBruicker Valliant, & Winch, 2015), it has not achieved sustained health impact in many settings (Wolf-Peter Schmidt & Cairncross, 2009) or global scale (T Clasen, 2009; Ojomo, Elliott, Goodyear, Forson, & Bartram, 2015), and it is a strategy that most governments have not considered as part of water safety efforts or technology/product oversight (WHO, 2016).

1.4 Evaluating household water treatment technologies

1.4.1 Introduction to HWT evaluation methods

The current, widely-accepted method to evaluate HWT technologies is to first establish the product's ability to remove organisms of concern from test waters in the laboratory setting (termed "efficacy"), and then to measure the product's ability to reduce diarrheal disease in controlled health impact trials in developing country communities (Daniele S Lantagne et al., 2006). These are both done in highly controlled settings. Field evaluations are also conducted by researchers and practitioners to measure other HWT metrics like acceptability, use, and ability to remove indicator organisms from household water (termed "effectiveness"). Common methods and metrics for laboratory efficacy testing, health impact trials, and field evaluations are described in detail below.

1.4.2 Laboratory efficacy testing

Microbiological efficacy testing uses standard procedures to establish a HWT technology's ability to remove or inactivate reference pathogens from test water under ideal laboratory conditions. As "infectious diseases caused by pathogenic bacteria, viruses and parasites (e.g. protozoa and helminths) are the most common and widespread health risk associated with drinking-water" (WHO, 2011b), test organisms or surrogates are chosen to represent each of those three classes of pathogens: bacteria, viruses, and protozoan cysts. To do the testing, test waters are spiked with a high concentration of organisms, and then treated with the HWT process. Organism concentrations are quantified in untreated and treated samples, and a percent reduction or log reduction value (LRV) is calculated to quantify performance (US EPA, 1987; WHO, 2011a).

WHO introduced a methodology for evaluating laboratory efficacy of HWT technologies in 2011, based on a quantitative microbial risk assessment (QMRA) model which combines: 1) reference organism identification, 2) pathogen exposure assessment, and 3) dose-response data to develop a estimates of the probability of infection associated with pathogen exposure in drinking water (WHO, 2011b).

Specific test organisms were selected for each class of organism (bacteria, virus, and protozoa) because they are present in human populations and fecally-contaminated water, and have well-characterized dose-response relationships (WHO, 2011a). Target LRV values were established based on a reference level of risk in terms of disability-adjusted life years (DALY) per person per year, and considering: assumed raw water quality (concentration of organisms), volume of water consumed per day, probability of infection per organism, risk of diarrheal illness given infection, disease burden (DALYs per case), and susceptible fraction of the population.

This methodology established three health-based targets for HWT microbiological performance, termed at the time: *highly protective* (4-log bacteria and protozoa reduction and 5-log virus reduction)*, protective* (2-log bacteria and protozoa reduction and 3-log virus reduction), or *limited protection* (achieving protective target for two pathogen classes and epidemiological evidence demonstrating disease reduction) (WHO, 2011a).

1.4.3 Health impact trials

Beginning in the 1970s, simple longitudinal (before-after intervention) and then case-control epidemiologic studies were undertaken to measure health impacts of water and sanitation interventions. At this time, most of the drinking water interventions were water supply projects and randomized, controlled trials (RCTs) of this type of intervention was considered infeasible. While the case-control studies were perceived to be the best available option, they were subject to selection bias and confounding. In the 1990s, the focus shifted away from water supply interventions in developing countries, and more towards household water treatment and hygiene education – particularly handwashing campaigns. These interventions were better-suited to conducting RCTs, and much evaluation effort was placed there (Blum & Feachem, 1983; W.-P. Schmidt et al., 2011; Wolf-Peter Schmidt, 2014).

Today, diarrheal disease reduction of HWT in household settings is frequently evaluated by conducting RCTs after laboratory efficacy has been established. These RCTs are typically short-term (3-6 months), with frequent measurement (often weekly). Diarrheal disease is self-reported by users or caregivers over a set amount of time – often three days to two weeks prior to the household visit. Results are typically presented as odds ratios (OR) or risk ratios (RR) of diarrheal disease comparing treatment groups to control groups (T. F. Clasen et al., 2015; W.-P. Schmidt et al., 2011).

Epidemiologically, these studies are difficult to conduct, and there is debate about their utility (Hunter, 2009; Wolf-Peter Schmidt, 2014; Wolf-Peter Schmidt & Cairncross, 2009). Some shortcomings of these types of studies including lack of blinding in interventions; difficulty in assessing exposure, including the imperfect correlation between water quality indicators and disease outcomes; and biases in self-reported diarrhea incidence (Blum & Feachem, 1983; Moe, Sobsey, Samsa, & Mesolo, 1991; W.-P. Schmidt et al., 2011; Wolf-Peter Schmidt, 2014; Wolf-Peter Schmidt & Cairncross, 2009; Zwane et al., 2011). Blinded or placebo-controlled HWT may not always be feasible or ethical (Thomas Clasen & Boisson, 2016), and more recent HWT meta-analyses have adjusted diarrheal disease estimates for non-blinding (Wolf et al., 2014) to account for this effect.

The most recent meta-analysis of HWT diarrheal disease reduction trials summarized disease reduction estimates as approximately one quarter for disinfection products like chlorine, one half for filters, and one third for SODIS (T. F. Clasen et al., 2015). Summarized diarrheal disease reductions for specific HWT methods with sufficient published information are listed in Table 1-1. Additionally, safe water storage (in a covered container with a small opening) has been shown to reduce diarrheal disease by about 15% (Wolf et al., 2014).

Table 1-1: Summarized diarrheal disease reduction estimates for HWT methods in low and middle income countries from (T. F. Clasen et al., 2015)

HWT Method	**Risk Ratio (95% CI)**
Chlorination only	0.77 (0.65-0.91)
Flocculant disinfectants	0.69 (0.58-0.82)
Ceramic filters	0.39 (0.28-0.53)
Biosand filters	0.47 (0.39-0.57)
Lifestraw® filters	0.69 (0.51-0.93)
SODIS	0.62 (0.42-0.94)

1.4.4 Field evaluation metrics

Laboratory efficacy and health impact trials are both conducted with highly controlled evaluation methodologies. Field evaluations are generally non-RCTs which are used to evaluate HWT technologies and programs.

A 2012 WHO Toolkit for Monitoring and Evaluating Household Water Treatment and Safe Storage Programs outlined 20 HWT program indicators in five categories: reported and observed use; correct, consistent use; knowledge and behavior; other environmental health interventions; and water quality (WHO, 2012). Note that these indicators were developed specifically around *program* evaluations rather than purely *technological* evaluations; however, several metrics are pertinent to both. A listing of six common field evaluation metrics along with general measurement methods is provided below.

Reported use is determined by asking a respondent what they do to make water safer to drink. As a self-reported measure, reported use is subject to over-reporting due to social desirability bias.

Observed use, also sometimes called confirmed use, is a more objective indicator of HWT use. To measure this, enumerators ask to see the HWT device and make specific observations (e.g. whether there is water in a filter) or measurements (e.g. free chlorine residual in chlorine-treated water) (WHO, 2012).

Correct use may be determined by one of two methods: asking knowledge questions or asking a user to demonstrate HWT method use. This indicates whether users have knowledge of HWT technology operation and maintenance (WHO, 2012).

Consistent use is a metric used to quantify how frequently householders use HWT methods. Consistent use, also sometimes replaced by adherence or compliance in academic literature, is measured and reported by many disparate methods (T. F. Clasen et al., 2015). Consistent use can be determined by asking how recently or frequently the HWT method is used and when it is not used

(WHO, 2012), or may be defined as: the proportion of consumed drinking water that is treated (Joe Brown & Clasen, 2012; Kyle S Enger, Nelson, Rose, & Eisenberg, 2013), the percent of households with measureable chlorine in drinking water (Arnold & Colford, 2007), the percent of households self-reporting use (Boisson et al., 2010), the percent of households reporting using a HWT method and that have improved water quality in treated samples (Peletz et al., 2012), or the percent of repeated household visits where users reportedly had treated water (Rosa & Clasen, 2017; Rosa, Huaylinos, Gil, Lanata, & Clasen, 2014; Rosa, Kelly, & Clasen, 2016).

Field effectiveness is a measure of a HWT technology's ability to reduce microbiological contamination in drinking water in actual users' homes. It is determined by measuring *E. coli* or thermotolerant coliform concentrations in paired treated and untreated water samples, and calculating a percent reduction or LRV. Microbiological effectiveness testing is often conducted with field-adapted membrane filtration or most probable number bacteria enumeration methods (CDC, 2010). Reductions in field evaluations are often lower than those in laboratory evaluations, partially because starting bacteria concentrations in natural samples are lower than those of spiked laboratory samples.

Effective use describes the percentage of the target population that uses a HWT method to improve microbiologically contaminated water to internationally-accepted guidelines (Daniele S Lantagne & Clasen, 2012). For a household to "effectively use" a HWT technology, they must have microbiologically contaminated water (be at risk), actually use the technology correctly, and the technology must be effective at reducing microbiological contamination. This metric is primarily relevant as a programmatic measure, which incorporates a technological metric (effectiveness) within it.

In summary, HWT technologies are evaluated primarily through microbiological laboratory efficacy, reported as percent reductions or LRVs, followed by health impact trials, where diarrheal disease reduction is reported as odds ratio or risk ratios. Field evaluation metrics are less standardized and range from usage variables like reported, observed, correct, and consistent use, to microbiological efficacy, to a combination metric like effective use.

1.5 Regulating household water treatment technologies

1.5.1 Introduction to HWT guidelines, standards, and regulation

Until recently, no international certification scheme existed for certifying, approving, or registering HWT-specific products. However, some voluntary standards and country-specific regulations have been in place. The United States Environmental Protection Agency (US EPA) registers some products sold in the US, and the independent standards organization NSF International (NSF) certifies products against various protocols. In 2014, the WHO introduced an International Scheme to Evaluate HWT Technologies specifically to inform HWT product selection for WHO member states and UN agencies (WHO, 2016). However, these methods are neither comprehensive, nor widely used, and compliance with most of these standards is voluntary. Additionally, guidelines and standards are often specific to particular technology types and may refer to particular requirements (e.g. microbiological efficacy or chemical safety).

A listing of known standards and guidelines is provided below, listed per HWT treatment method. A list of known HWT country regulations follows.

1.5.2 Existing HWT guidelines and standards

General HWT technologies

The US EPA Guide Standard for Testing Microbiological Water Purifiers was established in 1987 as a standard protocol for testing POU treatment products primarily for consumer and military applications in the United States. This protocol requires 6-log bacteria, 4-log virus, and 3-log protozoan cyst reductions in the laboratory in order to be termed a “microbiological water purifier” (US EPA, 1987). Although testing is voluntary, and no list of passing products is available, US products are commonly tested against this standard, and manufacturers list these claims in product literature.

NSF International established two protocols, P231: Microbiological Water Purifiers and P248: Military Operations Microbiological Water Purifiers, based on the US EPA Guide Standard (NSF International, 2003). Testing against P231 is voluntary. Passing products are listed in the NSF Product and Service Listings (NSF International, n.d.-a), although only one product was listed for P231 as of June 2017.

Recognizing a gap in international performance specifications for HWT in developing countries, WHO launched an International Scheme to Evaluate HWT

Technologies (WHO Scheme) in 2014, based on the performance specifications defined by the 2011 Evaluating HWT Options document described in section 1.4.2 above. In the WHO Scheme, performance LRV targets remained the same, although were renamed as three star, two star, and one star (Figure 1-2), and recommended test organisms were modified for ease of testing procedures.

Under the WHO Scheme, two approved laboratories test technologies against a standard protocol that divides products into two categories: chemical addition products and flowing systems. Testing is performed with both general test water, which represents high-quality groundwater or rainwater, and challenge test water, which represents surface water and varies based on specific technology. Provisions are in place to address clogging of flowing systems and end-of-life indicators for durable products such as filters (WHO, 2014d).

Following efficacy testing and establishment of LRVs for bacteria, viruses, and protozoa, technologies are classified according to the star rating achieved (Figure 1-2), and WHO publishes product classifications on their website. Ten HWT technologies were evaluated in Round I of the WHO Scheme. Of these, two technologies received a three-star rating, three received a two-star rating, three received a one-star rating, and two technologies did not qualify for any rating (WHO, 2016). An additional 39 technologies were submitted for Round II testing, and evaluation of a subset of these is currently underway as of June 2017 (Majuru, 2017).

Performance classification	Bacteria (log_{10} reduction required)	Viruses (log_{10} reduction required)	Protozoa (log_{10} reduction required)	Interpretation (assuming correct and consistent use)
★★★	≥ 4	≥ 5	≥ 4	Comprehensive protection (very high pathogen removal)
★★	≥ 2	≥ 3	≥ 2	Comprehensive protection (high pathogen removal)
★	Meets at least 2-star (★★) criteria for two classes of pathogens			Targeted protection
–	Fails to meet WHO performance criteria			Little or no protection

Figure 1-2: WHO recommended microbiological performance criteria for HWT technology performance classification, figure reprinted from (WHO, 2016)

Water filters and ultraviolet systems

NSF International tests drinking water treatment units such as filters and ultraviolet (UV) point-of-use and point-of-entry systems against specific standards relevant to both health-related and non-health related contaminant removal (NSF International, 2017).

Standards relevant to water filters include NSF/ANSI Standard 53: Drinking Water Treatment Units – Health Effects, which evaluates removal of heavy metals (arsenic, cadmium, lead), inorganics (fluoride and nitrate), volatile organic chemicals, and specific organisms like *Cryptosporidium* that have implications on public health. This standard, however, is not a comprehensive microbiological protocol. Filters are also evaluated for their ability to remove non-health-related contaminants like chlorine, taste, and odor under NSF/ANSI 42: Drinking Water Treatment Units - Aesthetic Effects, or trace levels of chemicals such as pharmaceuticals, herbicides and pesticides, and specific chemical compounds like flame retardants and plasticizers under NSF/ANSI 401: Emerging Compounds/Incidental Contaminants (NSF International, n.d.-d, 2017).

Ultraviolet (UV) treatment systems are tested against NSF/ANSI Standard 55: Ultraviolet Microbiological Water Treatment Systems, which evaluates laboratory performance of reduction of bacteria, virus, protozoa test organisms (NSF International, 2017)

These four NSF International standards for filters and UV systems are all voluntary.

Chemical treatment technologies

NSF International certifies chemical treatment technologies against NSF/ANSI Standard 60: Drinking Water Treatment Chemicals – Health Effects, which evaluates toxicological safety in terms of chemical type and the concentration in treated water (NSF/ANSI, 2012).

US EPA registers chemical treatment products as pesticides. US EPA reviews environmental safety and specific microbiological reduction claims to register treatment chemicals as “public health pesticides” if the product claims to reduce organisms of public health concern (US EPA, 2010). Although laboratory data must be confirmed for specific organism reduction claims, registration does not require comprehensive testing of bacteria, viruses, and protozoa by the treatment technology.

Both NSF/ANSI Standard 60 and US EPA registration are mandatory for manufacture, sale, or distribution of chemical treatment products in the US.

1.5.3 National HWT regulations

While several voluntary standards exist for HWT technologies in the US, these are mostly geared towards verifying performance for consumer confidence in commercial treatment technologies or military applications. The only enforceable regulations are US EPA Registration for chemical treatment technologies, which focuses more on chemical safety than comprehensive microbiological performance (US EPA, 2010).

National microbiological performance standards exist in several other countries (Israel, Japan, Mexico, Australia, New Zealand, Brazil, and Venezuela) for verifying laboratory efficacy of point-of-use treatment technologies, but only the Australia/New Zealand standard is applicable to "unsafe," non-potable water sources (NSF International, n.d.-b). At this time, there are no known comprehensive national regulation frameworks specific to HWT technologies.

1.6 Research objectives

1.6.1 Overall research objectives

Given the current state of rapid HWT technology development, lack of industry standard metrics for HWT evaluation in households, and weak regulation frameworks, this dissertation took a multi-faceted approach to exploring HWT evaluation and regulation. This body of work is unique in its breadth of laboratory, field, and policy research, as well as its use of realistic evaluation settings rather than controlled trials.

The overall research objective was to investigate methodologies of evaluating HWT technology performance for both technology improvement and regulatory decision-making. To achieve this overall objective, six independent research projects were conducted, including work recommending field laboratory methods to test HWT technologies, conducting HWT technology performance evaluations in realistic settings, and establishing a national HWT regulation framework. These are included in the following chapters, as listed below:

- Chapter 2: Accuracy, precision, usability, and cost of free chlorine residual testing methods (field lab method testing)
- Chapter 3: The effect of sodium thiosulfate dechlorination on bacteria enumeration: laboratory and field data (field lab method testing)
- Chapter 4: Fouling in hollow fiber membrane microfilters used for household water treatment (field performance evaluation – existing technology)
- Chapter 5: Laboratory efficacy and field effectiveness of hollow fiber membrane microfilters used for household water treatment in Honduras (field performance evaluation – existing technology)
- Chapter 6: Evaluation of consistent use, barriers to use, and microbiological effectiveness of three new household water treatment technologies in Haiti, Kenya, and Nicaragua (field performance evaluation – prototype technologies)
- Chapter 7: Need for certification of household water treatment products: examples from Haiti (national HWT regulation framework)

1.6.2 Specific research objectives

Specific research objectives for each of these projects are listed below.

Accuracy, precision, usability, and cost of free chlorine residual testing methods

This laboratory research evaluated seven commonly-used, portable free chlorine residual (FCR) test kits to establish recommendations for water quality testing in low-resource field settings. In addition to evaluating accuracy and precision of measurements at various chlorine concentrations in the laboratory, this work also evaluated usability, cost, and impacts of reading results under different lighting conditions.

The effect of sodium thiosulfate dechlorination on bacteria enumeration: laboratory and field data

Microbiological water quality test methods recommend collecting samples in containers with sodium thiosulfate, a dechlorination agent. However, not all water quality monitoring institutions follow these recommendations, even when testing chlorinated drinking water supplies. There is limited evidence describing the extent to which this practice affects drinking water quality results, and therefore interpretation of disease risk of drinking water. To fill this gap, this research compared *E. coli* counts of samples collected with and without sodium thiosulfate and otherwise processed identically. Testing was performed with both laboratory samples spiked with high concentrations of *E. coli*, and samples collected by water quality monitoring institutions in sub-Saharan Africa.

Fouling in hollow fiber membrane microfilters used for household water treatment

This research stemmed from an HWT program implementer's monitoring which identified poorly performing hollow membrane fiber filters in Honduras. Six filters, which had initially performed well shortly after installation, but later had poor microbiological performance, were removed from households and investigated in the laboratory to evaluate failure mechanisms. Controlled microbiological testing was performed to identify biofouling, and scanning electron microscopic imaging and elemental analysis was performed to characterize fouling of membranes.

Laboratory efficacy and field effectiveness of hollow fiber membrane microfilters used for household water treatment in Honduras

Hollow fiber membrane microfilters are increasingly promoted for HWT use, although there is limited quantitative microbiological performance data in household settings. The goal of this research was to better understand microbiological performance of these filters by: verifying laboratory efficacy of new filters, comparing to controlled natural water efficacy of new filters, and evaluate microbiological effectiveness of filters in household settings in Honduras.

Evaluation of consistent use, barriers to use, and microbiological effectiveness of three new household water treatment technologies in Haiti, Kenya, and Nicaragua

It is largely accepted that, in order to achieve health gains, HWT technologies be microbiological effective and used correctly and consistently by those at risk of diarrheal disease. However, HWT consistent use, barriers to use, and microbiological effectiveness are not systematically measured, reported, or addressed in advance of new HWT technology sales or distributions. The aim of this research was to evaluate consistent use, identify barriers to use, and measure microbiological effectiveness of three prototype HWT technologies in realistic household settings to inform future technological design and implementation decisions.

Need for certification of household water treatment products: examples from Haiti

In the years following the 2010 Haiti earthquake and cholera outbreak, several manufacturers aimed to distribute HWT products in Haiti. The Haitian Ministry of Health, the responsible group for regulating HWT, had recently adopted an HWT product certification process considering microbiological efficacy, toxicological safety, product quality, and ability for the population to use the product. The work presented here was in applying that process to the review of four chemical treatment products seeking approval for use in Haiti.

Together, this research explored many facets to the methodologies of evaluating HWT technology performance for both technology improvement and regulatory decision-making. The core research chapters (Chapters 2-7) are followed by Conclusions and Recommendations (Chapter 8) and References (Chapter 9).

1.7 A note on terminology

Please note that throughout this dissertation, the terms HWT and HWTS are used interchangeably to mean household water treatment and/or household water treatment and safe storage.

The terms HWT technology, option, product, and method are sometimes used interchangeably. “Options” or “methods” may be inclusive of methods like boiling or SODIS, which do not depend on the use of a particular device, whereas “technology” or “product” often refers to a manufactured HWT device.

2 Accuracy, precision, usability, and cost of free chlorine residual testing methods

2.1 Abstract

Chlorine is the most widely used disinfectant worldwide, partially because residual protection is maintained after treatment. This residual is measured using colorimetric test kits varying in accuracy, precision, training required, and cost. Seven commercially available colorimeters, color wheel and test tube comparator kits, pool test kits, and test strips were evaluated for use in low-resource settings by: 1) measuring in quintiplicate 11 samples from 0.0-4.0 mg/L free chlorine residual (FCR) in laboratory and natural light settings to determine accuracy and precision; 2) conducting volunteer testing where participants used and evaluated each test kit; and 3) comparing costs. Laboratory accuracy ranged from 5.1-40.5% measurement error, with colorimeters the most accurate and test strip methods the least. Variation between laboratory and natural light readings occurred with one test strip method. Volunteer participants found test strip methods easiest and color wheel methods most difficult; and were most confident in the colorimeter and least confident in test strip methods. Costs range from 3.50-444 USD for 100 tests. Application of a decision matrix found colorimeters and test tube comparator kits were most appropriate for use in low-resource settings; it is recommended users apply the decision matrix themselves, as the appropriate kit might vary by context.

2.2 Introduction

Chlorine is the most common drinking water disinfectant worldwide, and has been used in municipal water treatment in the United States and Europe since the early 20th century. Chlorination of drinking water is considered one of the advances that virtually eradicated epidemic diarrhea in the United States and Europe (Cutler & Miller, 2005). The advantages of chlorine disinfection are that it is inexpensive; simple to use; effective at inactivating most disease-causing pathogens in water; and residual chlorine is maintained in the water, which protects against recontamination in water distribution, transport, and storage (WHO, 2011). The drawbacks of chlorine disinfection include user taste acceptability, chlorine's ineffectiveness against the protozoa *Cryptosporidium*, and the formation of potentially-cancer-causing disinfection byproducts (DBPs) such as trihalomethanes (THMs) and haloacetic acids (HAAs). However, "the risks to health from these byproducts are extremely small in comparison with the risks associated with inadequate disinfection, and it is important that disinfection efficacy not be compromised in attempting to control such byproducts" (WHO, 2011). Although alternative disinfectants exist (ozone, ultraviolet light, and halogens like iodine and bromine), 98% of water treatment facilities in the United States that disinfect water do so with chlorine-based disinfectants (Black & Veach, 2010).

When chlorine is added to water for disinfection, it reacts irreversibly with various constituents that exert chlorine demand; including natural organic matter, ammonia, nitrogen, hydrogen sulfide, and metals such as iron and manganese.

The chlorine that has reacted becomes unavailable for disinfection. What remains after chlorine demand is met is known as total chlorine residual (TCR), and consists of: 1) combined chlorine, which is chlorine combined with ammonia to form chloramines (monochloramine: NH_2Cl, dichloramine: $NHCl_2$, and trichloramine: NCl_3); and 2) free chlorine residual (FCR), consisting primarily of hypochlorous acid (HOCl) and hypochlorite (OCl^-). Free chlorine is a more effective disinfectant than is combined chlorine; combined chlorine concentration must be increased 25-fold, or the contact time 100-fold, to achieve the same inactivation of various microorganisms as that of free chlorine (APHA/AWWA/WEF, 2005; Black & Veach, 2010).

The efficiency of chlorine disinfection depends on several factors, including the type and concentration of organisms being inactivated, chlorine dosage and contact time, water temperature and pH, and the presence of interfering substances in the water that exert a chlorine demand (Black & Veach, 2010). Initial chlorine dosages for water treatment are calibrated to meet chlorine demand and maintain a free chlorine residual sufficient for adequate disinfection during water distribution, transport, and storage. Thus, FCR presence in drinking water indicates two things: 1) the water was treated with a chlorine dose sufficient to inactivate most viruses and bacteria that cause diarrheal disease, and 2) the system is operating effectively and the water is safe against recontamination (CDC, 2008). The World Health Organization (WHO) recommends a minimum FCR concentration in drinking water of 0.2 mg/L and a maximum of 5.0 mg/L. The maximum recommendation is a conservative health-based maximum guideline, as “no specific adverse treatment-related effects have been observed in humans and experimental animals exposed to chlorine in drinking-water” (WHO, 2011). WHO also notes that a taste barrier exists for FCR well below 5.0 mg/L, and sometimes as low as 0.3 mg/L. The United States Environmental Protection Agency (USEPA) maximum contaminant level (MCL) for FCR is 4.0 mg/L (USEPA, 2006).

In addition to continuous dosing in piped water supplies in areas with infrastructure systems, chlorine is also used to disinfect pipes and installations after construction, repair, or cleaning, and is used to directly disinfect stored household drinking water in low-resource settings, such as developing countries and in emergencies where there is little reliable infrastructure (WHO, n.d.). For household water treatment programs using chlorine in these environments, the Centers for Disease Control and Prevention (CDC) recommends a maximum FCR of 2.0 mg/L one hour after chlorine addition (to not exceed taste acceptability concerns) and a minimum of 0.2 mg/L 24 hours after chlorine addition to ensure protection against recontamination during transport and storage (CDC, 2008). One limitation with these recommendations is how to accurately test FCR in these low-resource environments.

There are several methods available, both titrimetric and colorimetric, for testing FCR and TCR in water. These include iodometric titration, amperometric titration, *N*,*N*-diethyl-*p*-phenylenediamine (DPD) ferrous titrimetric and DPD colorimetric methods, the syringaldazine (FACTS) method

(APHA/AWWA/WEF, 2005) , and orthotolidine (OTO) method. Colorimetric methods, such as DPD, OTO, and FACTS, are operationally simplest and best suited to field applications. The OTO colorimetric method for measuring TCR was developed in 1913 and is still used today, although orthotolidine was listed as potentially carcinogenic in 1966 and the method was excluded from *Standard Methods* beginning in 1980. Introduced in 1957, the DPD method can measure both FCR and TCR and is popular for field testing worldwide (Black & Veach, 2010). These colorimetric methods utilize a color change to determine residual concentration against a set of visual comparator standards or by use of a colorimeter. OTO uses a color change in the yellow spectrum, while DPD uses a red spectrum.

A variety of commercially available test kits – ranging in accuracy, precision, training necessary to use, and cost – are commonly used to test the presence of TCR and FCR in mg/L. These include colorimeters, color wheel comparator kits, test tube comparator kits, pool test kits, and test strips (Table 2-1). Colorimeters are hand-held electronic meters that analyze a sample's color intensity by measuring light absorbance at a particular wavelength. Test tube kits, color wheel kits, and pool test kits each require the user to fill a vial with sample, add a reagent, and visually compare the sample color to a standard chart. To use test strips, users submerge a test strip in water sample and visually compare the resultant test strip color to a standard color chart.

Table 2-1: Comparison of seven free chlorine residual (FCR) and total chlorine residual (TCR) test kits used in study.

	Measurement Range (mg/L)	Measurement Increment (mg/L)	Test Method	Measure of FCR/TCR	Equipment Cost, Initial	Incremental Test Cost	Total Cost, 100 Tests	Total Cost, 1000 Tests
LaMotte Colorimeter, model 1200	0.00 - 4.00	0.01	DPD Instrument Grade Tablets	FCR/TCR	$435.00	$0.09	$444.40	$529.00
Hach Color Wheel Test Kit, model CN-66	0.0 - 3.4	0.2	DPD Powder	FCR/TCR	$55.00	$0.16	$71.10	$216.00
Hach Color Wheel Test Kit, model CN-70	Low Range: 0.00-0.68 Mid Range: 0.0-3.4	Low Range: 0.04 Mid Range: 0.2	DPD Powder	FCR/TCR	$72.00	$0.16	$88.10	$233.00
LaMotte Test Tube Kit	0 - 3.0	0, 0.2, 0.4, 0.6, 0.8, 1.0, 1.5, 2.0, 3.0	DPD Rapid, Visual Grade Tablets	FCR	$5.85	$0.09	$15.25	$99.85
Pentair Rainbow Pool Chlorine Test Kit	0 - 3.0	0, 0.3, 1.0, 1.5, 3.0	OTO Liquid	TCR	$14.00	$0.05	$19.00	$64.00
Hach AquaChek Free and Total Chlorine Test Strips	0 - 10.0	0, 0.5, 1.0, 2.0, 4.0, 10.0	Test strips	FCR/TCR	-	$0.31	$30.58	$305.80
Precision Laboratories Very Low Level Chlorine Test Strips	0 - 5	0, 0.3, 0.5, 1, 2, 5	Test strips	FCR	-	$0.04	$3.50	$35.00

Field experience in developing countries indicates that users often make errors performing FCR tests or reading results. Some common errors include (Tom Armitage, personal communication, February 26, 2013): 1) the test tube or vial and cap are not rinsed before or after testing, allowing contamination between samples; 2) users do not fully dissolve the reagent before reading the result; 3) test samples are left in tubes/vials, which stain them and render subsequent results inaccurate; 3) the test tube/vial is stored without fully drying and is stained by water droplets; 4) color wheels or comparator charts are left in the sun, thus fading the calibrated standard; 5) incorrect reagent types or quantities are substituted for the correct reagent; 6) users fill the tube/vial to the improper level, which uses an incorrect dilution factor for the test kit reagent; 7) the colorimeter sample vial becomes scratched and yields inaccurate readings; 8) condensation forms on the colorimeter vial with cold water samples, which may affect the colorimeter reading; and 9) users forget to calibrate the colorimeter, which may result in inaccurate readings.

Several studies and reports have provided valuable information comparing chlorine residual test methods (Derrigan, Lin, & Jensen, 1993; Lishka & McFarren, 1971; Wilde, 1991), and further reviews of such studies have reported on the relative advantages and disadvantages of test methods (Gordon, Cooper, Rice, & Pacey, 1987; Harp, 2002). Most of these studies, however, focus solely on method accuracy, precision, and measurement interference, primarily on test methods appropriate for laboratory settings. While some evaluations discuss operator training required (Gordon et al., 1987; Harp, 2002), test method usability has not been quantified, and costs were not discussed. Lastly, the most recent of these studies was conducted over 10 years ago, and as such, more recent test methods (such as test strips) were not included in the analysis.

In this research, we evaluated seven FCR and TCR field test methods applicable for use in low-resource settings. In addition to considering accuracy and precision at a variety of sodium hypochlorite (NaOCl) concentrations and light settings, this study includes data on usability and cost.

2.3 Methods

2.3.1 Testing location

The full testing regime was conducted in the Civil and Environmental Engineering laboratory, classroom, and exterior locations on the Tufts University campus in Medford, Massachusetts, USA.

2.3.2 Test kit selection

Seven commonly-used, commercially available chlorine test kits in the United States were selected for comparison in this study; representing colorimeters, color wheel comparator kits, test tube comparator kits, pool test kits, and test strips manufactured by various companies (Table 2-1).

2.3.3 Test solution preparation

Eleven sodium hypochlorite (NaOCl) solutions of varying concentration were prepared in the Environmental Sustainability Laboratory at Tufts University. The concentration of NaOCl in Clorox® bleach was verified by Hach 8209 iodimetric titration method (APHA/AWWA/WEF, 2005). Bleach was added to deionized, chlorine demand-free water in plastic containers to create solutions at the following concentrations (subsequently referred to as Dose 1 through Dose 11): 0.0 mg/L, 0.1 mg/L, 0.2 mg/L, 0.5 mg/L, 1.0 mg/L, 1.5 mg/L, 2.0 mg/L, 2.5 mg/L, 3.0 mg/L, 3.5 mg/L, 4.0 mg/L. Solutions were prepared immediately before testing and discarded at the completion of testing.

2.3.4 Laboratory testing

Each of the seven test kits was used according to the manufacturer's instructions to measure the FCR and/or TCR (depending on test) in each test solution in quintiplicate, and an arithmetic mean was calculated for each set of readings. For test kits that measure both FCR and TCR, only FCR results were analyzed, as sample water was free of chlorine demand.

The Hach color wheel model CN-70 kit was used at both the mid- and low ranges to measure chlorine concentrations in Doses 1 through 4 (0.0-0.5 mg/L). The remaining doses (1.0-4.0 mg/L) were tested using the mid-range procedure only. The LaMotte colorimeter was calibrated each test day using non-expired calibration solutions at 0 mg/L, 0.2 mg/L, 1.0 mg/L, and 2.5 mg/L. When the instrument read "Er2," indicating a chlorine concentration above the meter's range, the sample was diluted with deionized water and retested. For tests requiring visual color matching, FCR or TCR values were recorded at the closest matched color shade on the comparator standard; Hach Aquachek test strips and

Hach color wheel kits were read at intermediate increments where applicable, as per manufacturer instructions.

Data was entered into Microsoft Excel 2010 (Microsoft Corporation, Redmond, WA) and analyzed in Excel and R statistical package, version 3.0.1 (R Foundation for Statistical Computing). Percent measurement error was calculated for mean readings at each dose, and a composite mean percent measurement error was calculated for each test kit across all doses. Error was defined as low (< 10% measurement error), medium (10-25% error), or high (> 25% error). In addition, the percentage of false negative and false positive readings were calculated, considering whether samples and their readings were within the CDC-recommended FCR range of 0.2-2.0 mg/L. False negative readings were defined as a measured value outside the recommended FCR range, where the actual sample FCR was within the range. False positive readings were those within the recommended FCR range, where the water sample FCR was outside the range. Values of 0.15-0.19 mg/L were rounded to 0.2 mg/L. Standard error was calculated across replicate readings at each dose for all test kits. The set of mean FCR measurements across all doses for each test kit was compared to that of a reference method (the LaMotte colorimeter) using a nonparametric test for equality of medians in a paired sample, the Wilcoxon signed rank test, to determine if the results differed at a 0.05 significance level.

2.3.5 Lighting conditions

The full laboratory procedure described above was repeated outside on a sunny day, taking care to store samples out of direct sunlight. Measurement errors from readings in sunlight were compared to those of the laboratory results, considering a measurement error differential threshold of 10%. A Wilcoxon signed rank test was used to compare the mean laboratory results of each test kit to mean outdoor results across all doses at a 0.05 significance level.

2.3.6 Reagent testing

Three test kits that use DPD tablet or powder reagents - Hach color wheel model CN-66, LaMotte test tube kit, and LaMotte colorimeter - were used in the laboratory with a variety of reagent combinations to test the FCR of three sample doses prepared as described above (0.2 mg/L, 0.5 mg/L, and 2.0 mg/L). Nineteen test kit / reagent combinations were evaluated, accounting for potential user errors such as: substituting a different manufacturer's reagent, interchanging instrument-grade and rapid-grade DPD tablets, using the LaMotte DPD #3 tablet without the first use of DPD #1 tablet, and correcting for a reagent's volume dilution factor.

Measurements were performed in quintiplicate and an arithmetic mean and measurement error were calculated. Measurement errors were compared to the laboratory testing errors, and test method / reagent combinations were categorized as: 1) effective (measurement error equal to, or lower than, laboratory error); 2) somewhat effective (measurement error higher than laboratory error, but within 25% error); or 3) ineffective (measurement error greater than 25%).

2.3.7 Volunteer testing

Three water samples at 0.2 mg/L, 0.5 mg/L, and 2.0 mg/L FCR were prepared using the procedures described above. Eight volunteer participants followed written instructions and used each kit to measure the FCR in all three water samples, with the exception of the Hach color wheel model CN-70 kit in the low range, which was used to test the 0.2 and 0.5 mg/L concentrations only. Each water sample was tested in duplicate with each test kit, for a total of 46 measurements for each volunteer participant. Sample concentrations were unknown to the participants, who were observed and photographed performing the test procedures. Following the water testing, participants completed a questionnaire including: 1) prior laboratory and water testing experience; 2) Likert-scale questions on relative difficulty of test procedures and their confidence in the results; 3) open-ended comments on difficulty of test kit procedures; 4) indication of the easiest kit, which results they were most confident in, and why; and 5) which test kit they would recommend for a variety of contexts and why. Standard error, average measurement error, and false negative readings were calculated for the volunteer test results, as described above. Free and informed consent of the participants was obtained and the study protocol was found to be exempt by the Social, Behavioral, and Educational Research Institutional Review Board at Tufts University (Protocol #1210007, October 12, 2013).

2.3.8 Cost

Costs for test equipment were calculated by adding fixed equipment and reagent costs from the manufacturers' websites in September 2012. The costs do not include shipping or handling.

2.3.9 Decision matrix

A template decision matrix was developed to determine which FCR test method is most appropriate for testing chlorine-treated drinking water in low-resource settings. Each test method was rated 0, 1, or 2 (where a lower number is more favorable) in each of five categories representing accuracy, usability, and cost. Precision was not included, as precision results were similar for all tests. Accuracy was ranked by the mean composite measurement error across all eleven doses tested, considering laboratory and volunteer test results. Method difficulty and confidence in results were ranked according to the mean reported values from volunteer testing questionnaires on those themes. Cost was ranked on the total equipment and reagent cost for performing 1000 tests. Values were summed, and the tests were listed according to the total score, where lower score is more favorable.

2.4 Results

2.4.1 Laboratory testing

Laboratory test results for FCR and/or TCR are presented in Figure 2-1 and Table 2-2. The LaMotte colorimeter was the most accurate in the laboratory across all doses (5.1% average composite measurement error), followed by the Hach color wheel models CN-70 and CN-66, and the LaMotte test tube kit (13.0-14.8% measurement error). The least accurate methods were the Hach AquaChek test strips, Pentair pool kit, and Precision Laboratories Very Low Level test strips (30.6-40.5% measurement error). In looking at frequencies of low, medium, and high measurement error occurring at each FCR dose (Table 2-2), the LaMotte colorimeter and LaMotte test tube kit had the most doses with low measurement error (9 and 7 of 11 doses, respectively). The Hach color wheel kits had the highest frequency of readings with medium measurement error (10 of 11 doses for model CN-66 and 6 of 11 doses for model 70). The Pentair pool kit and Hach AquaChek strips had high measurement error at 3 FCR doses each, and the Precision Laboratories Very Low Level test strips had high measurement error at 7 of 11 doses. Both color wheel methods gave readings consistently above the sample FCR, and the Precision Laboratories test strips gave readings primarily below the sample FCR (Figure 2-1).

Considering only the FCR/TCR doses for which a value exists on the comparator standard for those tests that rely on visual color matching, the measurement error decreased substantially for the LaMotte test tube kit (from 14.8% to 1% average measurement error) and Pentair pool test kit (from 34.0% to 0% average measurement error).

The most precise method was the Pentair pool kit (standard error of 0.0 across all doses), and the least precise was the Precision Laboratories test strip method, particularly at high FCR ranges (standard error of 0.73 and 0.60 at Doses 10 and 11, respectively). The remaining test methods had standard errors under 0.20 for all readings (Figure 2-1).

The two test strip methods had the highest levels of false positive and false negative readings; with 32% false negative and 13% false positive for the Hach strips, and 20% false negative and 43% false positive for the Precision Laboratories strips. All other test kits exhibited false negative and positive readings at or below 20% (Table 2-2).

None of the results from other test kits differed significantly from those of the reference test (LaMotte colorimeter). The tests kits with the highest probability of producing different results (i.e. the least accurate tests) were the Precision Laboratories test strips (p=0.054) and Hach test strips (p=0.08), followed by Hach color wheel CN-66 and CN-70 (p=0.18), Pentair pool kit (p=0.52), and LaMotte test tube kit (p=0.64).

Table 2-2: Measurement accuracy of laboratory and volunteer FCR test measurement results.

a. Laboratory Testing Accuracy

	FCR Concentration (mg/L)											Mean	False	False
	0.0	0.1	0.2	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	Error	Negative	Positive
LaMotte Colorimeter	L	L	M	M	L	L	L	L	L	L	L	5.1%	20%	0%
Hach Color Wheel (CN-66)	L	M	M	M	M	M	M	M	M	M	M	14.1%	20%	3%
Hach Color Wheel (CN-70) Low Range	L	M	M	M	-	-	-	-	-	-	-	13.0%	0%	0%
Hach Color Wheel (CN-70) Mid Range	L	M	L	H	L	M	M	M	M	L	M	13.3%	20%	3%
LaMotte Test Tube Kit	L	H	L	L	L	L	L	M	L	M	M	14.8%	0%	20%
Pentair Pool Test Kit	L	H	H	H	L	L	M	M	L	M	M	34.0%	0%	17%
Hach AquaChek Test Strips	L	H	H	H	M	L	L	M	L	M	L	30.6%	32%	13%
Precision Labs Very Low Level Test Strips	L	H	H	H	H	H	H	M	H	L	M	40.5%	20%	43%

L	Low Measurement Error: < 10%	H	High Measurement Error: > 25%
M	Medium Measurement Error: 10% - 25%	-	Not Tested

b. Volunteer Testing Accuracy

	FCR Concentration (mg/L)											Mean	False	False
	0.0	0.1	0.2	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	Error	Negative	Positive
LaMotte Colorimeter	-	-	L	L	-	-	L	-	-	-	-	4.5%	17%	-
Hach Color Wheel (CN-66)	-	-	H	M	-	-	L	-	-	-	-	21.5%	13%	-
Hach Color Wheel (CN-70) Low Range	-	-	M	L	-	-	-	-	-	-	-	14.9%	0%	-
Hach Color Wheel (CN-70) Mid Range	-	-	M	M	-	-	M	-	-	-	-	28.8%	17%	-
LaMotte Test Tube Kit	-	-	L	L	-	-	M	-	-	-	-	6.6%	0%	-
Pentair Pool Test Kit	-	-	H	H	-	-	M	-	-	-	-	34.2%	2%	-
Hach AquaChek Test Strips	-	-	H	H	-	-	H	-	-	-	-	54.0%	44%	-
Precision Labs Very Low Level Test Strips	-	-	H	M	-	-	M	-	-	-	-	28.8%	21%	-

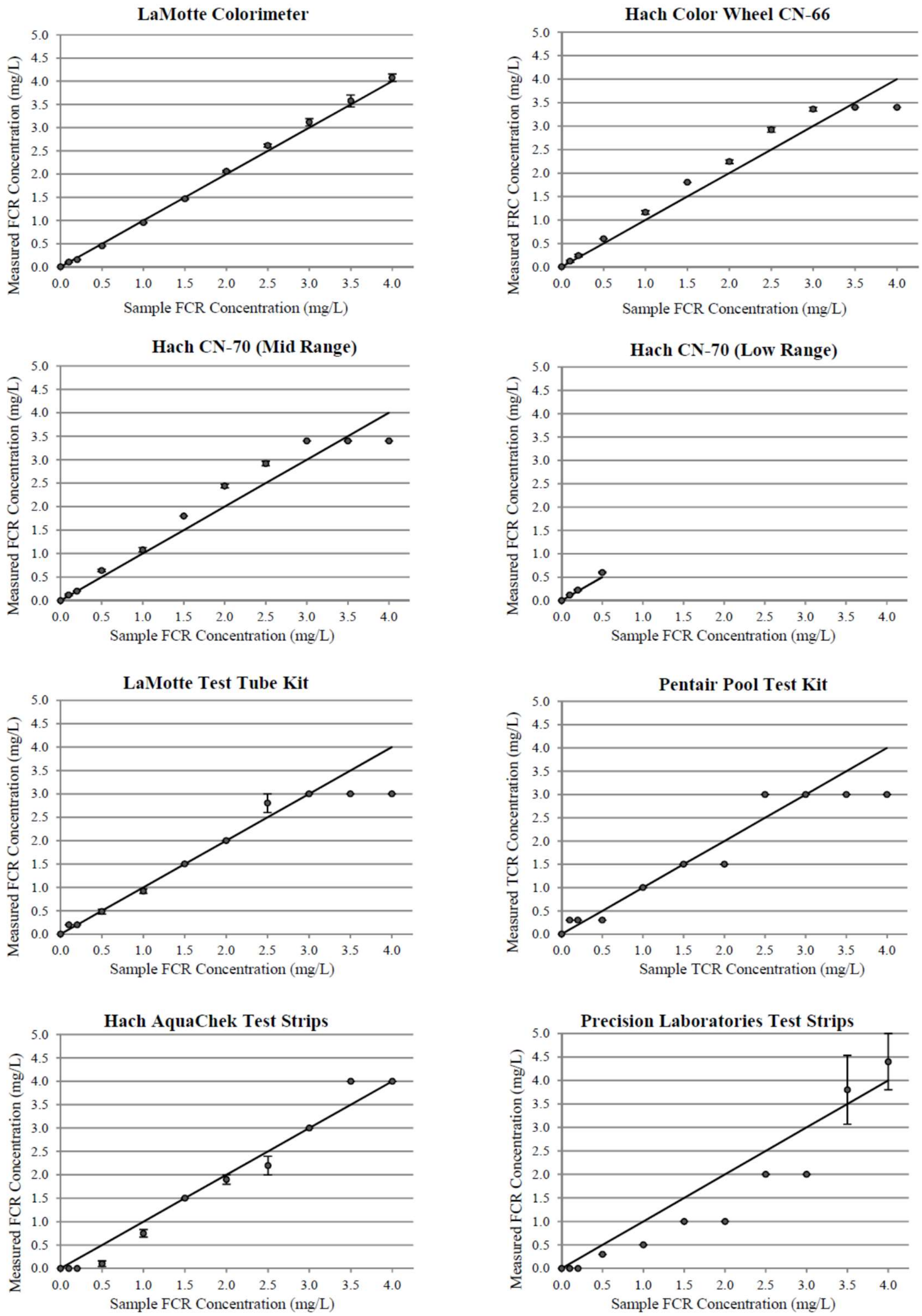

Figure 2-1: Average laboratory free chlorine residual (FCR) measurement results with standard error bars for each test kit and chlorine dose. Results in FCR, except pool test kit, which measures total chlorine residual (TCR). Lines represent "ideal" readings.

2.4.2 Lighting conditions

The Hach AquaChek test strips were the only visual test that showed greater than 10% average difference between the values determined under fluorescent light and under direct sunlight, considering all tested doses. FCR readings differed by at least 10% between sunlight and laboratory lighting for four sample doses: 0.5 mg/L (100% measurement error), 1.0 mg/L (53% error), 2.5 mg/L (36% error), and 3.5 mg/L (10% error). Additionally, TCR measurement error was greater than 10% for four doses. None of the test kits, however, showed statistically significantly different FCR measurements between outdoor and laboratory results when considering all doses ($p>0.05$).

2.4.3 Volunteer testing

Eight Tufts University undergraduate and graduate students participated in volunteer testing. All participants (8/8) reported some general lab experience, and 88% (7/8) reported prior experience testing for water quality parameters. Of those who had water testing experience, 57% (4/7) self-reported a beginner level, and 43% (3/7) self-reported an intermediate level of experience.

Volunteer testing measurement results are presented in Table 2-2. The most accurate test kits across three sample doses were the LaMotte colorimeter and LaMotte test tube kit (4.5-6.6% measurement error), followed by the Hach color wheel kits and Precision Laboratories test strips (14.9%-28.8% error). The Pentair pool test kit and Hach AquaChek test strips were least accurate (34.2-54.0% error). The Hach AquaChek test strips had 44% false negative readings, while the remaining kits were at or below 21% (Table 2-2). The most precise test method was the colorimeter (0.00 – 0.02 standard error). The least precise were the test strip methods, particularly at the highest FCR concentration, with standard errors of 0.26 and 0.12 for the Precision Laboratories and Hach AquaChek test strips, respectively. Accuracy in the volunteer testing was lower than that of the laboratory testing for the Hach color wheel kits and Hach AquaChek test strips, but higher for the Precision Laboratories test strips and LaMotte test tube kit. Precision remained the same or decreased in volunteer testing as compared to that of the laboratory testing for all methods but the colorimeter.

Participants found the Precision Laboratories very low level test strips easiest to use, and the Hach color wheel model CN-70 the most difficult (Table 2-3). Participants judged the easiest test based on it being simple to perform (5/8), quick to complete (3/8), and easy to match the indicator colors (3/8). All participants (100%) wrote that both test strip methods were “easy,” “simple,” or “straightforward.” Similar comments were written by 75% of volunteers about the LaMotte test tube kit, 63% about the Pentair pool kit, 50% for the Hach color wheel CN-66, 38% for the LaMotte colorimeter, and 25% for the Hach color wheel CN-70 procedure. Eighty-eight percent of respondents (7/8) described the Hach color wheel CN-70 as having “difficult directions,” “many steps,” or being “difficult to set up,” and 75% (6/8) of volunteers thought the LaMotte colorimeter “took too long,” was “hard or confusing at first,” or had “a lot of instructions and a confusing calibration procedure.”

Participants also commented on the difficulty of matching the sample color to the color comparator standard. Half of respondents (4/8) had difficulty matching color shades for each of the following test methods: Hach AquaChek test strips, LaMotte test tube kit, Pentair pool test kit, and the Hach color wheel kits, while only 25% (2/8) of respondents had difficulty matching color with the Precision Laboratories very low level test strips.

All participants were most confident in the colorimeter results (Table 2-3) due to: measurement precision/numerical feedback (5/8), calibrating to a standard (4/8), and trust in technology over human error in judging color (4/8). While the responses were divided regarding test kit preference for developing countries, (Table 2-3), 88% (7/8) people chose a particular test because of its simplicity or ease of use. Thirty-eight percent (3/8) chose a particular test because it was quick to complete, and 38% (3/8) chose because it is precise or seemed to “give good data.”

Users had more confidence in the tests that they perceived to be more difficult, when the colorimeter results are removed (R^2= 0.90). The average reported confidence level was weakly correlated with average measurement error (R^2 = 0.44), where tests with higher confidence have lower error. Average reported difficulty was not associated with average measurement error of the volunteer testing results (R^2 = 0.14).

Table 2-3: Summary of volunteer testing questionnaire responses to several questions about test kit usability (n=8).

	Difficulty of Test Procedure[1] Ave (Min, Max, SD)	**Confidence in Test Results**[2] Ave (Min, Max, SD)	**Easiest**[3,7] (Frequency)	**Most Confident**[4] (Frequency)	**Choice for use in US Laboratory**[5] (Frequency)	**Choice for use in Developing Countries**[6] (Frequency)
LaMotte Colorimeter	2.6 (1, 5, 1.4)	5.0 (5, 5, 0.0)	1	8	8	1
Hach Color Wheel (CN-66)	3.3 (1, 5, 1.2)	3.1 (2, 4, 0.8)	1	0	0	1
Hach Color Wheel (CN-70)	4.3 (3, 5, 0.9)	3.4 (1, 4, 1.1)	0	0	0	1
LaMotte Test Tube Kit	2.4 (1, 3, 0.7)	2.9 (1, 4, 0.8)	1	0	0	1
Pentair Pool Test Kit	2.4 (1, 3, 0.7)	3.0 (2, 4, 0.8)	0	0	0	0
Hach AquaChek Test Strips	1.5 (1, 2, 0.5)	2.3 (1, 3, 0.9)	1	0	0	1
Precision Laboratories Very Low Level Test Strips	1.1 (1, 2, 0.4)	2.3 (1, 4, 1.0)	5	0	0	3

Notes:

1. "Indicate the difficulty of each test procedure on a scale of 1-5, where 1 is the simplest and 5 is the most difficult."
2. "Indicate your confidence level in each test's results on a scale of 1-5, where 1 is least confident and 5 is the most confident."
3. "Which test did you find to be the easiest to perform today?"
4. "Which of the test results are you most confident in?"
5. "If you were to receive chlorine test results from a laboratory in the United States, which test would you be most confident receiving results from?"
6. "If you were to train local people in a developing country to take chlorine measurements and report them to you, which test would you be most confident receiving results from?"
7. One respondent chose two responses (Hach test strips and Precision Laboratories test strips)

2.4.4 Reagent testing

Of the 19 combinations tested, six were effective, six were somewhat effective, and seven of the combinations were ineffective. Substituting a different manufacturer's reagent was effective with the Hach color wheel and the LaMotte colorimeter; however, the LaMotte test tube kit was only somewhat effective with the Hach DPD reagent. Interchanging instrument-grade and rapid-grade tablets was effective for the test tube kit, but the rapid-grade tablets were ineffective with the colorimeter. Using the LaMotte DPD #3 tablet without the first use of DPD #1 tablet was ineffective in all cases. Tests which corrected for the reagent's intended volume were less effective than those which did not alter the test kit volume. Data is available from the authors upon request.

2.4.5 Cost

The total cost for performing 100 and 1000 tests with each test kit varied from 3.50-444.40 USD for 100 tests and 35-529 USD for 1000 tests, with the colorimeter being the most expensive and the Precision Laboratories test strips the least expensive (Table 2-1). Note that at just over 2000 samples, the Hach AquaChek test strips surpass the colorimeter as the most expensive method.

2.4.6 Decision matrix

A decision matrix ranking each test based on these results is displayed in Table 2-4. The LaMotte colorimeter and test tube kit scored most favorably, and the Hach AquaChek test strips scored least favorably.

Table 2-4: Summary of recommended FCR test methods; considering accuracy, usability, and cost. Each category is rated as 0, 1, or 2, where low numbers are more favorable, and test methods are listed in preferential order.

	Accuracy, Lab	Accuracy, Volunteer Testing	Difficulty, Volunteer Testing	Confidence, Volunteer Testing	Cost	Total
LaMotte Colorimeter	0	0	1	0	2	3
LaMotte Test Tube Kit	1	0	1	1	0	3
Precision Laboratories Test Strips	2	1	0	2	0	5
Pentair Pool Test Kit	2	2	1	1	0	6
Hach Color Wheel Test Kit (CN-66)	1	1	2	1	1	6
Hach Color Wheel Test Kit (CN-70)	1	1	2	1	1	6
Hach AquaChek Test Strips	2	2	0	2	1	7

2.5 Discussion

Commercially available FCR test kits vary in terms of measurement accuracy, precision, usability, and cost. Accuracy in the laboratory varied between 5% and 40%. The colorimeter was most accurate in both laboratory and volunteer testing and the two test strip methods were least accurate, considering measurement error, statistical analysis, and false positive/false negative readings in both laboratory and volunteer testing. Accuracies of laboratory results were largely comparable to those of volunteer testing; however, some differences are due to variability in operator experience, training, and visual judgment. No test method results were statistically significantly different in different lighting conditions, although the largest average measurement error between results occurred with the Hach AquaChek test strips. Precision did not vary widely between test kits, although the Precision Laboratories test strips were least precise, and the Pentair pool kit was the most precise. Usability was evaluated in terms of difficulty and confidence in results from a group of relatively inexperienced volunteer users. Participants found test strip methods easiest to perform, but were least confident in those results. They found color wheel methods most difficult, and were most confident in the colorimeter results. Overall costs for FCR test kits depend on the number of tests performed, as some test kits have high fixed equipment costs (colorimeter), and some only have a cost per test (test strip methods). For a lifetime of 1000 tests, costs vary between 35 USD for the Precision Laboratories test strips and 529 USD for the LaMotte colorimeter. In substitute test reagents testing, using a different manufacturer's FCR reagent can yield results within the error of measuring with the intended reagent, although it does not in the majority of cases. While not recommended, a substitution could be made when options are limited and concurrent and retrospective tests are completed to show consistent results.

While test kit measurements did not significantly differ from the reference method (0.05 level), the nonparametric test significance levels confirm and correspond with the accuracy evaluated with mean measurement error. Using a significance level of 0.10, both test strip methods, which also exhibited the highest mean error and false positive and negative rates, differed significantly from the reference method.

When considering all the results presented here, a ranking system (Table 2-4) indicates that a test tube comparator kit or colorimeter is most appropriate for measuring FCR concentrations in drinking water in low-resource settings. While neither method was considered easiest in volunteer testing, both tests ranked well on measurement accuracy and user confidence. The primary difference between these two test methods is equipment cost.

Each of the five categories is weighted equally in this decision matrix; however, category weights, or additional categories, may be applied to reflect particular program priorities or constraints. Researchers and practitioners should understand differing FCR test kit options in order to evaluate trade-offs and make an informed decision about the preferred method for their circumstances. Some factors that may affect this decision-making process are: 1) testing application, including the range of expected FCR readings; 2) the intended use of collected data; 3) the accuracy and precision required; 4) who will be performing the tests and how they will be trained; 5) how many readings will be made; 6) the available budget; and 7) project location in terms of equipment portability and availability of replacement parts or reagents. For example, the decision-maker should evaluate the measurement precision needed in light of equipment cost and the final use of the data. The colorimeter provides a digital reading to the hundredths place, but at a high cost, and the user may only be interested to know if water has an FCR within a wide acceptable range. Additionally, different methods have strengths in different measurement ranges. Both test strip methods were less accurate at low FCR concentrations and had a high rate of false-negative readings on the low end of the acceptable FCR range (Table 2-2). In the laboratory testing, color wheel methods were also more likely to overestimate FCR, while the Precision Laboratories test strips were more likely to underestimate (Table 2-2).

All but one of the evaluated kits relies on the user to judge color intensity of the water sample. With these kits, the researcher found that the colors had a different character under fluorescent lighting versus sunlight, and they were easier to match under sunlight conditions. Despite this, the color intensity was mostly judged equally in both settings. When volunteer test users were asked to comment on the procedures, several expressed difficulty comparing colored water samples to the standards, regardless of the test procedure's simplicity. The volunteers had high confidence in colorimeter results because "the machine is designed to test differences in color intensity, so it can do it much better than I can." This suggests that training on visual colorimetric FCR test kits use may benefit from "eye calibration," where users practice measuring samples with a known FCR. However, it is known that individuals view color shades differently from one another, and individuals may change their color perceptions from one time to another (Culpepper, 1970). This is a point of variation for both the results of this study and for general use of this type of test kit.

The limitations of this research include: 1) there is potential bias in laboratory measurements due to reliance on subjective visual color matching, and FCR doses being unblinded to the researcher; 2) volunteer testing results should be cautiously interpreted, as all participants were well-educated university students who all reported previous laboratory experience; 3) as these tests were performed with chlorine-demand-free water, we cannot comment on the efficacy of using total chlorine reagents, and testing was not performed with real waters that may have other interferences affecting FCR measurements. While these limitations are real, the data and recommendations are still valid: several FCR test kits were evaluated over a wide range of chlorine concentrations, accuracy was evaluated by several different measures, and volunteer test participants provided valuable data on measurement accuracy and quantitative information on ease-of-use for users new to FCR testing.

There are, however, opportunities for future research to refine these data and recommendations. Potential future research includes: 1) more rigorous laboratory testing with real-world waters, considering both FCR and TCR measurements; 2) additional volunteer testing with individuals of various educational backgrounds; 3) evaluating the effect of more extensive user training on the accuracy of readings among various users; and 4) consideration of environmental and/or human toxicological effects of different test reagents.

2.6 Conclusions

Chlorine is used worldwide to directly disinfect stored household drinking water in low-resource settings, and testing for FCR presence is important to ensure chlorine levels fall within recommended guidelines. Users are faced with a variety of commercially available FCR test kits with varying accuracy, precision, usability, and costs. Based on a ranking system developed to rate seven commonly-used tests, a test tube comparator kit or colorimeter were shown to be most appropriate for measuring FCR concentrations in drinking water in low-resource settings. This decision matrix considers accuracy by experienced and inexperienced users, ease-of-use, confidence in the results, and cost. Decision-makers may consider additional criteria or weighting schemes to choose an appropriate FCR test to match their individual priorities.

2.7 Citation

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3 The effect of sodium thiosulfate dechlorination on bacteria enumeration: laboratory and field data

3.1 Abstract

In microbiological water quality testing, sample dechlorination with sodium thiosulfate is recommended to ensure that results accurately reflect the water quality at sample collection. Nevertheless, monitoring institutions in low-resource settings do not always dechlorinate samples, and there is limited research describing how this practice impacts drinking water quality results. The effect of dechlorination on indicator bacteria counts was evaluated by spiking laboratory water with five *Escherichia coli (E. coli)* concentrations (10^4-10^8 CFU/100 mL), chlorinating at six doses (0-0.6 mg/L), holding samples with and without sodium thiosulfate for 5-7 hours, and enumerating *E. coli* by membrane filtration with m-lauryl sulfate media. Additionally, sub-Saharan African water suppliers enumerated fecal coliform by membrane filtration in paired chlorinated water samples collected with and without sodium thiosulfate. Across all *E. coli* and chlorine doses in the laboratory, and all field tests, samples held without sodium thiosulfate had lower bacteria counts ($p<0.001$). Additionally, chlorinated water supply samples held without sodium thiosulfate had an 87.5% false negative rate. Results indicate the importance of dechlorinating microbiological water quality samples, discarding data from chlorinated samples collected without dechlorination, and reinforcing dechlorination recommendations in resource-limited environments to improve water safety management.

3.2 Introduction

The provision of treated drinking water prevents disease and protects public health. To ensure water safety, agencies such as the World Health Organization (WHO) and United States Environmental Protection Agency (USEPA) recommend ongoing monitoring of physical, chemical, and microbiological contaminants in drinking water (USEPA, 2009; WHO, 2011b). Microbiological water safety is widely assessed using bacterial indicator species, including *Escherichia coli (E. coli)* and fecal (thermotolerant) coliforms. WHO guidelines and USEPA regulations require drinking water to be free of detectable *E. coli* and/or fecal coliforms (USEPA, 2009; WHO, 2011b), and indicator levels are often used to classify diarrheal disease risk (WHO, 1997).

Most microbiological water quality test methods include the recommendation to collect chlorinated water samples in bottles containing sodium thiosulfate ($Na_2S_2O_3$), a dechlorinating agent (WHO/OECD 2003; APHA/AWWA/WEF 2005; CDC 2010; USEPA 2013). Dechlorination is recommended to ensure that microbiological test results reflect the actual water quality at the time of sample collection, by preventing ongoing disinfection during sample holding and analysis. Recommendations to dechlorinate water samples from treated water supplies with sodium thiosulfate have existed since at least 1939 (Ministry of Health, 1939).

Research conducted in the 1950s shaped current recommendations to add sodium thiosulfate to all potentially-chlorinated water samples and to complete analysis within eight hours of collection (APHA/AWWA/WEF 2005). This research identified that sodium thiosulfate: 1) did not affect *E. coli* survival in unchlorinated samples stored up to six hours (The Public Health Laboratory Service Water Sub-committee, 1953); 2) favored survival in unchlorinated samples stored for 18 hours (Noble & Gullans, 1955); and 3) also effectively neutralized residual copper, another disinfectant originating from distribution pipes (Hoather, 1957).

Due to the ubiquity of the sodium thiosulfate recommendation, few recent studies have investigated the effects of dechlorination. One study found that omitting sodium thiosulfate during sample collection resulted in false negative readings of legionella in hot water supplies held for 30 minutes before analysis (Wiedenmann *et al.* 2001). A second investigation of mycobacteria in chlorinated swimming pools identified varying effects of dechlorination on bacteria detection by different methods with holding time up to two weeks (Iivanainen et al., 1999). Lastly, a study on acidified sodium chlorite, a disinfectant used in poultry and meat processing, concluded that sodium thiosulfate had no deleterious effect on *E. coli* survival, and that disinfection continued in spiked water samples stored for five minutes without sodium thiosulfate (Kemp & Schneider, 2000). These recent studies have not impacted the dechlorination recommendations.

Through the Monitoring for Safe Water (MfSW) program, the Aquaya Institute collaborated with 26 water utilities and public health agencies in six sub-Saharan African countries to evaluate microbiological water quality practices and build capacity for improved monitoring. All of these partners collected drinking water quality data, including indicator bacteria and free chlorine residual (FCR). A review of eleven water suppliers in July 2014 determined that five (45%) did not add sodium thiosulfate to dechlorinate water samples collected for microbiological analysis. This finding suggests that, in resource-limited contexts, sampling drinking water without dechlorinating may be common. However, there is a lack of research quantifying the extent to which this practice affects indicator bacteria counts (and therefore diarrheal disease risk levels) specific to drinking water quality monitoring.

The goal of this investigation was to evaluate the effects of dechlorination on the microbiological analysis of chlorinated drinking water supplies analyzed with current laboratory techniques. This was accomplished by measuring fecal indicator bacteria in both: 1) *E coli*-spiked and chlorinated laboratory water samples, and 2) water samples collected from chlorinated drinking water supplies across sub-Saharan Africa to determine if there was a detectable difference in indicator bacteria counts between samples held with and without sodium thiosulfate.

3.3 Methods

3.3.1 Laboratory methods

Culture and water spiking

E. coli (ATCC® 25922) from pre-prepared, frozen stock was inoculated into Difco™ LB Broth (Difco Laboratories, Sparks, MD) and incubated overnight (18-

24 hours) at 35ºC to reach stationary growth phase, and then re-inoculated into growth media and incubated at 35ºC to reach log-growth phase (2-3 hours). Cell concentrations in inoculated broth were estimated from OD-600 reading (GeneQuant 100 Spectrophotometer, GE Healthcare, Pittsburgh, PA) and a pre-developed conversion factor, and confirmed by plating serially-diluted broth on Difco™ LB Agar, incubating at 35ºC for 18-24 hours, counting colonies, and averaging plate counts within a countable range. Cells were washed from broth by centrifuging twice at 2600g at 4ºC in an Eppendorf 5810R centrifuge (Eppendorf, Hamburg, Germany) and re-suspending in sterile, 0.05M phosphate-buffered saline solution.

The *E. coli* suspension was added to six liters of 0.001 M phosphate-buffered water (pH: 7.6; temperature: 20-24 ºC; total dissolved solids: 80-180 mg/L) to attain one of five target *E. coli* concentrations between $1x10^4$ CFU/100 mL and $1x10^8$ CFU/100 mL. Spiked water was stirred with a magnetic stir bar at 300 RPM for a minimum of 30 minutes.

Chlorinating and sampling

E. coli-spiked water and unspiked buffered control water (600 mL samples) were chlorinated at each of five target FCR doses (0.0, 0.1, 0.2, 0.4, 0.6 mg/L) with diluted liquid sodium hypochlorite (Clorox® Bleach, The Clorox Company, Oakland, CA). Samples were stirred for 5 seconds with a plastic-coated magnetic stir bar at 300 RPM, and then samples were collected aseptically in sterile 4-oz glass bottles with and without sodium thiosulfate (0.1 mL of 3% solution (4)). Collected samples were immediately placed on ice in a cooler.

In all samples, FCR was measured in triplicate with a LaMotte 1200 Colorimeter (LaMotte Company, Chestertown, Maryland) immediately after chlorine dosing, and again in all samples held for 4.0 - 5.5 hours with and without sodium thiosulfate. Unchlorinated spiked water was assayed for *E. coli* within one hour of spiking to determine the starting *E. coli* concentration. All *E. coli*-spiked samples were assayed after holding 5 - 7 hours with and without sodium thiosulfate. Holding time was consistent between paired sets of samples in each experiment.

The entire protocol was repeated for a total of six spiked water tests: one at each of the five target *E. coli* concentrations, and a replicate experiment at the 1×10^5 CFU/100 mL *E. coli* concentration.

Bacteria enumeration

E. coli concentrations in water samples were enumerated using the membrane filtration method (APHA/AWWA/WEF 2005) with m-lauryl sulfate media (HiMedia Laboratories, Mumbai, India). This method was selected because it was identified as the most common microbiological test method among institutions in ten sub-Saharan African countries (Peletz *et al*. 2016). Samples were diluted appropriately with sterile buffered water, vacuum filtered aseptically through a 45-micron filter (Millipore, Billerica, MA), placed in a plastic petri dish with a media-soaked pad, and incubated for 6 hours at 25^{o}C, followed by 14 hours at 35^{o}C. Colonies were counted and concentrations calculated by averaging plate counts within a countable range (10-200 CFU/plate) after accounting for dilution factors. Ten percent of samples were duplicated, and a sterile water blank was run before each sample.

3.3.2 Field methods

Four African water suppliers from the MfSW program (a regional water supplier in Zambia, a town supplier in Kenya, and two water suppliers in Uganda) were selected to perform parallel testing of chlorinated drinking water. Suppliers were selected because they: 1) delivered chlorinated water through a piped network, 2) demonstrated a strong microbiological water quality testing program, 3) did not regularly use sodium thiosulfate in sampling, and 4) were willing to participate in the study. Two samples (one with sodium thiosulfate and one without sodium thiosulfate) were collected from sources including water treatment plants, storage tanks, and distribution network taps. Samples were placed on ice and assayed for fecal coliforms within 8 hours using membrane filtration with m-lauryl sulfate media. Plates were incubated at 44°C for 18-24 hours and counted.

3.3.3 Data analysis

Data were entered into, and analyzed in, Microsoft Excel (Microsoft Corporation, Redmond, WA) and R 3.0.1 (R Foundation for Statistical Computing, Vienna, Austria). Wilcoxon signed rank tests for paired samples were performed to determine if indicator bacteria concentrations differed between samples with and without sodium thiosulfate at 0.05 significance for: 1) chlorinated laboratory samples, 2) unchlorinated laboratory samples, and 3) field samples. A false negative rate for field-performed tests without sodium thiosulfate was also calculated.

3.4 Results

3.4.1 Laboratory results

Laboratory results of FCR and *E. coli* concentration are tabulated by individual trial in Table 3-1 through Table 3-6. Spiked water *E. coli* concentrations were: 1.45 x 10^4 CFU/100 mL, 1.59 x 10^5 CFU/100 mL, 6.98 x 10^4 CFU/100 mL (replicate), 1.56 x 10^6 CFU/100 mL, 1.44 x 10^7 CFU/100 mL, and 1.53 x 10^8 CFU/100 mL.

There were three general trends in the FCR readings (Table 3-1- Table 3-6): 1) spiked water FCR was less than or equal to unspiked water FCR both before and after holding, probably because *E. coli* exerted chlorine demand; 2) FCR readings in spiked samples after holding were similar with increasing *E. coli* concentration, until a threshold of 10^7 CFU/100mL was met (Table 3-5 and Table 3-6); and 3) FCR declined over the holding time in all samples (comparing FCR at collection and FCR after holding). Additionally, FCR readings for samples held with sodium thiosulfate were ≤0.03 mg/L, indicating that sufficient sodium thiosulfate was added to quench all chlorine (data not shown).

Across all trials, chlorinated samples collected without sodium thiosulfate had no detectable *E. coli* after the holding period, with the exception of one sample with 1 CFU/100 mL (Table 3-5).

At the lowest starting *E. coli* concentration ($1.45x10^4$ CFU/100 mL), *E. coli* was present in only one sample dosed with chlorine and collected with sodium thiosulfate (Table 3-1). In contrast, in all trials with *E. coli* concentrations $>1.45x10^4$ CFU/100 mL, *E. coli* was detected in all samples dosed with chlorine and collected in bottles with sodium thiosulfate. Within each trial, *E. coli* concentrations in samples collected with sodium thiosulfate usually decreased with increasing chlorine dose. Across the trials, *E. coli* concentrations in samples collected with sodium thiosulfate generally increased with increasing starting concentration (Table 3-1 - Table 3-6). For a starting concentration of $\sim 10^5$ CFU/100 mL, chlorinated samples had 5-190 CFU/100 mL in one trial (Table 3-2) and 36-7,600 in another (Table 3-3). For a starting concentration of $\sim 10^6$ CFU/100 mL, chlorinated samples had 60-2,100 CFU/100 mL (Table 3-4). For starting concentrations of $\sim 10^7$ and $\sim 10^8$ CFU/100 mL, chlorinated samples had 180-16,000 CFU/100 mL and 330-13,200 CFU/100 mL, respectively (Table 3-5 and Table 3-6).

E. coli concentrations in chlorinated water samples collected without sodium thiosulfate were consistently lower than concentrations in equivalent samples collected with sodium thiosulfate (Table 3-1 - Table 3-6). Considering all paired samples, *E. coli* concentrations differed significantly between samples collected with and without sodium thiosulfate ($p<0.001$). No significant difference was seen between unchlorinated samples collected with and without sodium thiosulfate ($p=0.84$), indicating that sodium thiosulfate alone did not affect *E. coli* survival (Table 3-1 - Table 3-6).

Table 3-1: Free chlorine residual (FCR) and E. coli counts in laboratory water samples. Starting E. coli concentration $1.45x10^4$ CFU/100 mL.

	FCR at Collection (mg/L)		FCR after Holding (mg/L)		*E. coli* after Holding (CFU/100 mL)	
Target Cl Dose	Unspiked	Spiked	Unspiked	Spiked	With $Na_2S_2O_3$	Without $Na_2S_2O_3$
0	0.01	0.02	0.01	0.00	2.00E+03	2.20E+03
0.1	0.06	0.09	0.01	0.01	48	0
0.2	0.21	0.19	0.11	0.07	0	0
0.4	0.41	0.39	0.26	0.23	0	0
0.6	0.59	0.53	0.51	0.39	0	0

Table 3-2:Free chlorine residual (FCR) and E. coli counts in laboratory water samples. Starting E. coli concentration $1.59x10^5$ CFU/100 mL.

	FCR at Collection (mg/L)		FCR after Holding (mg/L)		*E. coli* after Holding (CFU/100 mL)	
Target Cl Dose	Unspiked	Spiked	Unspiked	Spiked	With $Na_2S_2O_3$	Without $Na_2S_2O_3$
0	0.00	0.00	0.01	0.00	8.26E+04	1.15E+05
0.1	0.07	0.07	0.04	0.02	190	0
0.2	0.18	0.17	0.12	0.09	8	0
0.4	0.41	0.37	0.35	0.24	5	0
0.6	0.58	0.61	0.59	0.45	6	0

Table 3-3: Free chlorine residual (FCR) and E. coli counts in laboratory water samples. Replicate test with starting E. coli concentration $6.98x10^4$ CFU/100 mL.

	FCR at Collection (mg/L)		FCR after Holding (mg/L)		*E. coli* after Holding (CFU/100 mL)	
Target Cl Dose	Unspiked	Spiked	Unspiked	Spiked	With $Na_2S_2O_3$	Without $Na_2S_2O_3$
0	0.02	0.02	0.00	0.01	1.61E+05	1.12E+05
0.1	0.12	0.08	0.03	0.02	7600	0
0.2	0.20	0.14	0.15	0.08	139	0
0.4	0.40	0.38	0.33	0.30	59	0
0.6	0.59	0.60	0.48	0.52	36	0

Table 3-4: Free chlorine residual (FCR) and E. coli counts in laboratory water samples. Starting E. coli concentration 1.56x10⁶ CFU/100 mL.

Target Cl Dose	FCR at Collection (mg/L)		FCR after Holding (mg/L)		*E. coli* after Holding (CFU/100 mL)	
	Unspiked	Spiked	Unspiked	Spiked	With $Na_2S_2O_3$	Without $Na_2S_2O_3$
0	0.02	0.01	0.00	0.01	1.08E+06	4.22E+05
0.1	0.09	0.09	0.05	0.03	2100	0
0.2	0.17	0.16	0.14	0.07	700	0
0.4	0.35	0.35	0.30	0.27	150	0
0.6	0.57	0.56	0.52	0.45	60	0

Table 3-5: Free chlorine residual (FCR) and E. coli counts in laboratory water samples. Starting E. coli concentration 1.44x10⁷ CFU/100 mL.

Target Cl Dose	FCR at Collection (mg/L)		FCR after Holding (mg/L)		*E. coli* after Holding (CFU/100 mL)	
	Unspiked	Spiked	Unspiked	Spiked	With $Na_2S_2O_3$	Without $Na_2S_2O_3$
0	0.02	0.01	0.00	0.02	4.44E+06	3.33E+06
0.1	0.09	0.06	0.06	0.01	16000	0
0.2	0.21	0.17	0.15	0.02	2900	1
0.4	0.40	0.36	0.40	0.11	540	0
0.6	0.58	0.54	0.52	0.26	180	0

Table 3-6: Free chlorine residual (FCR) and E. coli counts in laboratory water samples. Starting E. coli concentration 1.53x10⁸ CFU/100 mL

Target Cl Dose	FCR at Collection (mg/L)		FCR after Holding (mg/L)		*E. coli* after Holding (CFU/100 mL)	
	Unspiked	Spiked	Unspiked	Spiked	With $Na_2S_2O_3$	Without $Na_2S_2O_3$
0	0.02	0.02	0.01	0.01	9.30E+07	1.13E+08
0.1	0.08	0.06	0.06	0.02	2000	0
0.2	0.18	0.14	0.10	0.02	13200	0
0.4	0.37	0.31	0.23	0.03	330	0
0.6	0.60	0.51	0.47	0.02	5060	0

3.4.2 Field results

Seventy-nine paired water samples were collected from five water distribution systems managed by the four suppliers at: network taps (67), network storage tanks (7), and treatment plants (5). The median FCR was 0.2 mg/L (range 0-0.8 mg/L, n=79). Fecal coliforms were detected in 24 samples (30%) collected with sodium thiosulfate, with median 2 CFU/100 mL (range 1-9 CFU/100 mL) (Table 3-7). Fecal coliforms were detected in three samples (3.8%) collected without sodium thiosulfate, with median 2 CFU/100 mL (range 1-6 CFU/100 mL) (Table 3-7). Fecal coliform counts in samples collected with sodium thiosulfate were statistically significantly higher than counts in samples collected without sodium thiosulfate ($p<0.001$). Tests completed on samples without sodium thiosulfate had a false negative rate of 87.5% (21 of 24 samples had no detectable fecal coliform, whereas paired samples with sodium thiosulfate had detectable fecal coliform).

Table 3-7: Fecal coliform results for paired samples collected with and without sodium thiosulfate from chlorinated water supplies in sub-Saharan Africa.

	With $Na_2S_2O_3$ (N=79)	Without $Na_2S_2O_3$ (N=79)
Samples with detectable fecal coliform, N(%)	24 (30%)	3 (4%)
Fecal coliform in positive samples, median (range)	2 (1-9)	2 (1-6)

3.5 Discussion

In both laboratory *E. coli*-spiked water and chlorinated drinking water supplies in sub-Saharan Africa, samples collected without sodium thiosulfate had statistically significantly lower indicator bacteria counts than paired samples dechlorinated with sodium thiosulfate. There was also no evidence that sodium thiosulfate alone affected *E. coli* survival in unchlorinated samples. It is important to note that the actual presence of false negative readings in drinking water samples depends on bacterial concentration, free chlorine residual levels, and sample holding time, but the false negative rate for tests performed on samples without sodium thiosulfate from five African chlorinated piped water distribution systems was 87.5%. These results demonstrate that unquenched chlorine can continue to disinfect during holding time and analysis, and highlight: 1) the importance of dechlorinating all drinking water samples collected for microbiological analysis, and 2) the difficulty in interpreting microbiological data collected without sample dechlorination. Our results are consistent with other published data (The Public Health Laboratory Service Water Sub-committee, 1953; Wiedenmann et al., 2001) but are more comprehensive at quantifying the effect of sodium thiosulfate in terms of potential error magnitude and false negative rates in microbiological testing applied to treated drinking water quality monitoring.

While it is unlikely that contamination on the level of the laboratory-spiked water would be found in chlorinated drinking water supplies, observed differences up to 1.6×10^4 CFU/100 mL in laboratory samples illustrate the potential for large errors in microbiological test results if chlorinated water is collected without dechlorination. Additionally, field test results demonstrate that even small differences in indicator bacteria counts between samples collected with and without sodium thiosulfate can cause drinking water samples to be misclassified as complying with microbiological standards (<1 CFU/100 mL) when they do not. Because of these high potential errors, prior data collected without the use of sodium thiosulfate should not be used.

In laboratory testing, samples with positive FCR readings had no detectable *E. coli*, as would be expected. However, among historical data collected by water suppliers participating in the MfSW program, there were samples that exhibited *both* positive FCR readings *and* positive fecal coliform counts (data not shown). There are several explanations for why this could occur in the field: 1) visual colorimetric FCR tests could have been misread by users (Murray & Lantagne, 2015); 2) interference from other components, such as bromine, could have inflated FCR readings; 3) microbiological contamination during sampling or analysis could have inflated coliform counts; or 4) biofilms in distribution systems could allow bacteria to resist disinfection (LeChevallier, 1990; Percival & Walker, 1999; USEPA, 2002). These conditions, however, are not easily replicable in the laboratory setting.

Additionally, laboratory-prepared water had little chlorine demand, which is not realistic of natural water conditions. *E. coli*-spiked laboratory tests were also performed with water containing various amounts of chlorine demand in the form of bacteria growth media (data not shown). Similar trends in paired *E. coli* samples were observed in those tests; samples collected with sodium thiosulfate dechlorination had consistently higher *E. coli* concentrations than those collected without sodium thiosulfate. This was true even when all free chlorine was consumed (>0.6 mg/L) and *E. coli* remained in all tested samples. These results suggest that trends exhibited here would also apply across other, more realistic, water conditions.

This work has some limitations. First, rapid chlorine disinfection rates required spiking with high *E. coli* concentrations, sampling precisely, and diluting highly-concentrated samples, which can result in measurement uncertainties. Disinfection rates up to 4.5-log *E. coli* removal in 5 seconds in this study were consistent with those previously reported (Rice *et al.* 1999; Zhao *et al.* 2001), and presented a challenge for developing laboratory methods. Nevertheless, consistent trends between trials and the application of quality control measures contribute to the internal validity of these laboratory test results. Second, inherent differences between prepared laboratory water and natural waters prohibit direct data extrapolation. As such, we do not estimate a magnitude of difference in laboratory *E. coli* counts taken from samples collected with and without sodium thiosulfate that is directly applicable to natural waters or treated drinking water supplies. Future research is recommended to confirm these results with *E-coli*-spiked natural waters, which may have slower disinfection kinetics and other test interferences; however, those results would be unlikely to change this study's conclusions.

Existing international water quality monitoring and drinking water sampling recommendations recommend dechlorination of samples before microbiological analysis. National policies often mandate routine drinking water quality testing (Steynberg 2002; Rahman *et al.* 2011), but the prevalence of dechlorination recommendations in national policies is unknown. The MfSW program has identified several monitoring and surveillance institutions in sub-Saharan Africa that do not dechlorinate samples from chlorinated supplies collected for microbiological analysis. These institutions may not have testing protocols that specify dechlorination, or they may lack sufficient quality control procedures to ensure that protocols are followed. Our results indicate that dechlorination recommendations should be reinforced to improve water safety management in all settings providing chlorinated supplies, as artificially low or false negative microbiological test results may cause incorrect classification of disease risk from drinking water, provide a false sense of security, and prevent institutions from taking necessary actions to remedy potentially unsafe water supplies.

3.6 Conclusions

In microbiological water quality testing, it has long been recommended to dechlorinate samples with sodium thiosulfate upon collection. Despite this, research shows that many drinking water quality monitoring institutions in sub-Saharan Africa do not dechlorinate samples, and the impact of this practice on drinking water safety is unclear. We tested fecal indicator bacteria in paired samples collected with and without dechlorination in two settings: *E. coli*-spiked, chlorinated, laboratory water, and drinking water supplies in sub-Saharan Africa.

In all cases, bacteria counts were lower in samples that were not dechlorinated with sodium thiosulfate before processing. These results highlight the importance of adhering to sample dechlorination guidelines due to the risk of artificially low or false negative bacteria counts. There may also be a need to reinforce microbiological test procedures among resource-limited monitoring institutions to improve water safety management.

3.7 Acknowledgements

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3.8 Citation

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4 Fouling in hollow fiber membrane microfilters used for household water treatment

4.1 Abstract

The Sawyer PointOne hollow fiber membrane microfilter is promoted for household water treatment in developing countries. Critical limitations of membrane filtration are reversible and irreversible membrane fouling, managed by backwashing and chemical cleaning, respectively. The PointOne advertised lifespan is 10-years; users are instructed to backwash as maintenance. Due to reduced turbidity and bacterial removal efficiencies, six PointOnes were removed from Honduran homes after 23 months of use. In the laboratory, we tested sterile water filtrate for turbidity and bacterial presence before and after backwashing and chemical cleaning. Sterile water filtrate from uncleaned filters had turbidity of 144->200 NTU and bacteria counts of 13->200 CFU. Cleaned filter effluent was positive for total coliforms. On one new and one used, cleaned filter, we imaged membranes with scanning electron microscopy, and characterized surface elemental compositions with spectroscopy. Images and spectroscopy of the used, cleaned membrane revealed a dense, cake fouling layer consisting of inorganic metal oxides, organic material, and biofouling. Burst fibers were visually observed. This PointOne was thus irreversibly fouled and non-functional after <2 years of use. Further research is recommended to determine: impacts of source water quality on PointOne performance, a cleaning regimen to manage fouling, and an appropriate filter lifespan.

4.2 Introduction

Worldwide, an estimated 780 million people drink water from unimproved sources (UNICEF/WHO, 2012) and an estimated 1.2 billion more drink contaminated water from improved sources (Onda et al., 2012). Providing reliable, centrally-treated piped water to every household is the ultimate goal, but the World Health Organization (WHO) also supports incremental water supply improvements – such as household water treatment and safe storage (HWTS) options – to accelerate the heath gains associated with safer drinking water for those with unsafe supplies (WHO, 2011b).

In 2014, to address recent increased interest in developing new HWTS options, WHO launched an international scheme to evaluate HWTS product laboratory performance in removing bacteria, viruses, and protozoan cysts that cause diarrheal disease (WHO, 2014b). This scheme established tiered, health-based targets, classifying HWTS products as 'highly protective' (4-log bacteria and protozoa reduction and 5-log virus reduction), 'protective' (2-log bacteria and protozoa reduction and 3-log virus reduction), or 'limited protection' (achieving protective target for two pathogen classes and epidemiological evidence demonstrating disease reduction) based on a quantitative microbial risk assessment model (WHO, 2011a).

The Sawyer PointOne Filter (PointOne) is a microfilter consisting of hollow membrane fibers bundled in a U-shape inside a plastic casing (Sawyer Products Inc., Safety Harbor, FL, USA). The PointOne is promoted for recreational use, disaster relief, and HWTS in developing countries (Sawyer Products, n.d.-a, 2014b). For household use, users attach the PointOne in-line with a delivery hose to a 20-liter bucket. Water flows via gravity into the filter casing inlet, through the 0.1 micron (µm) porous hollow fiber membrane walls into the membrane cores, and exits the casing into a second storage container (Figure 4-1). Users are instructed to backwash the filter when flow slows, using the provided syringe and clean water. The filter lifespan is advertised as “10+ years,” “decades,” “one million gallons,” and even potentially “never need[ing] to be replaced,” with a maximum daily throughput of 1,117 liters at sea level. PointOne filters have been distributed in over 70 countries worldwide (Sawyer Products, 2014a; Sawyer Products, 2014b; Sawyer Products, n.d.).

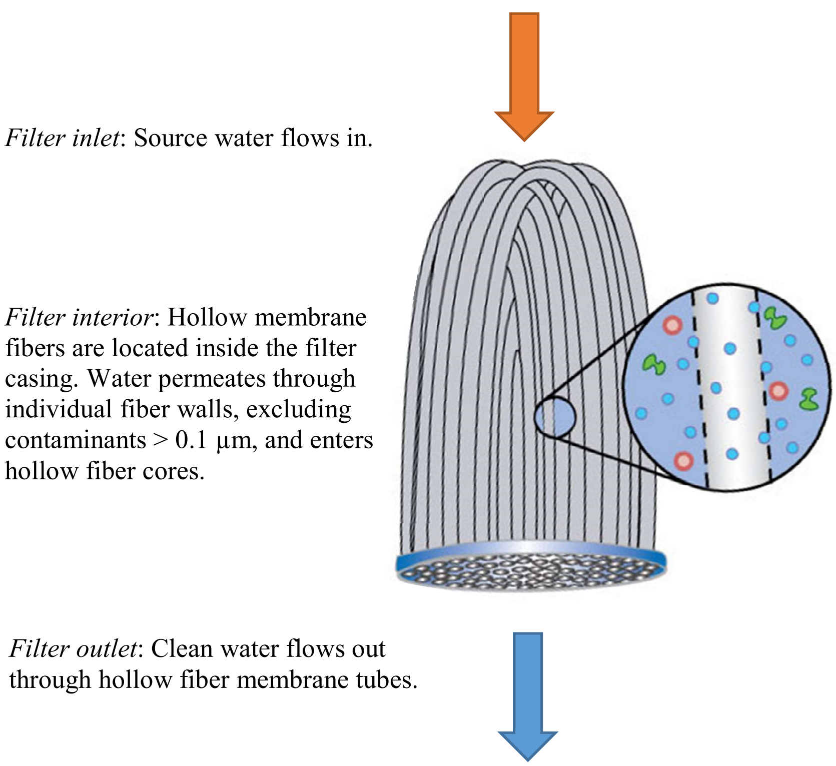

Figure 4-1: Diagram of Sawyer PointOne filter interior membrane and filtering mechanism (modified diagram courtesy of Sawyer Products).

Documented benefits of the PointOne include that, in the laboratory setting, the PointOne is efficacious at removing bacterial (>6-log reduction) and protozoal (>5-log reduction) organisms that cause diarrheal disease (Hydreion, 2005). Additionally, in users' homes, the PointOne is simple to operate and maintain. High acceptance and usage – up to 100% over 3 months – has been documented during short-term follow-up (Brune et al., 2013; Give Clean Water, 2009; Goeb, 2013d; MAP International, 2011).

However, documented potential shortcomings of the PointOne include filter blockage and breakage, lost or broken syringes for backwashing, requirement of clean water for backwashing, and low consistent use over longer periods of time (Goeb, 2013b; Kohlitz et al., 2013; MAP International, 2011). In one 3-year study, 52% of users reported consistent filter use, and 32% of filters were in disuse due to lost or broken parts (Kohlitz et al., 2013). Additionally, field effectiveness data has found bacterial contamination in 18-54% of tested filter effluent water and 51-70% of stored, filtered water in studies ranging from 3 months to 3 years of use (Brune et al., 2013; Goeb, 2013c, 2013b; Kohlitz et al., 2013).

Membrane filtration is an emerging technology used in biomedical, food service, wastewater, and drinking water treatment; it is appropriate for HWTS because it provides a physical barrier, removes turbidity, and can improve water taste (Peter-Varbanets, Zurbrügg, Swartz, & Pronk, 2009). The largest obstacle to filter performance in all applications is membrane blockage, or fouling. Fouling is caused by organic, inorganic, and bacterial constituents, and leads to loss of membrane permeability, observable by declining flow rate through the filter. Fouling behavior is complex, and depends on solution chemistry, membrane characteristics, filter operating conditions, and physical and chemical properties of the foulants. Membrane fouling can be *reversible*, where particulate material retained in a “cake” layer on membrane surfaces is removable by physical processes such as backwashing and air scouring; or *irreversible*, where solutes plug and adsorb to pores within the membrane, requiring other processes - such as chemical cleaning - to recover performance (Zularisam, Ismail, & Salim, 2006).

Pure Water for the World (PWW) is a non-governmental organization that provides safe drinking water, sanitation, and hygiene education to communities in developing countries. PWW installed over 200 PointOnes in six rural Honduran communities as a pilot between 2010 and 2013. Beneficiaries were trained on filter use and maintenance upon installation, and again during household follow-up visits two months after installation. Usage rates ranged from 50-95% 9-13 months after distribution, and 66-68% 23 months after distribution (Goeb, 2013a). Reported reasons for filter disuse included: broken casings, clogged filters, broken or missing syringes, damaged hoses, casings which had been opened by users, and filters abandoned by users (Goeb, 2013b, 2013c, 2013d).

In one community, 52% of the 29 filters tested after 23 months of use produced effluent with >10 colony forming units (CFU) *Escherichia coli* (*E. coli*) per 100 mL, which is considered intermediate to high health risk (WHO, 1997). Six of these filters had demonstrated >99.6% mean *E. Coli* and 98-99% mean turbidity removal efficiencies when tested shortly after distribution in October 2011, but 21 months later demonstrated only 54% mean *E. Coli* and 59% mean turbidity removal efficiencies, with no visible damage to the filters (Goeb, 2013b).

In this study, we present the results of controlled laboratory testing completed to investigate reduced performance of these six filters, including: bacteria and turbidity testing of filtered sterile water effluent following manufacturer-recommended cleaning, to identify biofouling; and scanning electron microscopic (SEM) imaging and elemental analysis of membrane fouling layers, to characterize the fouling layer and its constituents.

4.3 Methods

Six PointOne filters were removed from homes in Trojes, Honduras in September 2013, stored in a sealed plastic bag, and transported to the University of Maine in Orono, Maine, USA, and investigated in November 2013. A new PointOne was purchased from a Sawyer retail distributor to serve as a control.

4.3.1 Filtrate Bacteria and Turbidity Testing

Thirty mL of sterile water was pipetted through each filter. Filtrate turbidity was measured with a Lab Quest turbidimeter (Vernier Software and Technology, Beaverton, OR), and each filtrate was swabbed and streaked onto a trypticase soy agar (TSA) plate. Plates were incubated at 37°C for 48 hours, and bacteria colonies were counted. Colonies were considered too numerous to count above 200 CFU.

Sawyer Products was contacted for information on membrane cleaning procedures, beyond backwashing specified in product literature, recommended to restore filter flow. Per recommendations, all six used filters were soaked in hot water for 30 minutes and backwashed four times with 60 mL deionized water, then soaked for 30 minutes in 5% white distilled vinegar and backwashed with deionized water four additional times (personal communication, John Smith, Sawyer Products). Additional sterile water was filtered through each unit. The visually least-turbid filter effluent was chosen for microbiological assessment using the membrane filtration method; 100 mL was filtered through a 0.45 μm membrane filter, the filter incubated at 37ºC for 48 hours on a TSA plate, and colonies were counted.

To identify unexpected live cultures, effluent from the new filter and two used filters with low turbidity was swabbed and streaked onto an Eosin methylene blue (EMB) plate to determine total coliform presence, and a MacConkey agar (MAC) plate to determine fecal coliform presence. Plates were incubated at 37ºC for 48 hours, and clonal growth described. A MUG-agar plate was inoculated from the EMB and MAC plates of both used filters to determine *E. coli* presence. The MUG plates were incubated at 37ºC for 48 hours and colonies counted.

4.3.2 Membrane Imagery and Surface Elemental Analysis

The used filter with highest effluent bacteria count and a new PointOne filter were each cut open at the inlet side, visually examined, and photographed. One membrane fiber from each filter was removed and imaged with a Zeiss NVision

40 SEM (Carl Zeiss, Jena, Germany) at increasing magnification levels. Samples were imaged uncoated near the second crossover voltage to minimize charging effects.

The used and new filter imaged as described above were stored at the University of Maine, and then sent to Tufts University in April 2014, and imaged with a Phenom G2 Pure Tabletop SEM (FEI, Netherlands). Membranes were frozen in liquid nitrogen and fractured using a microtome blade for cross-sectional imaging, and cut with a razor along the hollow core to image interior membrane surfaces. Samples were sputter-coated with gold (~1 nm) to prevent charging and beam damage.

Energy dispersive spectroscopy (EDS, Bruker, Germany), integrated into a Hitachi TM-3000 tabletop SEM (Hitachi, Japan) was used to characterize elemental composition of inner and outer membrane surfaces (top 1-10 μm) from each filter. Uncoated samples were used in low vacuum charge-up reduction mode, and spectra were collected for 60-90 seconds to obtain good signal-to-noise ratio.

4.4 Results

4.4.1 Filtrate Bacteria and Turbidity Testing

When first flushed with sterile water, the new filter effluent measured 0.1 nephelometric turbidity units (NTU), and the effluent from five of six used filters ranged from 114 - >200 NTU (Table 4-1). One used filter (Filter #7) accepted 10 mL, but produced no effluent. There was no bacterial growth on the TSA plate for the new filter effluent; used filter effluent ranged from 13-18 CFU, with one plate too numerous to count (Table 4-1). Soaking and backwashing restored flow in the blocked filter, but effluent from all used, cleaned filters was visually turbid. Effluent from Filter #4 was visually least-turbid (10 NTU), suggesting that it may have been the cleanest of the filters; however, analysis by membrane filtration showed confluent colony growth on a TSA plate, indicating bacterial presence in filtered sterile water effluent.

There was no bacterial growth on the EMB or MAC plates from the new filter's effluent, indicating the absence of total coliforms and fecal coliforms. Plates from both used filter effluents showed dark pink lactose(+) growth on the EMB plates, and light pink presumptive of lactose(+) growth on the MAC plates, indicating potential total coliforms in effluent from both used, cleaned filters. MUG-agar plates of these two filter effluents exhibited no fluorescence, indicating the absence of *E. coli* in effluent from the cleaned filters.

Table 4-1: Turbidity and bacterial growth in sterile water filtered through Sawyer PointOne filters. Filter 1 is a new filter, and Filters 2-7 were removed from households 23 months after distribution.

Filter Number	Turbidity of filtrate (NTU)	Bacterial growth of filtrate swabbed on TSA plate (CFU)
1	0.1	0
2	>200	18
3	>200	15
4	114	14
5	168	13
6	>200	TNTC
7	-	-

Notes:
TSA: Trypticase soy agar
Filter #7: water did not pass through filter, although 10 mL was introduced
TNTC: "too numerous to count"
Turbidimeter detection limit 200 NTU

4.4.2 Membrane Imagery and Surface Elemental Analysis

Visual inspection of the cleaned, used filter interior (Filter #7) showed discolored membrane fibers and high sediment build-up as compared to the new filter (Figure 4-2). Membrane fibers from the used filter were brittle, in contrast to new filter fibers, which were flexible and difficult to break. Additionally, several fibers appeared to have broken, potentially allowing water to enter the hollow fiber tubes directly, without filtration through porous fiber walls.

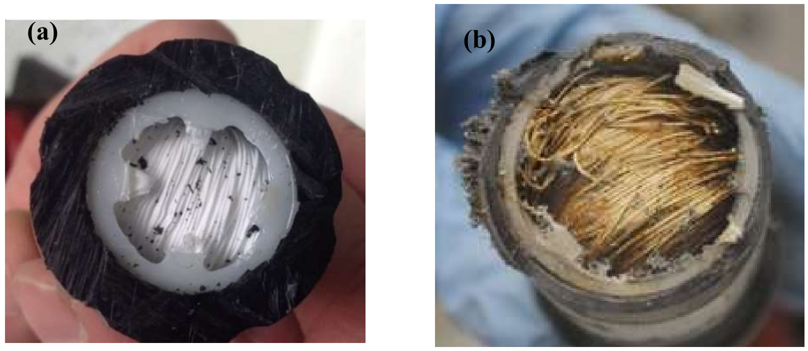

Figure 4-2: (a) Interior of inlet end of a new Sawyer PointOne filter, showing the looped ends of the hollow membrane fibers. (b) Interior of inlet end of a Sawyer PointOne filter removed from the field after 23 months of household use and cleaned in the laboratory. Filter interior shows discoloration and sediment build-up indicative of membrane fouling.

In SEM imagery of a membrane fiber removed from the new filter, individual open pores can be observed; but those pores are blocked by a cake layer in the used, cleaned filter membrane (Figure 4-3). The inner surface of the hollow membrane fiber (Figure 4-4a) is highly porous, with large circular voids and a larger effective pore size. Deposits were observed on these inner pores of the used membrane (Figure 4-4 b-c). Observation of cross-sectional membrane fiber images confirms the presence of a thick cake layer on the exterior, and a thin, but dense, cake layer and particles on the inner fiber surface (Figure 4-4 d-f).

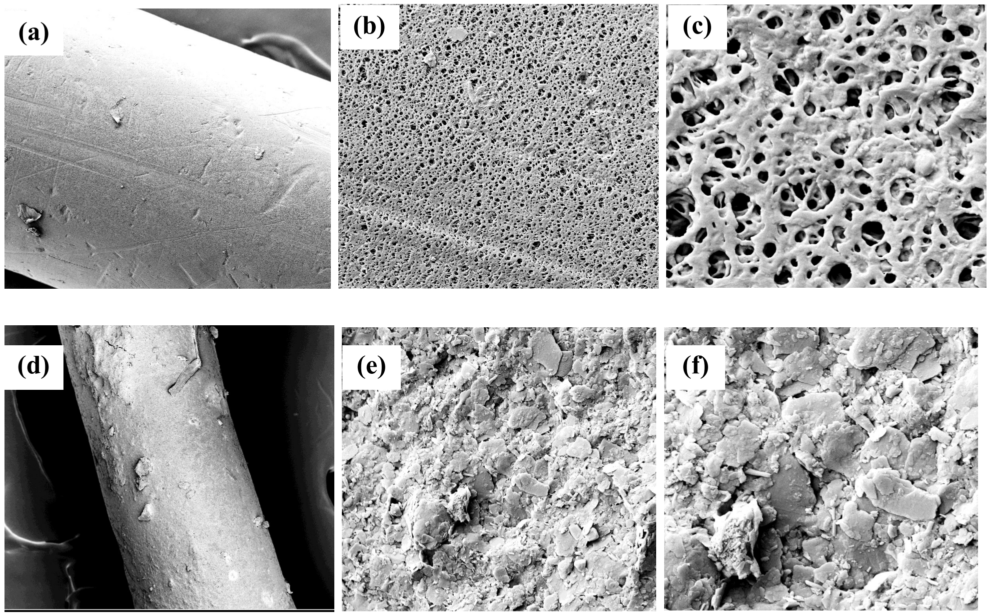

Figure 4-3: Scanning electron microscope (SEM) images of a new Sawyer PointOne filter hollow fiber membrane (a-c), and a membrane from a PointOne removed from the field after 23 months of household use and cleaned in the laboratory (d-f), showing a fouling layer.

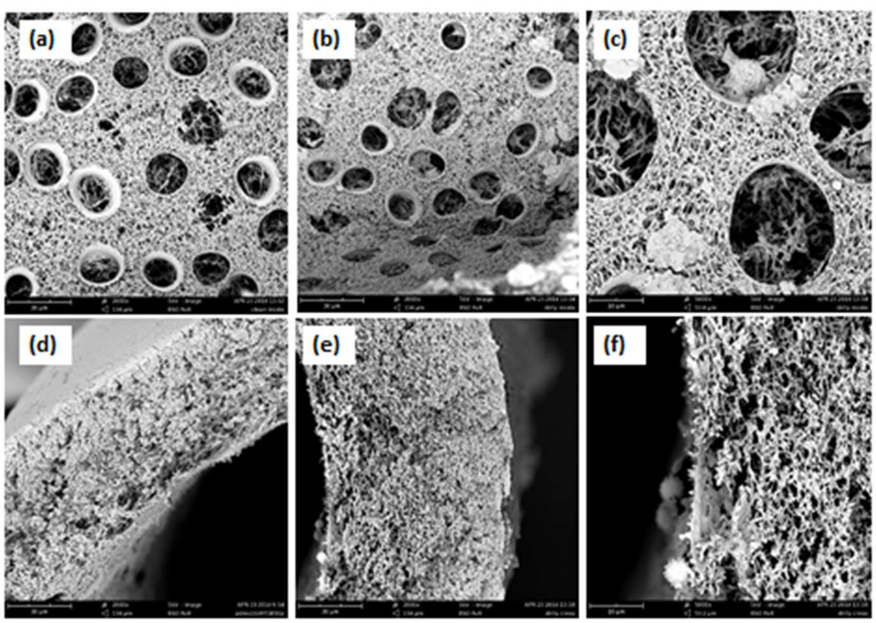

Figure 4-4: Scanning electron microscope (SEM) images of Sawyer PointOne filter hollow fiber membranes. (a) Inner surface of a new membrane (2000x), (b-c) Inner surface of membranes removed from the field after 23 months of household use, showing fouling within the inner pores of the membrane (b: 2000x, c: 5000x). (d) Cross-sectional image of the new membrane (2000x). (e-f) Cross-section of used membranes as above, showing fouling layer on the outside and particles on the inner surface (e: 2000x, f: 5000x).

EDS of the new filter's membrane surface identified carbon, oxygen and sulfur, as expected for polysulfone or polyethersulfone membranes typically used for water treatment (Table 4-2). Nitrogen was also observed on the inner surface, possibly from a preservative or adhesive used in manufacture. The used filter's membrane surface showed little carbon and sulfur, key elements found in the base membrane, but contained large amounts of oxygen, silicon, aluminum, iron, and lead; and lesser amounts of calcium, potassium and magnesium on the outer surface (Table 4-2). The inner membrane surface contained a significant amount of lead, and other elements (Table 4-2), indicating fouling penetrating into the hollow fiber membrane interior.

Table 4-2: Elemental surface composition of a new PointOne filter membrane, and a membrane from a filter removed from a household after 23 months of use and cleaned in the laboratory.

	Normalized weight %			
Element	**New membrane, outer surface**	**New membrane, inner surface**	**Used membrane, outer surface**	**Used membrane, inner surface**
Carbon	75.4	70.0	19.6	58.5
Oxygen	13.3	19.8	34.9	15.1
Sulfur	6.4	8.8	2.2	14.4
Nitrogen	0.0	1.5	0.0	0.0
Silicon	0	0	8.2	1.4
Aluminum	0	0	6.6	1.2
Iron	0	0	4.4	0.7
Lead	0	0	1.8	8.0
Potassium	0	0	0.8	0.2
Calcium	0	0	0.5	0.4
Magnesium	0	0	0.4	0.1

4.5 Discussion

In this laboratory investigation of six Sawyer PointOne filters removed from the field after 23 months of use and cleaned with physical and chemical processes per manufacturer recommendations, we observed: 1) filtered sterile water exiting with turbidity and bacteria loading; 2) pore blockage by a fouling layer of inorganic metal oxides and organic matter on exterior and interior membrane fiber surfaces; and 3) brittle and burst membrane fibers. These results indicate irreversible membrane fouling, including biofouling, and potential short-circuiting of unfiltered water within this membrane. It is not known if these conditions represent an isolated incident or are indicative of an endemic problem with the PointOne in Honduras or other developing country settings; however, the results raise three concerns: 1) the Sawyer PointOne filter's applicability for treating source waters of varying quality, 2) appropriate filter membrane cleaning procedures, and 3) the filter's useful life span.

Membrane fouling depends on interrelated water quality parameters including, but not limited to: turbidity; particulates; organic content; biofilm-forming bacteria; hardness; and metal ions such as iron, manganese, and lead (Alpatova, Verbych, Bryk, Nigmatullin, & Hilal, 2004; Peng, Escobar, & White, 2004). Irreversible fouling occurs when organic biomacromolecules, such as proteins, humic acids, and polysaccharides, adsorb to the membrane (Kimura, Hane, Watanabe, Amy, & Ohkuma, 2004). Some of these compounds, such as natural organic matter (NOM), are naturally present in surface water; others are generated by organisms in the water source. Biomacromolecules can: 1) bind together inorganic particulates, exacerbating cake fouling and preventing removal by physical methods (Schafer, Fane et al. 1998); and 2) initiate biofouling by helping microorganisms in the influent water adhere to the membrane surface. These microorganisms can then grow and form impermeable biofilms (Peng et al., 2004). Irreversible fouling can become increasingly difficult to manage if not remedied early in the biofilm formation process.

The used filter membrane analyzed herein contained a complex mixture of metal oxides on the outer membrane surface, with especially high quantities of silicon, aluminum, and iron (Table 4-2). Positive bacteria presence in sterile water effluent from used filters suggests membranes were biofouled. This indicates the irreversible fouling layer is likely a composite of inorganic particles held together by organic foulants and/or microorganisms, and that various source water constituents contributed to filter membrane fouling.

Consistent with common microfiltration fouling prevention techniques, Sawyer Products recommends two methods to minimize PointOne fouling: pretreating source waters, and backwashing when flow is reduced (Sawyer Products, 2014a). Chemical cleaning instructions were only available upon request. Some implementing organizations also recommend pretreatment of turbid source water by filtration, sedimentation, or coagulation with locally-sourced alum before PointOne use, and backwashing the filter with each use, regardless of whether flow is blocked (Brune et al., 2013; MAP International, 2011).

Results presented herein demonstrate that operation and maintenance of the PointOne is essential, as seen with other HWTS options, but cleaning according to manufacturer's instructions is not always sufficient. The six poorly-performing PointOnes were removed from households where users received filter operation and maintenance instruction, demonstrated correct knowledge of backwashing procedure, and self-reported backwashing with adequate frequency (Goeb, 2013b). With the exclusive use of backwashing, all commercially available filter membranes will eventually foul irreversibly, resulting in progressively reduced flow (Guo, Ngo, & Li, 2012). Irreversible fouling is controllable by chemical cleaning with acidic, alkaline, or biocide solutions (Gao et al., 2011). A membrane cleaning regimen should be chosen in accordance with known water parameters; for example, backwashing to partially remove cake layers on membrane surfaces, alkaline solution to remove microorganisms and organic material, and acidic cleaning to remove inorganic scale (Mo & Huanga, 2003).

The PointOne filter's membrane structure, which features small pores on the exterior (Figure 4-3), and large circular voids with porous walls on the interior (Figure 4-4a, d), is a common structure that sustains high permeability while offering mechanical support. Its outside-in membrane configuration, where microorganisms and particulates are retained on the surface and purified water permeates into the hollow interior, provides a large surface area. However, during backwashing, this geometry concentrates mechanical stress where U-shaped membrane fibers attach to the module. PointOne backwashing instructions encourage users to "be forceful" to dislodge the cake layer. While this approach is sound when the fouling mode is reversible and the cake layer is loose, in the presence of extensive irreversible fouling, forceful backwashing may push fibers to their burst pressure. Broken membrane fibers could lead to improved flow mistaken for the successful removal of the cake layer, when in fact it allows short-circuiting of influent water and loss of turbidity and bacterial removal. After this point, the filter will no longer filter microorganisms, and may instead act as a reservoir for biofilm-forming bacteria. If PointOne membrane fibers burst, functionality cannot be restored without filter replacement and there is no external indication to the user that PointOne use should be discontinued.

The Sawyer PointOne has not yet been assessed under the WHO HWTS product evaluation scheme, but based on available evidence, the PointOne could meet WHO requirements for the "limited protection" classification. The results presented herein highlight the need to test products with representative water sources (specifically with high turbidity, hardness, and NOM), complete the recommended "clogging point" sample (WHO, 2014d), and evaluate product longevity and end-of-life indicator mechanisms before classifying a HWTS product.

Limitations of this work include that few filters were analyzed, and the lack of source water testing beyond turbidity and bacteria. Source water in the homes from which the poorly-performing PointOnes were removed had mean turbidity of 62 NTU (range 7-87 NTU), as measured in stored, untreated water in the home at the time of filter testing (Goeb, 2013b), and may not be representative of source waters in other settings where PointOnes are recommended for HWTS. Additionally, although users were trained in filter operation and maintenance, self-reported user behavior cannot be verified. As such, we cannot isolate source water characteristics that contributed to filter membrane fouling, determine the extent of irreversible fouling in PointOne distributions, or know the extensibility of these results to situations with different water sources or program implementation.

The Sawyer PointOne microfilter has been shown to be effective at removing bacteria and protozoan cysts in the laboratory setting and improving the microbiological quality of household drinking water over the short-term, when applied where technologically appropriate and accompanied by user education. However, this case study illustrates the need for further research of PointOne performance before scaling-up distribution, including: 1) establishment of bacterial removal rates and filter effectiveness in household settings; 2) characterization of the impact of variable water quality, including turbid, high-NOM, and hard influent water on filter microbiological and flow rate performance in the laboratory; 3) further investigation of membrane fouling, biofilm formation, and burst fibers within deployed filters; 4) determination of recommended backwashing and chemical cleaning regimen for filter fouling management; 5) long-term filter performance studies in laboratory and household settings, including component breakage and membrane fouling rates, to establish filter lifespan; and 6) development of an end-of-life indicator to prevent users from drinking effluent water that may be more contaminated than influent water.

4.6 Conclusions

The Sawyer PointOne filter is capable of bacteria and protozoan cyst removal in the laboratory setting, and is a HWTS option widely promoted for long-term use in developing countries. In this investigation of poorly-functioning PointOnes used for 23 months for household water treatment, we identified an internal membrane that: exhibited a dense, highly cohesive irreversible fouling layer of inorganic particles, organic biomacromolecules, and biofouling on the exterior membrane fiber surface; was fouled on the inner fiber surface; and appeared to have burst fibers. Further research of PointOne membrane filter performance is recommended, including: characterizing filter effectiveness and the impact of source water quality on filter performance, investigating the extent of membrane fouling and bacterial growth within deployed filters, establishing a cleaning regimen to manage fouling, and developing an appropriate filter lifespan and end-of life indicator.

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4.8 Citation

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5 Laboratory efficacy and field effectiveness of hollow fiber membrane microfilters used for household water treatment in Honduras

5.1 Abstract

The Sawyer PointONE™ hollow fiber membrane filter is increasingly promoted for long-term household water treatment in developing countries. Limited data demonstrate PointONE™ microbiological laboratory efficacy and short-term diarrheal disease reduction among users, but household microbiological data is lacking. To compare laboratory and household PointONE™ filter microbiological performance, we enumerated *Escherichia coli* (*E. coli*) and total coliforms in source and filtrate water from: 1) one new filter with *E. coli*-spiked water (10^7-10^9 CFU/100 mL) in the laboratory, 2) one new filter with natural Maine and Honduran surface waters, and 3) fifty filters used in Honduran homes for 1-3 years. In laboratory tests, all filtrate samples had <1 CFU/100 mL *E. coli* (>99.99999% reduction). In natural surface waters, all filtrate samples had ≤1 MPN/100 mL *E. coli* (≥99.5% reduction). In households, filtrate samples had geometric mean 5.1 MPN/100 mL *E. coli* (90% reduction), with only 30% of filtrate samples complying with international standards of undetectable *E. coli*. Total coliform presence in natural water filtrate varied for both new and household filters. The discrepancy between laboratory and household results and premature filter failure are not well understood. Further research is recommended to understand this performance disparity and determine filter failure mechanisms in households.

5.2 Introduction

Worldwide, an estimated 748 million people drink water from unimproved sources (WHO/UNICEF, 2014) and an estimated 1.2 billion more drink contaminated water from improved sources (Onda et al., 2012). Providing reliable, safely managed, piped water to every household is the ultimate goal (WHO/UNICEF, 2014), but the World Health Organization (WHO) also supports incremental water supply improvements – such as household water treatment and safe storage (HWTS) options – to accelerate the heath gains associated with safer drinking water for those with unsafe supplies (WHO, 2011b). A growing body of evidence demonstrates that the use of HWTS options improves the microbiological quality of household water and reduces the burden of diarrheal disease among users (T. F. Clasen et al., 2015; Fewtrell et al., 2005; Waddington et al., 2009).

HWTS options are evaluated using laboratory efficacy testing, health impact trials, and field effectiveness testing. In the laboratory, product efficacy at removing organisms of concern (bacteria, viruses, and protozoa) from test waters is evaluated. Randomized, controlled trials in developing country communities measure a product's ability to reduce diarrheal disease among users. Field effectiveness is evaluated to measure a HWTS product's ability to reduce indicator organisms such as *Escherichia coli (E. coli)* or thermotolerant coliforms in drinking water in actual users' homes.

WHO guidance includes tiered, health-based targets which classify HWTS products according to laboratory efficacy performance as: *'Highly protective'* (4-log bacteria and protozoa reduction and 5-log virus reduction in laboratory settings), *'Protective'* (2-log bacteria and protozoa reduction and 3-log virus reduction), or *'Interim'* (achieving *2-star* target for two pathogen classes and having epidemiological evidence demonstrating disease reduction in health impact trials) (WHO, 2011a). These targets have since been termed *'3-star,' '2-star,'* and *'1-star'* performance classifications, respectively (WHO, 2016). WHO guidelines also categorize diarrheal disease risk based on indicator organism levels in users' drinking water (WHO, 1997).

One recently-promoted HWTS option is the Sawyer PointONE™ Filter, a hollow membrane fiber microfilter with 0.1μm pore size. The PointONE™ filter is distributed with an assembly kit with fittings to attach the filter to a five-gallon bucket (Figure 5-1). To use the filter, water is poured into this source water bucket and the filter head is lowered, allowing water to flow by gravity through a delivery tube and the hollow fiber membrane, into a secondary storage container. Users are instructed to backwash the filter when flow slows, using clean water and a syringe provided with the filter. PointONE™ filters have an advertised lifespan of up to 10 years, and have been distributed in over 70 countries (Sawyer Products, 2014; Sawyer Products, n.d.).

Figure 5-1: Sawyer PointONE™ Filter bucket assembly.

The PointONE™ filter has been shown to be efficacious in the laboratory at removing bacteria (>6-log reduction) and protozoan cysts (>5-log reduction) (Erikson et al., 2013; Hydreion, 2005). Virus removal has not been evaluated, as most viruses are smaller than the PointONE™'s pore size and high removal is not expected. Additionally, one study demonstrated a reduction in diarrheal disease prevalence among users under 5 years old over a short, three-month follow-up in a controlled study setting (Lindquist et al., 2014). This evidence – all conducted under highly controlled conditions with new filters – suggests that the PointONE™ filter could potentially meet the requirements of the WHO *1-star* performance target, although actual classification would require testing by an external independent laboratory.

Microbiological field effectiveness data has identified bacterial contamination in 18-54% of tested PointONE™ filter direct filtrate and 51-70% of stored, filtered water in studies where filters were used between three months and three years (Brune et al., 2013; Goeb, 2013b, 2013c; Kohlitz et al., 2013). However, only one of these studies was peer reviewed, and results were limited by the use of a semi-quantitative method of identifying bacterial contamination, lack of source water quality testing, and small sample size (24 filtrate samples and 37 stored water samples) (Kohlitz et al., 2013). To our knowledge, no quantitative microbiological field effectiveness data of the PointONE™ filter has been published in peer-reviewed format to date.

Pure Water for the World (PWW) is a non-governmental organization that provides safe drinking water, sanitation, and hygiene education to communities in developing countries. PWW installed over 250 PointONE™ filters in six rural Honduran communities between 2010 and 2013. Beneficiaries were trained on filter use and maintenance upon installation, and again during household follow-up visits approximately three months after installation. In follow-up evaluations by PWW, usage rates ranged from 50-95% 9-13 months after distribution in some communities, and 66-68% 23 months after distribution in others. Reported reasons for filter disuse included: broken casings, clogged filters, broken or missing syringes, damaged hoses, casings which had been opened by users, and filters abandoned by users (Goeb, 2013b, 2013c, 2013d). Additionally, an analysis of PointONE™ filters installed by PWW and used for almost two years identified membrane fouling as a challenge to long-term filter performance (Murray et al., 2015). Because of these unexpectedly high rates of disuse documented by PWW and the lack of available robust field effectiveness data, we sought to further understand the microbiological performance of PointONE™ filters used in the field over the long term, in addition to performance at removing organisms of concern in controlled environments.

In this research, we evaluated microbiological performance of the Sawyer PointONE™ filter by investigating: 1) microbiological efficacy of new filters in the laboratory, 2) microbiological efficacy of new filters in a controlled field environment, and 3) microbiological effectiveness of PointONE™ filters known to be used in household settings at least one year after distribution.

5.3 Methods

5.3.1 Laboratory efficacy testing

In March 2014, a new PointONE™ filter assembly was purchased from a distributor and fitted to a plastic 5-gallon bucket for laboratory testing at the University of Maine. The filter assembly was identical to the assembly employed in users' homes in Honduras. *E. coli* was grown in tryptic soy broth and then inoculated into 1.2 L of sterile deionized water at three doses: 10^7, 10^8, and 10^9 colony forming units (CFU)/100 mL. Each spiked water dose was poured into the filter source bucket and gravity-flowed through the PointONE™ filter. The first 100 mL of water was collected aseptically from the filter outlet in sterile bottles, and 100-mL samples were also collected after 500 mL and 1000 mL of flow. The filter was backwashed three times with deionized water before each challenge test, and the sampling procedure was repeated with increasing *E. coli* concentrations.

Samples were processed immediately using the membrane filtration method (APHA AWWA WEF, 2005) with m-ColiBlue24® media (Hach Company, Loveland, CO). Samples were diluted appropriately with sterile deionized water, vacuum filtered aseptically through a 45-micron filter (EMD Millipore, Billerica, MA), placed in a plastic petri dish with a media-soaked pad, and incubated for 24 hours at 35°C before counting colonies. A negative control PointONE™ filter assembly was run in parallel with deionized water, and positive control *E. coli* plates were processed alongside laboratory samples.

5.3.2 Field efficacy testing

In August 2014, one new PointONE™ filter was purchased and assembled as above for controlled microbiological efficacy testing with natural surface waters in Maine and Honduras. In Maine, five different locations along an urban stream were tested. Before each test, the filter was backwashed three times with deionized water, and the source bucket was rinsed three times and filled with stream water. This source water was gravity-flowed through the filter for at least one minute, and then a 100-mL filtrate sample was collected aseptically directly from the filter outlet in a sterile plastic bottle. A water sample was also collected aseptically from the source bucket. Samples were placed on ice and analyzed within eight hours using the most probable number (MPN) method (APHA AWWA WEF, 2005) for simultaneous detection of total coliform and *E. coli* using IDEXX Quanti-Tray® 2000 and Colilert® media (IDEXX Laboratories Inc., Westbrook, ME). Trays were incubated for 24 hours at 35°C, and then positive wells were counted.

Following this testing, the filter was disassembled and the membrane was backwashed three times, placed in a new plastic zipper storage bag, transported to Honduras, and then reassembled with a new source bucket. Efficacy testing was repeated, as above, with the same PointONE™ filter in five locations along a river in one Honduran community.

5.3.3 Household effectiveness testing

Household selection and survey methods

Two Honduran communities located in the Trojes region of Honduras were selected for study inclusion because they: 1) had at least 40 filter assemblies distributed in each, and 2) represented a variety of times since filter training and distribution. In Community 1, PointONE™ filters were distributed to 45 households in August 2011: three years prior to this study. PWW provided the research team with a list of the 23 households known to be using filters in this community, based on a follow-up visit completed in July 2013. All of these homes were visited as part of this research in August 2014. In Community 2, PointONE™ filters were distributed to 65 households in August 2013: one year prior to this study. PWW provided the research team with a list of all 65 beneficiary households. In August of 2014, the research team visited 27 of these homes, which were selected based on availability at the time of the announced visit, being a current PointONE™ filter user, and ease of access for the study team.

Household surveys were written in English, and then translated into and administered in Spanish to an adult household member after obtaining oral consent. Surveys included 20 questions on filter use and habits, as well as respondent demonstration of the backwashing maintenance procedure and observation of filter condition. All household visits were unannounced. The study protocol was approved by the University of Maine Institutional Review Board.

Household water quality testing

At each household, the PointONE™ filter was backwashed at least three times by the user. The filter source bucket was then filled with untreated household source water, which was allowed to gravity-flow through the filter for at least one minute before a 100-mL filtrate sample was collected aseptically directly from the filter outlet in a sterile plastic bottle. A source water sample was also collected aseptically from the source bucket. Samples were placed on ice and analyzed within eight hours by the IDEXX MPN method, as described above. At each household, source and filtrate turbidities were measured in duplicate with a Hach portable 2000P turbidity meter, and filter flow rate was measured.

Water quality data analysis

Data were entered into Microsoft Excel (Microsoft Corporation, Redmond, WA) and analyzed in R 3.0.1 (R Foundation for Statistical Computing, Vienna, Austria). For all statistical tests, p-values <0.05 were considered statistically significant.

E. coli, total coliform, and turbidity reductions between source and filtrate were calculated two ways: 1) the percent reduction in geometric mean of the parameter, and 2) the median percent reduction for the set of filters. In all cases, duplicate water quality measurements were averaged, and *E. coli* and total coliform values at the lower detection limit (<1 MPN/100 mL) were replaced with 0.5 MPN/100 mL, and values at the upper detection limit (>2420 MPN/100 mL) were replaced with 2420 MPN/100 mL. In calculating median percent reductions, values at the upper detection limit were removed to minimize bias. Water quality parameters were also compared using paired t-tests on log-transformed values.

Source and filtrate samples were categorized by WHO disease risk guidelines for *E. coli* results as: in conformity (<1 MPN/100 mL), low risk (1-10 MPN/100mL), intermediate risk (11-100 MPN/10mL), high risk (101-1000 MPN/100mL), and very high risk (>1000 MPN/100mL) (WHO, 1997). Fisher's exact test was used to determine if these category distributions differed between source and filtrate waters.

Bivariate analyses were performed to compare median filter *E. coli*, total coliform, and turbidity reductions based on: time since distribution (one year or three years), observed filter casing cracks (yes or no), and users' demonstration of filter backwashing procedure (correct or incorrect) using a Wilcoxon rank-sum test. A multiple logistic regression on the dichotomous outcome of filter *E. coli* reduction of ≥90% was also performed with the same three independent variables.

5.4 Results

5.4.1 Laboratory efficacy testing

Filtrate from spiked laboratory efficacy tests was negative for *E. coli* presence for all *E. coli* doses and all sample times (Table 5-1). This represents up to >9-log *E. coli* removal efficiency. Results are consistent with other spiked water laboratory tests that demonstrated >9-log bacteria removal within the first liter of flow through new PointONE™ filters (Erikson et al., 2013).

5.4.2 Field efficacy testing

The new control PointONE™ filter demonstrated geometric mean 99.7% *E. coli* reduction and >99.98% total coliform reduction across all five Maine efficacy tests (with all filtrate *E. coli* and total coliform samples having <1 MPN/100 mL). In Honduras tests, the filter removed geometric mean 99.5% *E. coli* (with all filtrate samples having ≤1 MPN/100 mL). Total coliform reduction ranged from 0-49% in all five tests (source: >2,420 MPN/100 mL; filtrate: 1,300 to >2,420 MPN/100 mL), though exact total coliform reductions could not be calculated from values at the detection limit (Table 5-1).

Table 5-1: Water quality test results for Sawyer PointONE™ Filter performance in the laboratory (laboratory efficacy), controlled field testing (field efficacy) in Maine and Honduras, and in Honduran homes (field effectiveness).

Water Source	**Parameter**	**Source Geometric Mean (95% CI)**	**Filtrate Geometric Mean (95% CI)**	**% Reduction in Geometric Mean**	**p-value[1]**
Laboratory spiked water	*E. coli* (CFU/100 mL)[2]	10^7 - 10^9	< 1	>99.99999%	-
Urban stream in Maine (n=5)	*E. coli* (MPN/100 mL)	186 (139, 249)	< 1	>99.7%	<0.001
	Total coliform (MPN/100 mL)	>2420[3]	< 1	>99.98%	<0.001
	Turbidity (NTU)[4]	-	-	-	-
River water in Honduras (n=5)	*E. coli* (MPN/100 mL)	124 (79.9, 192)	0.57 (0.44, 0.75)	99.5%	<0.001
	Total coliform (MPN/100 mL)	>2420	1921 (1530, 2414)	-[5]	0.12
	Turbidity (NTU)	5.9 (5.0, 8.8)	0.33 (0.24, 0.45)	94.3%	0.001
Honduran households (n=50)	*E. coli* (MPN/100 mL)	48.9 (32.7, 72.9)	5.1 (2.9, 9.0)	89.5%	<0.001
	Total coliform (MPN/100 mL)	1677 (1382, 2036)	539 (352, 824)	67.9%	<0.001
	Turbidity (NTU)	5.4 (3.7, 8.0)	0.60 (0.46, 0.79)	88.9%	<0.001

Notes:

CFU = Colony forming unit

MPN = Most probable number

NTU = Nephelometric turbidity units

1. p-values calculated with paired t-tests on log-transformed values
2. Spiked tests at 10^7, 10^8, 10^9 CFU/100 mL. Filtrate samples collected at three times (first 100 mL, after 500 mL, after 1000 mL of flow)
3. Upper detection limit: 2420 MPN/100 mL
4. No turbidity data available for Maine control testing
5. Total coliform percent reductions limited by test results at the upper detection limit

5.4.3 Household effectiveness testing

Survey results

Surveys were completed with 23 households (51% of filter recipients) in Community 1, where filters were distributed three years prior. This is believed to be all households currently using PointONE™ filters. Surveys were completed with 27 households (42% of filter recipients) in Community 2, where filters were distributed one year prior. In both communities, the source water used was primarily river water.

Overall, 80% of respondents reported using the PointONE™ filter within the previous day, and 64% of respondents reported treating water with the filter at least daily. When asked "what do you think of the filter?" 91% of respondents reported that it was "very good." When asked if they perceived a change in the family's health, all but one respondent (98%) reported an improvement in health. Over half of respondents (54%) reported that filters had blocked or had reduced flow in the past, and 81% of those who estimated the frequency of flow blockage reported that it happened once a month or less. Most respondents (94%) reported that they used a container other than the clean storage container to collect source water before treating, and 71% of respondents demonstrated the full, correct backwashing procedure (using a clean syringe with filtered water to backwash the filter 3-4 times in the correct direction). Seven filters (14%) had observable cracks or damage to the filter casing, and one filter had a leak in the tubing on the inlet end (Table 5-2).

Table 5-2: Sawyer PointONE™ Filter household user survey results (N=50).

		N	%
Last used filter (N=49)	Today or yesterday	39	80%
	Within the past week	9	18%
	> One month ago	1	2%
How often filter water (N=47)	> Once a day	12	26%
	Once a day	18	38%
	2-3 times per week	15	32%
	Once a week or less	2	4%
Respondent impression of filter (N=44)	Very good	40	91%
	Standard	3	7%
	Bad	1	2%
Change in family health since started using filter (N=48)	Better	47	98%
	No Change	1	2%
Filter has ever blocked up in the past (N=48)	Yes	22	46%
	No	26	54%
How often has the filter flow been reduced or blocked (N=42)	Never	26	62%
	Once a day	1	2%
	Once a week	2	5%
	Once a month	6	14%
	Every six months or less	7	17%
Container used to collect water (N=50)	Different container	47	94%
	Same container	3	6%
Observation of backwash procedure (N=49)	Correct	35	71%
	Incorrect	14	29%
Observed cracks in filter casing (N=50)	Yes	7	14%
	No	43	86%

Household water quality

The geometric mean filter flow rate was 77.2 mL/min (95% CI: 61.8, 96.4). The estimated average flow rate according to filter product literature is 719 mL/min (Sawyer Products, n.d.-b).

Between source and filtrate samples, geometric mean *E. coli* reduction was 90%, geometric mean total coliform reduction was 68%, and geometric mean turbidity reduction was 89% (Table 5-1). Median percent reductions for the set of all filters were 87% for *E. coli* (n=50), 65% for total coliform (n=19, excluding all readings at the upper detection limit), and 91% for turbidity (n=50). These median reductions for the set of filters are consistent with percent reductions in geometric means from source water to filtrate, and all three water quality parameters were statistically significantly lower in filtrate than in source water ($p<0.001$). Seven filters (18%) had higher *E. coli* concentrations in filtrate than in source water; the *E. coli* concentration increase was modest in two of the seven filters (7.4 to 8.1 MPN/100 mL and 66 to 73 MPN/100 mL), and greater in five filters, which had an average increase of 87.4 MPN/100 mL *E. coli* from source to filtrate. Of these seven filters, none had observable filter damage, and five users demonstrated correct backwashing.

When categorized by WHO risk levels based on *E. coli* concentrations, no source water was in conformity with the WHO guideline of <1 MPN/100 mL (Figure 5-2). Among source water samples, 12% were considered low risk, 62% intermediate risk, 24% high risk, and 2% very high risk. Among filtrate samples, the distribution was: 30% in conformity, 32% low risk, 32% intermediate risk, 6% high risk, and none very high risk. The categorical distribution was significantly different between source and filtrate samples ($p<0.001$). These results showing 30% of filtrate with no detectable indicator bacteria are consistent with previously-published PointONE™ filter effectiveness data (Kohlitz et al., 2013).

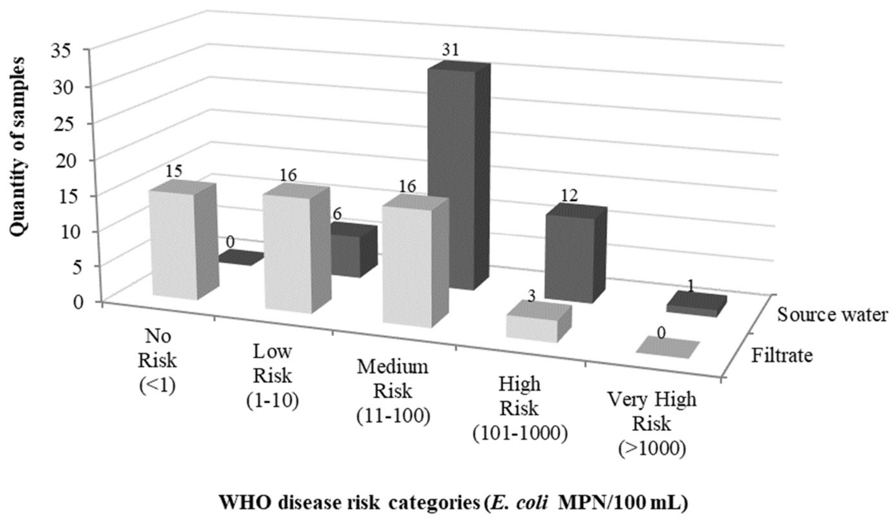

Figure 5-2: Classification of source water and filtrate from Sawyer PointONE™ filters in households according to World Health Organization (WHO) disease risk categories (N=50).

No statistically significant differences were found in bivariate analyses comparing filter performance based on time since distribution, observed filter casing cracks, or demonstrated backwashing procedure. Comparing filters in homes for one year and three years, the newer filters had higher median *E. coli* reduction (94% vs. 85%, n=50, p=0.08), lower median total coliform reduction (54% vs. 75%, n=19, p=0.69), and higher median turbidity reduction (93% vs. 88%, n=50, p=0.21). Comparing filters with visible casing cracks to those without, cracked filters had lower median *E. coli* reduction (67% vs. 91%, n=50, p=0.23), lower median total coliform reduction (44% vs. 68%, n=19, p=0.96), and higher turbidity reduction (97% vs. 90%, n=50, p=0.91). Filters in homes of users who demonstrated correct backwashing had higher median *E. coli* reduction (89% vs. 79%, n=50, p=0.42), higher median total coliform reduction (71% vs. 21%, n=19, p=0.41), and lower median turbidity reduction (88% vs. 92%, n=50, p=0.72) than those in homes where users did not demonstrate the full, correct procedure.

Associations in the multiple logistic regression model were also not statistically significant. Filters that were distributed one year prior had 1.22 times the odds of demonstrating ≥90% *E. coli* removal than did filters distributed three years prior, after correcting for backwashing and cracked status (95% CI: 0.90, 1.66; p=0.20). Filters with visible cracks had 0.88 times the odds of demonstrating ≥90% *E. coli* removal than did filters without visible cracks, when adjusting for filter age and backwashing (95% CI: 0.57, 1.35; p=0.57). Filters from users who demonstrated the correct backwashing procedure had the same odds of having ≥90% *E. coli* removal as those from users who did not, after correcting for filter age and cracking (OR=1.00, 95% CI: 0.72, 1.37; p=0.98).

We hypothesized that filters would have better microbiological performance if they were newer, not visibly damaged, and their users correctly demonstrated knowledge of backwashing maintenance. Median *E. coli* reduction was higher among filters that fit these criteria in bivariate analyses, and filters were more likely to have ≥90% *E. coli* reductions in a multivariate regression model if they were newer and not visibly damaged. These trends support our hypotheses; however, the small sample size limited our ability to detect statistically significant differences.

5.5 Discussion

In household microbiological effectiveness testing of PointONE™ filters still in use in homes after one or three years, most filters significantly improved drinking water quality. However, only 30% of filtrate samples complied with WHO microbiological guidelines, and 18% of samples had *more E. coli* in the filtered water than in source water. Additionally, up to half of distributed filters were no longer in use in these communities. These household-level results are in contrast to those of a newly-purchased filter, which removed all *E. coli* (>9-log) in spiked laboratory waters, and nearly all *E. coli* in controlled testing of both Maine and Honduran surface waters: data which supports that the PointONE™ could potentially achieve the WHO *1-star* classification based on laboratory efficacy at removing both bacteria and protozoa. These results, where laboratory efficacy is higher than household effectiveness and disuse is high, have been seen with other HWTS options (Boisson et al., 2013; Boisson, Schmidt, Berhanu, Gezahegn, & Clasen, 2009; Joe Brown, Sobsey, & Loomis, 2008; Levy et al., 2014; Reller et al., 2003; Christine E Stauber, Ortiz, Loomis, & Sobsey, 2009).

Average *E. coli* reduction in households (90%) is consistent with published data for locally-produced filters such as biosand filters (C.E. Stauber et al., 2006; Christine E Stauber, Kominek, Liang, Osman, & Sobsey, 2012). When compared to household performance of other commercially-produced membrane filters used for six months to two years, these PointONE™ filter results are consistent with the Nerox™ (A-Aqua, Oppegaard, Norway) flat-sheet 0.28 µm membrane filter (80-93% thermotolerant coliform reduction) (Ensink, Bastable, & Cairncross, 2015). However, they are lower than household performance of the 0.02 μm hollow fiber membrane Lifestraw® Family Filter (Vestergaard Frandsen, Lausanne, Switzerland), which has demonstrated 98-99.9% reduction in indicator organisms (Boisson et al., 2010; Peletz et al., 2012, 2013; Rosa, Majorin, et al., 2014), and a prototype household filter developed by the Swiss Federal Institute of Aquatic Science and Technology which utilizes a BIO-CEL® (MICRODYN-NADIR, Wiesbaden, Germany) 0.04 μm flat-sheet membrane (98% reduction) (Perron, 2012). Similarly to the PointONE™ filter, all of these household filters are intended for long-term household use. Comparative published quantitative data was not located for either the Sawyer PointONE™ or other 0.1 μm hollow fiber microfilters in household settings.

Total coliform reduction was lower than expected in household effectiveness testing. Interestingly, in controlled field efficacy testing, the new filter removed all total coliform in the Maine water, but only a partial amount in Honduran water (Table 5-1). The cause of this discrepancy is unknown, but some possible explanations are that: 1) different sizes of coliform species in the Honduran test water were not excluded by the 0.1 μm pore size; or 2) bacterial growth within the membrane persisted even after backwashing, and these bacteria recontaminated filtered water.

Backwashing is the only maintenance recommended by the PointONE™ filter manufacturer. While a demonstration of correct maintenance knowledge is an imperfect surrogate for actual user behavior, users in these communities reported relatively infrequent membrane blockage, or fouling, and most respondents (71%) correctly demonstrated how to backwash the filter. In household effectiveness testing, filters were backwashed prior to flow rate testing and water sample collection for microbiological analysis. The mean filter flow rate was only 11% of what would be expected of a new filter, which is consistent with previous research that identified that backwashing alone may be insufficient to clear severely fouled membranes (Murray et al., 2015).

Also, many filtrate samples contained *E. coli*. The hollow fiber membrane operates on the principle of size exclusion, so the reason for *E. coli* presence in filtrate is unknown. Possible explanations are that: 1) internal membrane fibers may have burst, allowing short-circuiting of unfiltered water; or 2) users may have backwashed the filter with contaminated water, and membranes were biofouled at the outlet side or on internal surfaces of hollow membrane fibers. Enumerators observed two users (4%) backwashing filters with unfiltered water during the survey. Despite users in these communities being trained on filter operation and maintenance and demonstrating proficiency at cleaning procedures, there was a high incidence of abandoned filters, and filters with slow flow rates and lower than expected microbiological performance.

This research is limited by selection bias, lack of household demographic data, small sample size, and variable microbiological methods. Households were not randomly selected, and those with nonworking or missing filters were excluded from selection, as a primary research objective was to test microbiological effectiveness of in-use filters. Overall, 45% of filter recipient homes were surveyed in the two communities, but not all homes were visited to determine if filters were in use. As such, the quantity of beneficiary households with nonworking or missing filters is unknown, and we should not extrapolate these results to estimate usage rates in this or other settings. Had non-filter-users been included, we would likely see a higher rate of broken filters and lower rates of satisfaction and recent filter usage. Also, the lack of demographic data collection did not allow us to analyze results controlled for variables such as socioeconomic status or water, sanitation, and hygiene behaviors that are often correlated with HWTS use (Figueroa & Kincaid, 2010); however, these factors may not affect objective measures such as microbiological removal rates. Additionally, the small sample size is prohibitive in identifying differences in sub-analyses of the data. While some trends were seen in water quality data (such as better *E. coli* removal performance in newer filters and filters without visible damage), these differences were not statistically significant. Finally, different microbiological detection methods were used in the laboratory and in field testing, so there are potential limitations in directly comparing data collected with different methods.

To our knowledge, this is the first peer-reviewed quantitative field effectiveness data evaluating the PointONE™ filter. Comprehensive microbiological testing with rigorous methods and objective outcomes of filter performance evaluated household effectiveness as well as controlled laboratory and field efficacy. Further research is recommended to confirm microbiological field effectiveness results over long-term follow-up with a larger sample size. More research is also needed to understand the discrepancy between new and used filter performance, partial total coliform removal in controlled field efficacy testing, and possible PointONE™ filter failure mechanisms.

5.6 Conclusions

The PointONE™ filter is a HWTS option promoted worldwide. It has been shown to be efficacious in laboratory settings and to reduce diarrheal incidence in short-term follow-up, although limited available field effectiveness data has shown reduced microbiological performance when employed in users' homes. This evaluation confirmed high *E. coli* reductions in controlled efficacy testing of new PointONE™ filters with laboratory-spiked and natural waters. In field effectiveness testing of PointONE™ filters in two communities where many filters had already been abandoned after 1-3 years, most remaining filters improved household drinking water quality, yet 70% of filtrate contained *E. coli,* and filter flow rates were slow. Total coliform reduction was also lower than expected in field efficacy tests and in users' homes. The microbiological performance discrepancy between new and used filters and potential PointONE™ filter premature failure mechanisms are not well understood; future research on these topics, and future field effectiveness research with larger sample sizes, is recommended.

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5.8 Citation

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6 Evaluation of consistent use, barriers to use, and microbiological effectiveness of three new household water treatment technologies in Haiti, Kenya, and Nicaragua

6.1 Abstract

There is growing interest in developing new household water treatment (HWT) technologies to improve drinking water quality and reduce diarrheal disease. HWT technologies are typically evaluated under ideal laboratory and field conditions, although true health gains depend on consistent, effective, household use, which is inconsistently reported. We conducted four evaluations of three prototype HWT technologies, two filters and one electrochlorinator, with 60-82 households each. Households were visited four times between 1 week-14 months after receiving the HWT technology. At each visit, enumerators administered a survey, observed if water was treated with the technology (confirmed use), and collected treated and untreated samples for microbiological analysis. Consistent use was defined as the proportion of total visits with confirmed use. Overall, 2-72% of households demonstrated 100% consistent use (confirmed use at all follow-ups). Consistent use was positively associated with baseline HWT knowledge and practice and belief that drinking water was unsafe, and negatively associated with technological problems. Barriers to use were behavioral, such as users forgetting or not being home, and technological device failures. Technologies demonstrated 68-96% E. coli reductions, with 18%-70% of treated samples having detectable E. coli. Results highlight the importance of realistic use evaluations within HWT technology design cycles, the need for standard evaluation metrics, and difficulties achieving both consistent HWT use and microbiological effectiveness.

6.2 Introduction

Globally, 663 million people lack access to an improved water source (WHO/UNICEF, 2015), and an estimated 1.2 million more depend on microbiologically contaminated sources (Onda et al., 2012). Approximately 502,000 deaths from diarrheal disease are attributed annually to drinking these inadequate water sources (Prüss-Ustün et al., 2014b). While an aim of the Sustainable Development Goals is to provide all households with reliable, safely-managed, piped drinking water (WHO/UNICEF, 2017), household water treatment (HWT) practices – such as boiling, chlorination, and filtration – are promoted as interim incremental improvements for those without safe drinking water (WHO, 2011b). Practicing HWT has been shown to improve microbiological water quality and reduce diarrheal disease among users (T. F. Clasen et al., 2015; Fewtrell et al., 2005; Waddington et al., 2009; Wolf et al., 2014).

Although an estimated 1.8 billion people practice HWT globally (Rosa & Clasen, 2010; Yang et al., 2012), and a variety of HWT technologies exist, there has been significant recent interest in developing new HWT technologies (Majuru, 2017). The goal is to develop one ideal technology that is microbiologically efficacious, robust, durable, sustainable, affordable, and easy to use to treat sufficient water volume in developing country household and emergency settings (CAWST, 2017a).

HWT technologies are typically evaluated by first conducting laboratory tests to determine microbiological efficacy at reducing disease-causing organisms, and then by conducting randomized controlled trials (RCTs) to evaluate health impact (Daniele S Lantagne et al., 2006). Between 2011-2014, the World Health Organization (WHO) established recommended HWT laboratory microbiological efficacy targets (WHO, 2011a), developed laboratory testing protocols (WHO, 2014d), and launched a voluntary scheme to complete this efficacy testing (WHO Scheme). The WHO Scheme establishes reduction rates for bacteria, viruses, and protozoa, and based on results classifies HWT technologies as: three-star (4-log bacteria and protozoa reductions and 5-log virus reduction), two-star (2-log bacteria and protozoa reductions and 3-log virus reduction), or one-star (achieves two-star target for any two pathogen classes) (WHO, 2016). After laboratory efficacy testing under the WHO Scheme or by others, HWT technologies generally undergo highly-controlled, short-term RCTs to evaluate if the HWT technology reduces users' diarrheal disease burden (Daniele S Lantagne et al., 2006). RCTs may be as short as three months, and measure household outcomes as frequently as each week (T. F. Clasen et al., 2015). These evaluations measure laboratory performance and disease reduction under ideal circumstances.

To achieve health gains in real-world situations, HWT technologies must be used correctly and consistently by populations at risk of diarrheal disease to improve household water quality (Thomas Clasen, 2015). Evidence suggests that diarrheal disease reductions are higher when HWT technologies are more consistently used (Arnold & Colford, 2007; T. F. Clasen et al., 2015), and even occasional consumption of contaminated water can limit health gains (Joe Brown & Clasen, 2012; Kyle S Enger, Nelson, Clasen, Rose, & Eisenberg, 2012; Kyle S Enger et al., 2013; Hunter, Zmirou-Navier, & Hartemann, 2009). Inconsistent HWT use may arise from barriers to use such as technologies being undesirable, impractical, or difficult to use (Boisson et al., 2009); or breaking and/or lacking supply chain for replacement parts (T. F. Clasen, Brown, & Collin, 2006). Users may also not perceive the need for treatment or be accustomed to treating drinking water (Ojomo et al., 2015). The HWT technology must also be microbiologically effective, or reduce disease-causing organisms in actual users' household drinking water.

Despite the importance of understanding consistent use, barriers to use, and microbiological effectiveness to optimize an HWT technology's success in households, these metrics are not systematically measured, reported, or addressed in advance of new HWT technology sales or distributions. The aim of this research was to evaluate consistent use over time, identify barriers to use, and measure microbiological effectiveness of three prototype HWT technologies – shown to be efficacious in the laboratory setting – in realistic household settings in order to inform future technological design and implementation decisions.

6.3 Methods

6.3.1 HWT technologies and study locations

Three HWT technologies were evaluated: locally-produced biosand filters (BSF) in four communities near San Juan del Sur, Nicaragua; a personal chlorine generator (electrochlorinator) in two communities near Leogane, Haiti; and a combination ceramic filter and bromine disinfectant system (ceramic filter) in two communities each near Leogane, Haiti and Kisumu, Kenya. Each evaluation lasted between 9-14 months (Table 6-1).

The BSF is a household-scale, intermittently-operated slow sand filter (CAWST, 2012). BSFs are typically housed in plastic or concrete casings, which are either expensive or difficult to produce and transport. Two inexpensive and lightweight plastic casing designs were evaluated in this study: a 10-inch diameter PVC sanitary pipe with similar design parameters to concrete filters (St. John, 2014), and a smaller 5-gallon plastic bucket design (Napotnik, 2014). To use either design, users pour water in the top, wait for it to pass through the sand, and dispense water from a tap on the secondary storage container. In laboratory testing, large BSFs similar to the PVC design have demonstrated >3-log bacteria, >0.3-log virus and >4 protozoan cyst reductions, and plastic bucket BSFs demonstrated >2-log bacteria, >0.4-log virus, and >4 protozoan cyst reductions (Napotnik, 2014).

The electrochlorinator is a hand-held chlorine generator that uses electrolysis to convert salt and water into sodium hypochlorite. To use the electrochlorinator, users dissolve salt into water in a provided bottle, pour the brine solution into the device's chamber, select the water volume to treat (1 gallon or 5 gallons), press the button, and wait for electrolysis to occur (30 seconds to 5 minutes, depending on selected volume). Users then pour the solution into their water storage container, and wait 30 minutes before drinking. The target chlorine dosage is 2.5 mg/L. The battery is charged with a provided cable or integrated solar panel. The electrochlorinator demonstrated >6-log bacteria and >3-log virus reductions in laboratory testing, and received a one-star rating under the WHO Scheme (WHO, 2016).

The ceramic filter system uses two-stage treatment: ceramic filtration, then bromine disinfection to enhance virus inactivation and residual protection. To use the filter system, users pour water into the top (7-L) reservoir and wait for it to pass through a 6-inch ceramic filter disk and a cartridge of bromine-impregnated polymer beads, which release 1-4 mg/L bromine. Users dispense filtered water from an integrated tap in the bottom reservoir. This technology demonstrated >7-log bacteria, >4-log virus, and >4-log protozoan cyst surrogate reductions in the laboratory with 4 mg/L bromine residual (Gittins, 2016). In the field evaluation of prototype units, the bromine dose was 1.5 mg/L to alleviate taste concerns and prevent the need for cartridge replacement midway through the evaluation.

6.3.2 Community and household selection and baseline survey

For each evaluation, at least two communities were identified by partner organizations to participate based on four criteria: primarily dependent on unimproved water supplies, accessibility for the study team, community willingness to participate, and availability of a health promoter. Within each identified community, partner staff or health promoters identified households for inclusion based on the following: households primarily relied on unimproved drinking sources, had at least one child under 5 years, and were willing to participate. The target number of households varied between 60-88 per evaluation (Table 6-1). Baseline surveys consisting of questions about demographics and drinking water treatment knowledge, attitudes, and practices, were conducted with all households. Surveys were administered preferentially to adult female heads of household by trained local enumerators. If no adult respondent was available, enumerators revisited the household at least once.

6.3.3 Community training and follow-up

Health promoters and research staff conducted 1-3 hour training sessions with heads of household in each study community. Meetings included general water, sanitation, and hygiene information, and HWT technology operation, assembly, and maintenance. Households received HWT units free of charge after the training. Paid health promoters visited homes once per month to answer questions and repair or replace broken units, except in the BSF evaluation, where partner staff visited households once or twice over the study period.

6.3.4 Household follow-up surveys

Four follow-up surveys were conducted, as above, with households at various unannounced times ranging from 1 week to 14 months after technology distribution (Table 6-1). Surveys focused on questions of HWT acceptability, use, operation, and maintenance, and HWT technology observations.

6.3.5 Water quality test methods

During each survey, respondents were asked for a cup of water they would drink, and if that water had been treated in the home. If yes, the enumerator asked for a cup of untreated water from the same source. Samples of untreated and treated water were collected aseptically in sterile 125-mL WhirlPak® bags with sodium thiosulfate (Nasco, Fort Atkinson, WI). For filters, samples were also collected directly from filter outlets. Samples were transported on ice to a field laboratory, stored in a refrigerator, and processed within 12 hours by membrane filtration (APHA AWWA WEF, 2005) with m-ColiBlue24® media (Hach Company, Loveland, CO) for simultaneous detection of *Escherichia coli (E. coli)* and total coliform. Samples were diluted appropriately with sterile buffered water, vacuum filtered through a 45-micron filter (EMD Millipore, Billerica, MA), placed in a plastic petri dish with a media-soaked pad, and incubated for 24 hours at 35°C. Colonies were then counted and concentrations calculated. For quality control, 10% of samples were duplicated, and a sterile buffered water blank was run every 20 plates.

For HWT technologies with chlorine or bromine, enumerators tested free chlorine residual (FCR) or total bromine residual (TBR) of treated and untreated samples at the household. Electrochlorinator samples were tested for FCR with a LaMotte DPD test tube kit (LaMotte Company, Chestertown, MD) and ceramic filter samples were tested for TBR with a Hach CN-70 color wheel test.

6.3.6 Data analysis and outcome measures

Household survey data was recorded on paper forms, entered into EpiData 3.1 (The EpiData Association, Odense, Denmark), exported to Microsoft Excel (Microsoft Corporation, Redmond, WA), and cleaned. Microbiological results were entered into Microsoft Excel. Statistical analyses were performed in R 3.3.1 software (R Foundation for Statistical Computing, Vienna, Austria). For all statistical tests and regression coefficients, p-values <0.05 were considered statistically significant.

Reported, confirmed, and consistent use

Reported use was defined as the proportion of households reporting still using the HWT technology. Confirmed use was defined as the proportion of households whose current drinking water was treated by the HWT technology, as determined by enumerator observation or positive FCR. Consistent use was defined as the proportion of completed follow-ups in which the household had confirmed use.

Barriers to use

Multiple logistic regression models were run with consistent use as a binary outcome (high or low). Explanatory variables, selected *a priori*, included household demographics and socioeconomic status (SES), baseline water practices and beliefs, and follow-up reported technical problems and support. SES was established using principal components analysis on household variables and segmenting the population into quintiles or tertiles. Final variables were selected using backwards stepwise regression choosing models with a low Akaike information criterion (AIC) value.

Additional barriers to use were identified by analyzing survey responses about why users sometimes drink untreated water, why they may not use the HWT technology, and reasons for no longer using the technology if use was abandoned. Technical issues were summarized by classifying reported problems as minor (could likely be remedied by the user) or major (would require large repair or replacement), and tallying user questions or comments about the HWT technology.

Microbiological effectiveness

Percent reductions in geometric mean *E. coli* and total coliform were calculated between untreated and treated samples, where those with undetectable bacteria were replaced with a value one-half the detection limit. Percent reductions were also calculated for paired samples limited to those with untreated water ≥100 CFU/100 mL, to identify minimum 2-log (99%) reduction. Bacteria concentrations were compared between samples taken directly from the filter tap and those collected in a user's cup to identify post-treatment contamination. Treated and untreated samples were categorized by health risk according to WHO guidelines for *E. coli* concentrations (WHO, 2011b) and compared using chi-squared tests of independence. Samples from BSF follow-up 1 were excluded from analyses, as required filter conditioning had not been reached.

Linear mixed effects regression models were run with log-transformed *E. coli* concentration in treated samples as the outcome. Household was entered as a random effect variable to account for repeated visits. Fixed effect variables, selected *a priori,* included untreated water quality, technology condition, reported use, demographics, and baseline water practices. Final variables were selected using backwards stepwise regression and choosing models with a low AIC value. P-values were obtained by likelihood ratio tests of the full model versus one without the effect in question.

6.3.7 Ethics approval

Each individual study protocol was approved by the Tufts University Institutional Review Board and by local government review boards where applicable.

Table 6-1: Summary of four HWT technology evaluations.

	Biosand filter (Nicaragua)	**Electrochlorinator (Haiti)**	**Ceramic filter (Kenya)**	**Ceramic filter (Haiti)**
HWT description	Plastic-casing biosand filter (small and large sizes)	Hand-held electrochlorinator for chlorine generation	Ceramic disk filter and bromine disinfection unit	Ceramic disk filter and bromine disinfection unit
Location	San Juan del Sur, Nicaragua	Leogane, Haiti	Kisumu, Kenya	Leogane, Haiti
Communities included	4	2	2	2
Households enrolled	88 households	60 households	76 households	76 households
Sample size for analysis	82 households	59 households	76 households	75 households
Timing of follow-up visits	1 week 2 months 6 months 14 months	2 weeks 6 months 8 months 13 months	2 weeks 3 months 6 months 10 months	2 weeks 4 months 6 months 9 months
Overall length of evaluation	14 months	13 months	10 months	9 months
Total follow-up surveys completed	293	228	287	287
Total paired samples analyzed	201	60	206	191

6.4 Results

6.4.1 Baseline information

Baseline surveys were completed with 88 BSF, 60 electrochlorinator, and 76 ceramic filter households in each country. Respondents were primarily women (84-100%). The majority of heads of households could read (80-91% female and 73-99% male), and most respondents attended school (Table 6-2). Most enrolled households (72-95%) owned a mobile phone. Almost all BSF households (95%), one of two enrolled communities in the Haiti electrochlorinator evaluation (43% of all households), and few ceramic filter households (3-7%) had wired electricity. Household construction varied, where 75-80% of Haitian households and 9% of Kenyan households had concrete floors. Reported diarrhea for children under five varied between 8-28% of households in different settings. Reported health problems were similar for the two Haiti populations, but were different for Nicaragua and Kenya populations (Table 6-2).

Table 6-2: Baseline household demographic information.

	Biosand filter (Nicaragua)		Electro-chlorinator (Haiti)		Ceramic filter (Kenya)		Ceramic filter (Haiti)	
	N=88[1]		N=60		N=76		N=76	
N(%) Female Respondents	73	(84%)	53	(88%)	76	(100%)	73	(96%)
Mean (sd) respondent age	38.5	(15.0)	34.2	(11.4)	28.2	(7.67)	35.9	(11.6)
N(%) Respondent attended some school	74	(85%)	51	(85%)	73	(96%)	63	(83%)
Mean (sd) Respondent number of years of school completed	6.1	(3.3)	9.5	(3.6)	6.9	- [2]	7.9	(2.8)
N(%) Female head of household can read	72	(86%)	49	(82%)	68	(91%)	61	(80%)
N(%) Male head of household can read	55	(73%)	47	(86%)	70	(99%)	55	(90%)
N(%) Houses with concrete floors	28	(32%)	45	(75%)	7	(9.2%)	61	(80%)
N(%) Households with wired electricity	82	(95%)	26	(43%)	5	(6.6%)	2	(2.6%)
N(%) Households with mobile phones	65	(75%)	56	(93%)	72	(95%)	55	(72%)
Mean (sd) Number of people per household	5.1	(2.3)	6.4	(2.7)	5.9	(2.0)	5.4	(1.9)
N(%) Households with children <5 yrs with diarrhea in past 2 weeks	7	(8%)	6	(9%)	28	(28%)	13	(21%)
N(%) Top three reported health problems								
Cold / flu	20	(24%)	34	(57%)	18	(24%)	-	-
Cough / respiratory	30	(36%)	-	-	30	(40%)	-	-
Headache	-	-	29	(48%)	-	-	36	(47%)
Malaria	-	-	-	-	47	(62%)	-	-
Stomach/abdominal pain	-	-	-	-	-	-	23	(30%)
Fever	-	-	48	(80%)	-	-	42	(55%)
Kidney problems	15	(18%)	-	-	-	-	-	-

Notes:

1. Surveys were conducted with 88 households, yet some questions were omitted by some respondents.
2. This survey asked for levels of school completed (primary, secondary, etc.). Average values of these ranges were used to extrapolate a mean number of years completed; however, standard deviation was not calculated.

Access to improved water sources was lowest among Kenyan households (17%) and highest among Haiti electrochlorinator households (62%), where one of two communities had access to piped water system with on-plot connections. This community also had the lowest proportion of households with stored drinking water (40%, data not shown). At baseline, microbiological contamination was lowest among electrochlorinator households (geometric mean *E. coli* 2.9 CFU/100 mL, with 57% of samples <1 CFU/100 mL) (Table 6-3).

Knowledge and practice of HWT was lowest among Nicaraguan households, where respondents named 1.7 HWT methods (versus 2.4-3.3 in other populations), and 55% of households reported ever treating their water (versus 93-98% of other populations). At baseline, 22% of BSF, 73% of electrochlorinator, 71% of Kenyan ceramic filter, and 36% of Haitian ceramic filter households reported treating their water frequently or daily. However, only 8%, 12%, 33%, and 18% of households (respectively) had treated water at the time of the baseline visit. This represents reported HWT use ranging from 2-6 times confirmed HWT use at baseline (Table 6-3).

Table 6-3: Baseline household water and sanitation information.

	Biosand filter (Nicaragua)		Electro-chlorinator (Haiti)		Ceramic filter (Kenya)		Ceramic filter (Haiti)	
	N=88		N=60		N=76		N=76	
N(%) Reported primary drinking water source								
Surface water	7	(8.0%)	1	(1.7%)	62	(82%)	35	(46%)
Piped system or kiosk	32	(37%)	29	(48%)	0	(0%)	18	(24%)
Unprotected well	31	(36%)	0	(0%)	1	(1.3%)	19	(25%)
Protected well	12	(14%)	0	(0%)	9	(12%)	3	(3.9%)
Unprotected spring	4	(4.6%)	22	(37%)	0	(0%)	0	(0%)
Protected spring	0	(0%)	8	(13%)	0	(0%)	0	(0%)
Rainwater	0	(0%)	0	(0%)	4	(5.3%)	1	(1.3%)
Purchased water	1	(1.1%)	0	(0%)	0	(0%)	0	(0%)
N(%) Primary drinking water source is improved	44	(51%)	37	(62%)	13	(17%)	22	(29%)
Median (IQR) minutes to collect water once	10	(30)	7.5	(29)	30	(30)	10	(25)
N(%) Households report paying for water	33	(38%)	1	(1.7%)	37	(49%)	8	(11%)
N(%) Top reported reasons for knowing if water is safe								
Water is treated	6	(29%)	33	(55%)	64	(84%)	60	(79%)
Water looks clear	-	-	30	(50%)	21	(28%)	18	(24%)
If we have used the source for a long time	5	(24%)	-	-	-	-	-	-
N(%) Top reported reasons for knowing if water is not safe								
Water looks cloudy or dirty	13	(19%)	47	(78%)	47	(62%)	39	(51%)
Water is not treated	31	(46%)	21	(35%)	42	(55%)	46	(61%)
Water has bacteria	10	(15%)	26	(43%)	14	(18%)	14	(18%)
N(%) Respondent thinks their current drinking water is safe	16	(20%)	47	(78%)	56	(75%)	50	(70%)
Mean (sd) Number of water treatment methods known	1.7	(0.76)	3.3	(0.93)	2.6	(0.87)	2.4	(0.81)
N(%) Reported ever using any water treatment method	49	(56%)	59	(98%)	74	(97%)	71	(93%)
N(%) Reported using any water treatment method frequently or daily	19	(22%)	44	(73%)	54	(71%)	27	(36%)
N(%) Household has access to a latrine	79	(93%)	33	(55%)	61	(81%)	52	(68%)
N(%) Household has soap for handwashing	28	(35%)	13	(22%)	67	(88%)	48	(63%)
N(%) Household has stored drinking water	74	(88%)	39	(65%)	69	(91%)	62	(82%)
N(%) Household has safe water storage container	5	(6.9%)	24	(41%)	9	(12%)	22	(31%)
N(%) Household's current drinking water was reportedly treated	6	(8.1%)	7	(12%)	25	(33%)	14	(18%)
Geometric mean (95% CI) *E. coli* concentration in drinking water	34	(22-52)	2.9	(1.5-5.7)	29	(14-58)	39	(18-81)
Geometric mean (95% CI) total coliform concentration in drinking water	1643	(1285-2104)	296	(144-609)	806	(441-1473)	469	(254-866)

6.4.2 Reported, confirmed, and consistent use

Following baseline, sample sizes reduced to 82 BSF households (4 filters never installed and 2 households moved), 59 electrochlorinator households (one household moved), and 75 ceramic filter households in Haiti (one respondent died). Additionally, differences were not observed between BSF types, and results were combined.

Reported use was higher than confirmed use at all follow-ups, and both declined over time (Figure 6-1). Confirmed use ranged from 95% at one week to 79% at 14 months for the BSF, and from 39% at two weeks to 13% at 13 months for the electrochlorinator. Confirmed use for the ceramic filter ranged from 89% at two weeks to 68% at 10 months in Kenya, and 93% at two weeks to 50% at nine months in Haiti.

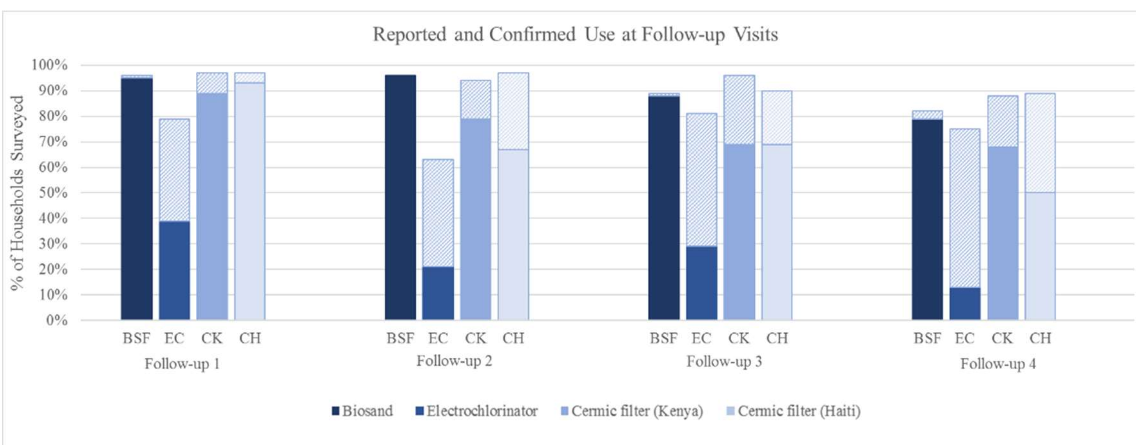

Figure 6-1: Reported and confirmed use of HWT technologies at four follow-up visits.
Note: Reported use is represented by the full bar; confirmed use is represented by lower solid portions of each bar.

Among BSF households, 72% had confirmed use at all follow-ups (or 100% consistent use), and among electrochlorinator households, one (2%) had 100% consistent use (Table 6-4). Overall, 43% and 33% of ceramic filter households in Kenya and Haiti, respectively, had 100% consistent use. In the Haiti evaluation, consistent use varied by community (16% in one community, and 51% in the other).

Table 6-4: N(%) Consistent use of HWT technologies

Consistent use (confirmed use proportion)	BSF (Nicaragua) N=82	Electrochlorinator (Haiti) N=59	Ceramic filter (Kenya) N=76	Ceramic filter (Haiti) N=75
0%	0 (0%)	22 (37%)	4 (5%)	2 (3%)
25%-33%	4 (5%)	23 (39%)	3 (4%)	11 (15%)
50%	3 (4%)	8 (14%)	13 (17%)	16 (21%)
67-75%	16 (20%)	5 (8%)	23 (30%)	21 (28%)
100%	59 (72%)	1 (2%)	33 (43%)	25 (33%)

6.4.3 Barriers to use

High and low consistent use cut-offs for regression models were chosen based on consistent use distributions (Table 6-4) as 100% for the BSF, 25% for the electrochlorinator, and 50% for ceramic filters. For the BSF, reporting using HWT frequently at baseline was associated with 101 times the odds of high consistent use at follow-ups (95% CI=3.38-3003), and an increase of one known HWT method at baseline was associated with 6.85 times the odds of high consistent use (95% CI=1.82-25.8) (Table 6-6). Reporting thinking drinking water was safe at baseline was associated with an 88% decrease in odds of high consistent use for the BSF (OR=0.12, 95% CI=0.02-0.94). For the electrochlorinator, an increase of one technological problem reported per visit was associated with a 98% decrease in odds of high consistent use (OR=0.02, 95% CI=0.001-0.62) (Table 6-7). For the ceramic filter in the Kenya evaluation, an increase of one problem reported per visit was associated with a 95% decrease in odds of high consistent use (OR=0.05, 95% CI=0.004-0.80) (Table 6-8). For the ceramic filter in the Haiti evaluation, reporting thinking drinking water was safe at baseline was associated with 90% decrease in odds of high consistent use (OR=0.10, 95% CI=0.02-0.52), and respondents in one community had 4.8 times the odds of high consistent use compared to respondents in the other community (95% CI=1.43-15.9) (Table 6-9). No clear trend between consistent use and SES or respondent education was observed (Table 6-6 - Table 6-9).

The proportion of respondents reporting sometimes drinking untreated water varied between evaluations, but increased with time. Overall, 24-33% of BSF users reported sometimes drinking untreated water (follow-ups 3 and 4 only), and 77-91% electrochlorinator users, 11-32% Kenyan ceramic filter users, and 17-73% Haitian ceramic filter users reported drinking untreated water at initial to final follow-ups.

When asked why they sometimes drink untreated water, 82-95% of respondents across all evaluations responded with a behavioral reason such as: “when I’m away from home,” “the treated water runs out,” “I forget,” or “I’ve been too busy.” For those reporting sometimes not using the HWT technology, (BSF n=32, electrochlorinator n=126, ceramic filter n=77 in Kenya, n=88 in Haiti), 59% of BSF and 75% and 93% of ceramic filter respondents in Kenya and Haiti, respectively, cited similar behavioral reasons. Only 40% of electrochlorinator users responded similarly, although the most common response ("battery is out of charge") could be interpreted either as a technical failure, or a lack of maintaining the device. Breakage or technical problems were cited as the reason for no longer using the HWT technology for 34% of BSF non-users (n=32), 82% of electrochlorinator non-users (n=51), and 47% of ceramic filter non-users (n=15 Kenya, n=17 Haiti)

Major problems accounted for 31% of BSF problems (n=52), 88% of electrochlorinator problems (n=105), 40% of Kenyan ceramic filter problems (n=52), and 60% of Haitian ceramic filter problems (n=45). Major problems were reported in <10% of all household surveys with the two filter technologies, and 41% of household surveys for the electrochlorinator. Major problems differed by technology. BSF units most commonly had cracked plastic casings/buckets or outlets blocked by sand. Post-mortem electrochlorinator analysis conducted by the manufacturer identified a defective interior seal, which caused electronics to fail after getting wet. Failed ceramic filter systems were most often due to separated bromine disinfectant cartridges or cracked ceramic filters.

Throughout all follow-up visits, 3-14% of respondents had technical usage questions. This was highest for the electrochlorinator (14% of respondents), which had 54 complete unit failures, and for the biosand filter (13%), where there was no regular health promoter visiting the households throughout the evaluation.

In contrast to barriers to use detailed above, self-reported user acceptability (positive responses to questions about liking water taste, ease of use, recommend to others, and plans to continue using) remained high throughout all evaluations. Overall, ≥87% of respondents gave positive responses to each question.

6.4.4 Microbiological effectiveness

Reductions in geometric mean *E. coli* were 80% for the BSF, 72% for the electrochlorinator, 68% and 96% for the ceramic filter in Kenya and Haiti, respectively. When limiting to untreated samples ≥100 CFU/100 mL, reductions in geometric mean *E. coli* were 97.5% for BSF (n=66), 99.7% for the electrochlorinator (n=4), and 97.4% and 99.0% for the ceramic filter in Kenya and Haiti, respectively (n=49, 105) (Table 6-5). *E. coli* and total coliform concentrations were statistically significantly lower in treated samples than in untreated samples in all cases (paired t-test on log-transformed values, $p<0.0001$) (Table 6-5). *E. coli* and total coliform concentrations were significantly lower in samples collected directly from filter outlets as compared to samples from a user's cup (paired t-test on log-transformed values, $p<0.05$, (Figure 6-3).

Treated samples met WHO guidelines of undetectable *E. coli* in 30% of BSF, 82% of electrochlorinator, 49% of ceramic filter in Kenya, and 47% of ceramic filter in Haiti samples (Figure 6-2). Treated samples met the low risk cutoff (<10 CFU/100 mL), in 62% of BSF, 93% of electrochlorinator, 62% of ceramic filter in Kenya, and 68% of ceramic filter in Haiti samples. Comparing percentages of untreated and treated samples in the no risk or low risk categories, improvements were seen for 26% of BSF, 23% of electrochlorinator, and 18% and 40% of ceramic filter samples in Kenya and Haiti, respectively (Figure 6-2). Untreated and treated categorizations were significantly different for all HWT technologies (p<0.02).

TBR was ≥0.2 mg/L in 21% of ceramic filter-treated samples in Kenya, and 17% of samples in Haiti.

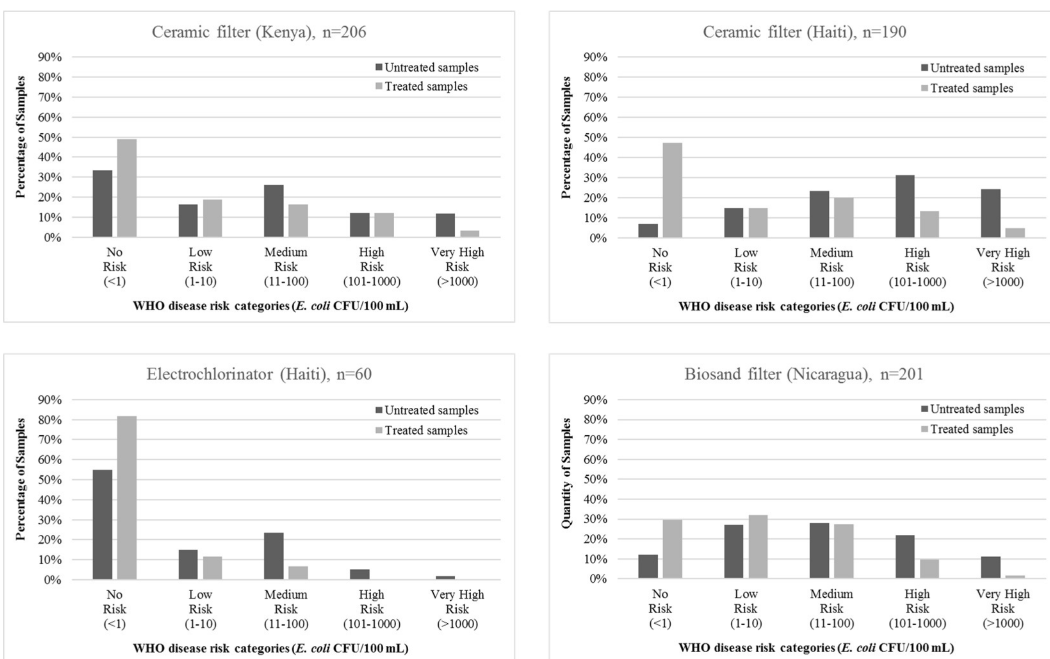

Figure 6-2:Categorized E. coli results into WHO health risk categories for untreated and treated samples, by HWT technology.

Table 6-5: E. coli and total coliform concentrations in paired untreated and treated samples with the HWT technology at all follow-ups. Results are presented for all samples, and then for only those samples which had untreated water with ≥100 CFU/100 mL, in order to demonstrate minimum 99% reductions. All reductions are statistically significantly different (p<0.05).

		E. coli **(CFU/100mL) Geometric mean (95% CI)**				**Total coliform (CFU/100mL) Geometric mean (95% CI)**			
		N	**Untreated**	**Treated**	**% Reduction**	**N**	**Untreated**	**Treated**	**% Reduction**
All processed samples	Biosand filter (Nicaragua)	201	28 (19-41)	5.8 (4.3-7.8)	79.6%	201	1636 (1276-2097)	406 (318-519)	75.2%
	Electrochlorinator (Haiti)	60	2.7 (1.5-4.8)	0.77 (0.60-1.0)	71.6%	60	179 (84-379)	4.2 (2.3-7.7)	97.7%
	Ceramic filter (Kenya)	206	12 (7.7-17)	3.8 (2.7-5.3)	67.6%	206	349 (238-512)	40 (26-63)	88.5%
	Ceramic filter (Haiti)	190	106 (72-157)	4.7 (3.2-6.9)	95.6%	190	2428 (1921-3069)	116 (74-180)	95.2%
Paired samples with untreated concentrations ≥100 CFU/100 mL	Biosand filter (Nicaragua)	66	681 (478-969)	17 (10-29)	97.5%	193	1944 (1569-2409)	416 (324-534)	78.6%
	Electrochlorinator (Haiti)	4	449 (96-2100)	1.2 (0.21-6.8)	99.7%	39	1191 (797-1781)	8.6 (3.8-19.2)	99.3%
	Ceramic filter (Kenya)	49	847 (600-1198)	22 (10-49)	97.4%	144	1613 (1264-2058)	67 (40-113)	95.8%
	Ceramic filter (Haiti)	105	820 (622-1080)	8.4 (4.8-14.8)	99.0%	180	3001 (2442-3688)	139 (89-217)	95.4%

For all HWT technologies, an increase in log *E. coli* concentration of untreated samples was significantly associated with an increase in geometric mean treated water *E. coli* concentrations (regression coefficients: 1.12-1.52, $p<0.005$, supplemental information (Table 6-10 - Table 6-13).

Variables significantly associated with log *E. coli* concentration in BSF treated water were follow-up number, although without a clear temporal trend (2.16 and 0.41 times change in geometric mean *E. coli* for follow-ups 3 and 4, respectively, as compared to follow-up 2, $p<0.001$), and reported time since treatment (0.96 times change in geometric mean *E. coli* for each hour increase in time since treatment, $p=0.01$) (Table 6-10). Variables such as filter design type, water source type, measured flow rate, reported frequencies of use and of cleaning components, and demographic variables were not significantly associated with treated water *E. coli* concentration (data not shown).

For the electrochlorinator, variables significantly associated with a decrease in treated water *E. coli* concentration were: having FCR ≥0.2 mg/L (0.11 times change in geometric mean *E. coli*, $p<0.001$), samples from a piped water source (1.98 and 13.9 times change in geometric mean *E. coli* for spring and rainwater, respectively, as compared to piped water, $p<0.001$), water safely stored in covered container with a small opening or tap (0.66 times change in geometric mean *E. coli*, $p=0.04$), users that demonstrated correct use (0.99 times change in geometric mean *E. coli*, $p=0.003$), higher SES (0.51 and 0.40 times change in geometric mean *E. coli* for SES tertiles 2 and 3, respectively, as compared to tertile 1, p=0.01), and reported time since treatment (0.99 times change in geometric mean *E. coli* for each hour increase in time since treatment, p=0.01) (Table 6-11). Variables not significantly associated with a change in treated water *E. coli* concentration include follow-up number and baseline water practices (data not shown).

For the ceramic filter in Kenya, follow-up number was significantly associated with treated water *E. coli* concentration (2.28, 5.36, and 7.08 times change in geometric mean *E. coli* concentration for follow-ups 2, 3, and 4, respectively, as compared to follow-up 1, $p<0.001$) (Table 6-12). TBR measurements were missing from the first follow-up, and were thus omitted from the regression. However, in a second regression model with reduced sample size (n=156 observations versus 206), TBR ≥0.2 mg/L was associated with a non-significant 0.62 times change in geometric mean *E. coli* concentration (p=0.31).

For the ceramic filter in Haiti, TBR was significantly associated with a decrease in treated water *E. coli* concentration (0.32 times change in geometric mean *E. coli* for each 1 mg/L increase, p=0.01). Variables significantly associated with an increase in treated water *E. coli* concentration were follow-ups after follow-up 2 (12.9 and 8.34 times change in geometric mean *E. coli* concentration for follow-ups 3 and 4, respectively, as compared to follow-up 1, $p<0.001$), and the ceramic filter disk having visible cracks (5.66 times change in geometric mean *E. coli* concentration, p=0.04) (Table 6-13).

For the ceramic filter in both locations, variables not significantly associated with a change in treated water *E. coli* concentration include water source type, observed filter water levels, reported frequencies of use and cleaning, reported time since treatment, and household demographic variables (data not shown).

6.5 Discussion

We evaluated consistent use, barriers to use, and microbiological effectiveness of three prototype HWT technologies in four developing country settings. Consistent use ranged from 2-78% of households and was associated with baseline factors such as knowledge and practice of HWT and belief that available drinking water was unsafe, community characteristics, and reported technological problems. Barriers to use included behavioral challenges such as users forgetting or not being home to drink treated water, and technological challenges such as device failures. These barriers existed even with regular household follow-up, availability of replacement parts, and technical assistance from health promoters. When used, technologies improved microbiological water quality, but effectiveness was lower than documented laboratory efficacy in all cases, as *E. coli* was present in 70% of BSF treated samples, 18% of electrochlorinator samples, and 52% of ceramic filter samples. These results from field evaluations of prototype HWT technologies highlight: 1) consistency with literature on existing HWT technologies, 2) the importance of realistic use evaluations within the HWT technology design cycle, 3) the need for standard consistent use and microbiological effectiveness metrics, and 4) the difficulty in achieving both consistent HWT use and microbiological effectiveness.

These results are generally consistent with literature on existing HWT technologies. Other published HWT trials have also reported wide ranges of consistent use, including 13% (Boisson et al., 2009), 68% (Boisson et al., 2010), and 95% (Doocy & Burnham, 2006; Peletz et al., 2012) of users consistently using HWT methods, although definitions and study durations varied. Similarly, among self-reported HWT users in non-trial settings in Zambia, Peru, and India, 4%, 23%, and 76% of rural households, respectively, consistently had treated water at all three study visits (Rosa & Clasen, 2017; Rosa, Huaylinos, et al., 2014; Rosa et al., 2016). Sustained adoption of water technologies is known to be associated with psychosocial factors (perceived disease severity and perceived benefits), contextual factors (age and gender), and technology factors (cost and durability) (Hulland et al., 2015), which is in line with barrier to use results seen here. Finally, HWT field effectiveness being lower than laboratory efficacy is commonly documented with other HWT practices (Boisson et al., 2013, 2009; Joe Brown et al., 2008; Joseph Brown & Sobsey, 2012; Levy et al., 2014; Murray et al., 2017; Psutka, Peletz, Michelo, Kelly, & Clasen, 2011; Christine E Stauber et al., 2009).

Evaluating consistent use, barriers to use, and microbiological effectiveness in realistic household settings helps identify technological design improvements and implementation considerations to optimize HWT use for health impact. On the technology side, these evaluations help HWT developers address design flaws, establish performance expectations, and recognize limitations before release to the public. Although manufacturers expected these prototypes to be market-ready, these evaluations identified design flaws – including bucket selection (BSF), component sealing (electrochlorinator), and bromine cartridge design (ceramic filter system) – to be addressed in subsequent design iterations. Awareness of technology limitations, such as ceramic filter performance with highly turbid water (data not shown), can also guide implementation decisions. By addressing design issues and limitations after laboratory efficacy is established, and then iterating on that design before conducting a health impact trial, technologies will be more robust and less likely to encounter performance-limiting flaws which may under power health impact trials due to breakage (Boisson et al., 2010) or low use (Boisson et al., 2009).

For implementation, results highlighted the importance of HWT users having access to use and maintenance information, technical resources like replacement parts, and behavior change communication. Even still, the provided trainings, graphical use and care instructions, and regular household visits by health promoters in these evaluations did not appear to alter households' preexisting habits, as evidenced by users reporting forgetting to drink treated water and more consistently using technologies if they previously used other treatment methods.

Currently, consistent use is infrequently reported in the literature, often not over time, and definitions vary. In HWT field trials, compliance (a proxy for consistent use) has been defined as the percentage of households with measureable chlorine in drinking water (Arnold & Colford, 2007), percentage of households self-reporting use (Boisson et al., 2010), or the percentage of households that have treated water with improved microbiological quality over untreated water quality (Peletz et al., 2012). Consistent HWT use should be systematically measured and reported alongside diarrheal disease reduction and microbiological effectiveness outcomes to better understand interrelationships. We propose the proportion of follow-up visits with observed or confirmed use as a standard metric for consistent use.

Interpreting microbiological effectiveness collected with varying influent water quality both between and within evaluations is challenging (Rayner, Murray, Joseph, Branz, & Lantagne, 2016). Influent water quality drives both measured *E. coli* reductions and treated water concentrations, as seen in water quality regression models presented here. *E. coli* percent reductions can appear artificially low with low starting concentrations. Limiting samples to high concentrations allows demonstration of higher reductions, but may limit sample sizes and artificially increase reported reductions. For example, the electrochlorinator demonstrated 71.6% *E. coli* reduction considering all samples (n=60), and 99.7% reduction with samples ≥100 CFU/100 mL (n=4). To understand both technology performance and likely disease risks, we propose microbiological results be presented as both reductions (for all samples and those with untreated concentrations ≥100 CFU/100 mL) and concentrations categorized into WHO risk levels.

Research indicates that both high consistent use and microbiological effectiveness are needed to achieve health gains from HWT (Joe Brown & Clasen, 2012; Kyle

S Enger et al., 2013). Many HWT trials report lower-than-expected consistent use and microbiological effectiveness (Rosa & Clasen, 2017; Rosa, Huaylinos, et al., 2014; Rosa et al., 2016), which seemingly call into question sustained HWT health impact in household settings. However, there may be settings, such as short-term emergencies or disease outbreaks, where long-term consistent use is not needed. Additionally, limited consistent use data, particularly in realistic settings, make it difficult to benchmark success. Interestingly, diarrheal disease reductions have also been reported with low consistent use (Boisson et al., 2009) or low microbiological reduction values (Christine E Stauber et al., 2009). Here, one of the best-performing technologies microbiologically, the electrochlorinator, had the lowest consistent use, while the lowest-performing, the BSF, had the highest consistent use. A clearer understanding of the tradeoffs of these two factors in terms of health effects is needed. Recent research suggests that less efficacious HWT technologies used more consistently produces better health outcomes than more efficacious HWT technologies used inconsistently (Brown et al, forthcoming). Given this, perhaps HWT research and development should shift from technology efficacy enhancement, and towards better understanding successful behavior change to encourage consistent HWT use. An HWT technology, no matter how efficacious in the laboratory, is only effective if used.

This work has limitations. First, as these were pilot trials, participants were not randomly selected and sample sizes were not powered to detect small associations in multivariable models. Second, selected communities and households did not always depend on unimproved water sources, and *E. coli* concentrations were sometimes low. Third, households were only provided one HWT technology, free of charge, and evaluation settings were disparate; user preferences may have been more impactful if multiple technologies were compared. Fourth, confirmed use estimates may be over-estimated due to: courtesy bias leading to higher reported use or misleading confirmed use, lack of a completely objective confirmed use indicator for filters (unlike FCR for the electrochlorinator), and users potentially changing behavior as a result of repeated measurements (Zwane et al., 2011). Fifth, electrochlorinator consistent use may be underestimated due to delayed replacement units.

Evaluations of consistent use, barriers to use, and microbiological effectiveness in realistic household settings are critical to follow laboratory efficacy studies of HWT technologies. HWT developers must design robust technologies, pilot them, remedy design flaws, and identify appropriate water quality parameters before scaled distributions or health impact trials. HWT trials should commonly report consistent use with objective indicators, and microbiological effectiveness requires multiple measures to capture nuance. Ensuring both high consistent use and microbiological effectiveness remains a challenge with HWT, and a clearer understanding of tradeoffs is needed to maximize health impact.

6.6 Supporting information

Table 6-6: Biosand filter consistent use logistic regression results (64 degrees of freedom).

	Estimate	Standard Error	p-value	OR (95% CI)
Intercept	-3.265	1.533	0.03	-
Concrete floor	-1.808	0.931	0.052	0.16 (0.03-1.02)
Think water is safe at baseline	-2.095	1.040	**0.04***	0.12 (0.02-0.94)
Report using water treatment frequently at baseline	4.612	1.732	**0.008***	101 (3.38-3003)
Quantity of treatment methods known at baseline	1.924	0.677	**0.004***	6.85 (1.82-25.8)
Community (reference: Community A)	-	-	-	-
Community B	1.330	0.972	0.17	3.78 (0.56-25.4)
Community C	2.027	1.057	0.055	7.59 (0.96-60.2)
Respondent education level (reference: no school)	-	-	-	-
Some primary	3.177	1.270	**0.01***	24.0 (1.99-289)
Completed primary	0.031	1.017	0.98	1.03 (0.14-7.56)
Some secondary	-0.757	1.026	0.46	0.47 (0.06-3.51)
Completed secondary or more	1.283	1.808	0.48	3.61 (0.10-125)

Table 6-7: Electrochlorinator consistent use logistic regression results (55 degrees of freedom).

	Estimate	Standard Error	p-value	OR (95% CI)
Intercept	-1.101	1.441	0.44	-
Female head of household can read	-1.443	0.859	0.09	0.24 (0.04-1.27)
Quantity of treatment methods known at baseline	0.710	0.406	0.08	2.03 (0.92-4.51)
Problems reported per visit	-3.783	1.688	**0.03***	0.02 (0.001-0.62)

Table 6-8: Ceramic filter (Kenya) consistent use logistic regression results (67 degrees of freedom).

	Estimate	Standard Error	p-value	OR (95% CI)
(Intercept)	4.638	1.765	0.01	-
Community	-1.076	0.670	0.11	0.34 (0.09-1.27)
Problems reported per visit	-2.919	1.378	**0.03***	0.05 (0.004-0.80)
SES (reference: level 1)	-	-	-	-
SES level 2	0.605	1.040	0.56	1.83 (0.24-14.1)
SES level 3	-0.098	0.938	0.92	0.91 (0.14-5.69)
SES level 4	-0.555	0.996	0.58	0.57 (0.08-4.04)
SES level 5	-1.880	0.954	**0.049***	0.15 (0.02-0.99)
Respondent education level (reference: no school)	-	-	-	-
Completed primary	-1.323	0.732	0.07	0.27 (0.06-1.12)
Completed more than primary	-1.596	0.899	0.08	0.20 (0.03-1.18)

Table 6-9: Ceramic filter (Haiti) consistent use logistic regression results (66 degrees of freedom).

	Estimate	Standard Error	p-value	OR (95% CI)
Intercept	-0.104	1.0833	0.92	-
Community	1.562	0.614	**0.01***	4.77 (1.43-15.9)
Think water is safe at baseline	-2.312	0.845	**0.006***	0.10 (0.02-0.52)
Had treated water at baseline	1.634	1.144	0.15	5.12 (0.54-48.2)

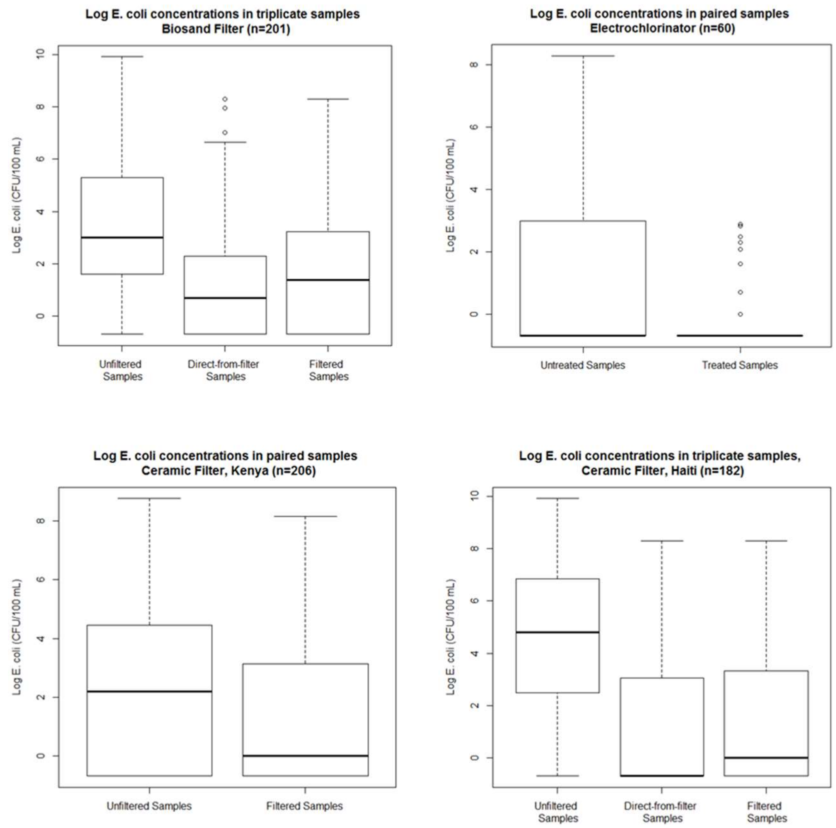

Figure 6-3: E. coli of treated and untreated samples (plus samples taken directly from filters where available) from each HWT technology.

Table 6-10: Biosand filter water quality multiple mixed effects linear regression results (N=191 observations in 78 groups).

	Estimate	**Standard Error**	**p-value**	**Change in Geomean of treated *E. coli* concentration**	**95% CI**
Intercept	1.159	0.296	-	-	-
log(untreated E. coli concentration)	0.245	0.054	**<0.0001***	1.28	(1.15-1.42)
Follow-up number (reference: Follow-up 2)	-	-	**<0.0001***	-	-
Follow-up 3	0.769	0.321	**-**	2.16	(1.15-4.05)
Follow-up 4	-0.895	0.330	**-**	0.41	(0.21-0.78)
Reported hours since treatment	-0.037	0.014	**0.01***	0.96	(0.94-0.99)

Table 6-11: Electrochlorinator water quality multiple mixed effects linear regression results (N=60 observations in 40 groups).

	Estimate	**Standard Error**	**p-value**	**Change in Geomean of treated *E. coli* concentration**	**95% CI**
Intercept	2.332	0.382	**-**	-	-
log(untreated *E. coli* concentration)	0.118	0.043	**0.004***	1.12	(1.03-1.22)
Free chlorine residual ≥0.2 mg/L	-2.193	0.310	**<0.0001***	0.11	(0.06-0.21)
Water source (reference: piped water)	-	-	**0.0002***	-	-
Spring[1]	0.683	0.306	**-**	1.98	(1.09-3.60)
Rainwater	2.632	0.718	**-**	13.90	(3.40-56.7)
Safe storage container	-0.419	0.222	**0.04***	0.66	(0.43-1.02)
Reported hours since treatment	-0.014	0.005	**0.003***	0.99	(0.98-1.00)
User demonstrated correct use	-0.012	0.004	**0.003***	0.99	(0.98-1.00)
SES levels (reference: Level 1)	-	-	**0.01***	-	-
SES level 2	-0.674	0.282	**-**	0.51	(0.29-0.89)
SES level 3	-0.910	0.358	**-**	0.40	(0.20-0.81)

Table 6-12: Ceramic filter (Kenya) water quality multiple mixed effects linear regression water quality results (N=206 observations in 71 groups).

	Estimate	**Standard Error**	**p-value**	**Change in Geomean of treated *E. coli* concentration**	**95% CI**
Intercept	-0.680	0.280	**-**	-	-
log(untreated *E. coli* concentration)	0.417	0.049	**<0.00001***	1.52	(1.38-1.67)
Follow-up number (in reference to Follow-up 1)	-	-	**<0.00001***	-	-
Follow-up 2	0.826	0.321	**-**	2.28	(1.22-4.28)
Follow-up 3	1.680	0.349	**-**	5.36	(2.70-10.6)
Follow-up 4	1.957	0.342	**-**	7.08	(3.62-13.8)

Table 6-13: Ceramic filter (Haiti) water quality multiple mixed effects linear regression results (N=186 observations in 70 groups).

	Estimate	Standard Error	p-value	Change in Geomean of treated *E. coli* concentration	95% CI
(Intercept)	-0.519	0.449	-	-	-
log(untreated *E. coli* concentration)	0.252	0.061	**<0.0001***	1.29	(1.14-1.45)
Follow-up number (reference: Follow-up 1)	-	-	**<0.0001***	-	-
Follow-up 2	0.145	0.468	-	1.16	(0.46-2.89)
Follow-up 3	2.557	0.456	-	12.90	(5.27-31.6)
Follow-up 4	2.122	0.489	-	8.34	(3.20-21.8)
Ceramic disk had visible cracks	1.734	0.877	**0.04***	5.66	(1.02-31.6)
Total bromine residual in treated water (mg/L)	-1.128	0.469	**0.01***	0.32	(0.13-0.81)

6.7 Acknowledgements

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6.8 Citation

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7 Need for certification of household water treatment products: examples from Haiti

7.1 Abstract

The objective was to evaluate four household water treatment (HWT) products currently seeking approval for distribution in Haiti, through the application of a recently-developed national HWT product certification process. Four chemical treatment products were evaluated against the certification process validation stage by verifying international product certifications confirming treatment efficacy and reviewing laboratory efficacy data against WHO HWT microbiological performance targets; and against the approval stage by confirming product composition, evaluating treated water chemical content against national and international drinking water quality guidelines and reviewing packaging for dosing ability and usage directions in Creole. None of the four evaluated products fulfilled validation or approval stage requirements. None was certified by an international agency as efficacious for drinking water treatment, and none had data demonstrating its ability to meet WHO HWT performance targets. All product sample compositions differed from labelled composition by >20%, and no packaging included complete usage directions in Creole. Product manufacturers provided information that was inapplicable, did not demonstrate product efficacy, and was insufficient to ensure safe product use. Capacity building is needed with country regulatory agencies to objectively evaluate HWT products. Products should be internationally assessed against WHO performance targets and also locally approved, considering language, culture and usability, to ensure effective HWT.

7.2 Introduction

Worldwide, an estimated 748 million people drink water from unimproved sources such as unprotected springs, open wells, and surface water (WHO/UNICEF, 2014).The Joint Monitoring Program classifies water sources as improved or unimproved as a proxy for water safety; however an estimated 1.2 billion additional people drink contaminated water from “improved” sources (Onda et al., 2012). Providing reliable, safely managed, piped water to every household is the ultimate goal (WHO/UNICEF, 2014). Meanwhile, for those with unsafe supplies, World Health Organization (WHO) supports incremental improvements, such as household water treatment (HWT), to accelerate health gains associated with safer drinking water (WHO, 2011b). A growing body of evidence demonstrates that HWT options improve the microbiological quality of household water and reduce the burden of diarrheal disease among users (Thomas Clasen et al., 2007; Fewtrell et al., 2005; Waddington et al., 2009), although there remains active debate over the magnitude of the effect (Engell & Lim, 2013; Hunter, 2009; Wolf-Peter Schmidt & Cairncross, 2009).

Until recently, no international certification process existed for HWT products. Point-of-use drinking water treatment products, such as treatment chemicals and water filters, have been certified by the independent standards organization NSF International (NSF) or registered in the United States (US) with the Environmental Protection Agency (EPA). NSF certification is voluntary and consists of product sample review to determine if it meets standards, followed by periodic audits (NSF International, n.d.-c). NSF certifies drinking water treatment chemicals under NSF/American National Standards Institute (ANSI) Standard 60 to ensure minimal health effects (NSF/ANSI, 2012). EPA registers treatment chemicals in the US under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and labels them as: 1) public health pesticides, which reduce organisms of public health concern; or 2) non-public health pesticides, which control microorganisms of economic or aesthetic significance (US EPA, 2010). Registration helps ensure pesticides are used according to approved labels and will not cause environmental harm (US EPA, 2012a). NSF and EPA catalogue certified chemical treatment products and pesticide product labels, respectively, in online databases. Additionally, WHO, EPA and European Union (EU) guidelines for drinking water quality recommend health-based and aesthetic limits for chemical contaminants.

In 2012, WHO introduced a quantitative microbial risk assessment based methodology for evaluating HWT product microbiological performance. This method established tiered, health-based targets classifying HWT products as '*highly protective'* (4-log bacteria and protozoa reduction and 5-log virus reduction), '*protective*' (2-log bacteria and protozoa reduction and 3-log virus reduction), or '*limited protection*' (achieving protective target for two pathogen classes and epidemiological evidence demonstrating disease reduction) (WHO, 2011a). NSF adapted the methodology into protocol P415, and WHO launched a product evaluation scheme in 2014 (WHO, 2014c). These methodologies provide unified guidance for third-party HWT product evaluations, but are not yet widely used. At this time, only first round testing on ten products has begun under the

WHO scheme for evaluating household water treatment technologies (Beetsch, 2014).

HWT products have long been promoted in Haiti, particularly after the 2010 earthquake and subsequent cholera outbreak. In 2012, 59.9% of urban and 78.0% of rural Haitian households, who typically collect and store water in 1-gallon or 5-gallon containers, reported treating drinking water, and approximately 90% of those reported using chlorine products (Cayemittes et al., 2013). Chlorine-based HWT products have been shown to improve microbiological water quality (John A Crump et al., 2005), reduce diarrheal disease incidence in developing countries (Arnold & Colford, 2007), and be an effective long-term HWT intervention in Haiti (Harshfield, Lantagne, Turbes, & Null, 2012). Concerns about taste acceptability (Figueroa & Kincaid, 2010) and trihalomethane formation (D S Lantagne, Blount, Cardinali, & Quick, 2008) with chlorination has generated interest in alternative, non-chlorine-based products; and the HWT market has responded to these concerns by introducing new, chlorine-alternate products, some of which are promoted in Haiti.

The Ministry of Health/Ministère de la Santé Publique et de la Population (MSPP) is responsible for approving HWT products in Haiti. In 2013, MSPP requested technical assistance from Tufts University and US Centers for Disease Control and Prevention (CDC) to develop a national HWT product certification process. The resultant process consists of a validation stage followed by an approval stage (Figure 7-1). To pass the validation stage, product efficacy must be demonstrated through either: 1) certification for drinking water use by an independent organization requiring efficacy data; or 2) laboratory results demonstrating the product's ability to reduce bacteria, viruses, and protozoa to WHO targets. Validated products are evaluated through an approval stage, to determine if a product sample: 1) contains the labeled composition, 2) would produce effluent treated water complying with chemical drinking water quality guidelines, and 3) is labeled with complete information in Haitian Creole and is able to deliver the recommended dosage. Products passing both stages are approved for distribution in Haiti, and MSPP informs manufacturers of the determination. Here we describe the review of four novel, chlorine-alternate HWT products (SAFI, SCI-62®, SilverDYNE®, and Antinfek™10H) evaluated through this certification process in Haiti.

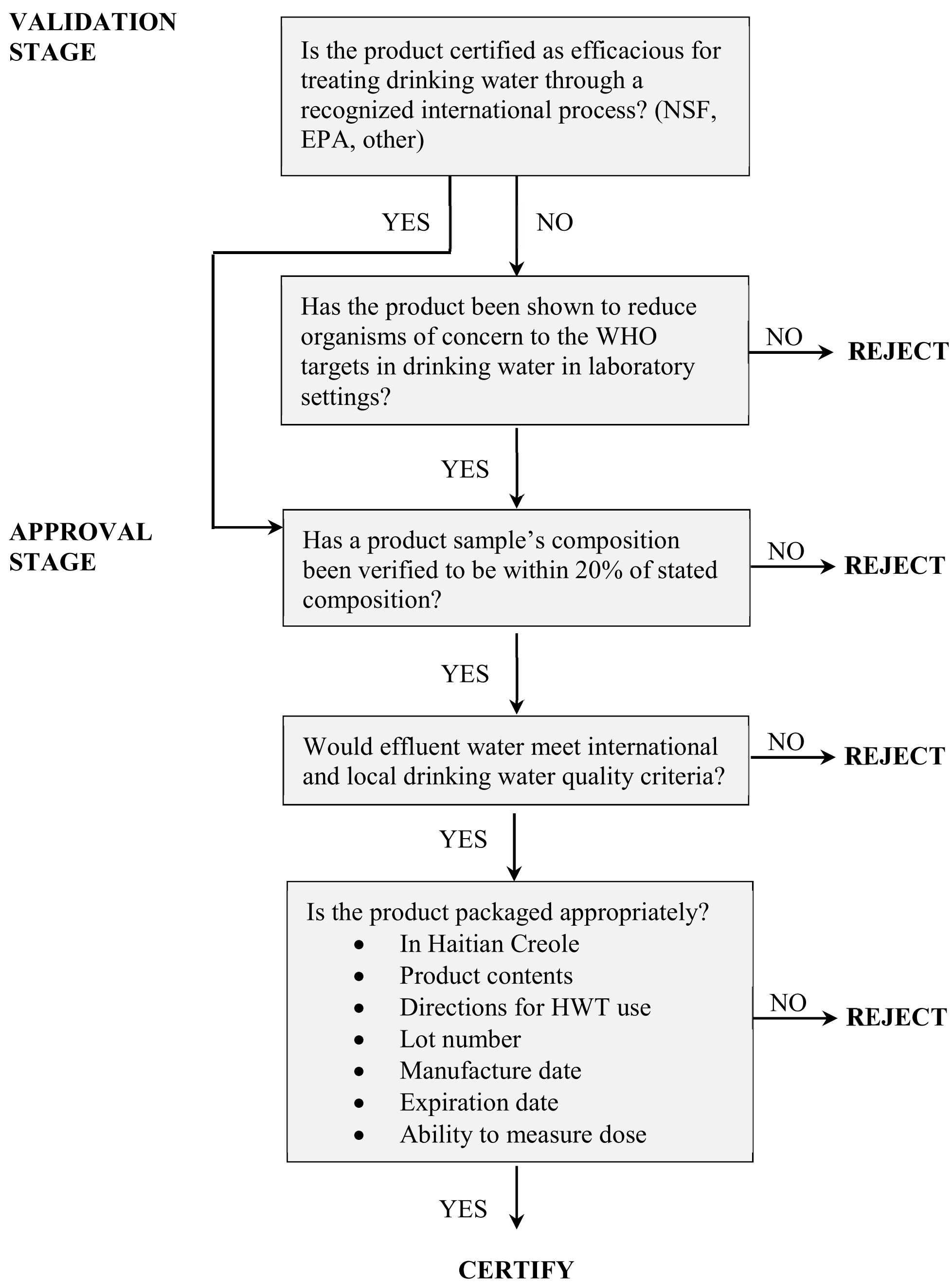

Figure 7-1: Household water treatment (HWT) product certification process framework for treatment chemicals in Haiti.

7.3 Methods

MSPP selected the four initial products for review because manufacturers were currently seeking approval for distribution. Product manufacturers provided MSPP with one or two product samples, and documentation of certifications, efficacy test results, and/or technical manuals. To assess products for approval (Figure 7-1), we reviewed: product certifications, efficacy information, sample composition, compliance with drinking water quality guidelines, and packaging materials.

Online databases were searched to verify product listings with NSF/ANSI Standard 60 – Drinking Water Treatment Chemicals (NSF International, n.d.-a), and registration with EPA as a public health pesticide for drinking water treatment (US EPA, n.d.). We independently investigated additional manufacturer-provided product certifications.

Laboratory efficacy was determined by reviewing manufacturer-provided test data and available literature on efficacy tests of the product (or others with similar composition). Data were considered valid if they: 1) documented results from the product/composition under review; 2) tested the product at manufacturer-recommended dosage and contact time; and 3) demonstrated reduction of bacteria, viruses, and protozoa as recommended by WHO and NSF. The product was considered efficacious if data confirmed its ability to meet the WHO *limited protection* target.

Metals scans (US EPA, 1994) were performed on one sample of each product by an independent, Massachusetts Department-of-Environmental-Protection-certified laboratory (New England Chromachem, Salem MA, USA), identifying the four metals with highest concentrations. Primary constituent metal concentrations listed in product literature were compared with tested concentrations. The percent difference was calculated between actual and expected concentrations, with a maximum acceptable difference of 20%.

For each product, expected chemical concentrations in treated drinking water were calculated using the tested sample chemical concentrations and recommended product dose (liquid drop equal to 0.05 mL (Rowlett, 2012)), and compared to WHO Guidelines for Drinking Water Quality (WHO, 2011b), US EPA Drinking Water Regulations (USEPA, 2009), and EU water quality guidelines (European Commission, 1998).

Product bottles and labels were reviewed for complete information necessary for a household to correctly use the product, including: 1) writing in Haitian Creole; 2) usage directions, including dosage; 3) a mechanism to deliver the dose; and 4) listing of chemical contents, manufacturing lot number, and manufacture and expiration dates.

7.4 Results

7.4.1 SAFI

SAFI, also known as SafeWaterDrops™ ("Safe Water Drops," 2013), is a HWT product marketed by Clean Water Environmental, LLC and manufactured by Haviland Products (Grand Rapids, Michigan, USA) ("Clean Water Environmental," n.d.). Produced in several formulations of zinc sulfate and/or copper sulfate in solution, it is marketed (although not MSPP-approved) in Haiti, Rwanda, and Pakistan (Hilbrands & Hoogewerf, 2012). Directions are to add 1 drop/gallon of water and wait 60 minutes before drinking.

SAFI is not currently listed with NSF/ANSI Standard 60 (NSF International, n.d.-a), although the NSF logo appears on the label and the manufacturer provided an out-of-date registration certificate. SAFI was listed with NSF/ANSI Standard 60 in 2011 (Beetsch, 2014). The product is not EPA-approved for drinking water, but registration is "pending approval for use in wastewater treatment and swimming pools" ("Clean Water Environmental," n.d.). The manufacturer provided documentation of facility ISO 9001:2008 certification and US Food and Drug Administration (FDA) registration; neither certification is relevant to HWT products.

The SAFI manufacturer did not provide MSPP with laboratory efficacy data. Metals such as ionic copper are known to be effective bactericides in aqueous systems, and a literature review of the combined use of copper and zinc for HWT identified two publications. One, a preliminary study of combined copper and zinc efficacy, demonstrated the WHO *limited protection* target can be met; however, results were achieved with 2 mg/L copper and zinc (four times the copper and six times the zinc recommended for SAFI dosing) and six hour contact time (six times that recommended) (Komandur, Malone, & Sobsey, 2013). The second publication, a study of bacterial removal by several SAFI formulations, demonstrated varying performance - dependent on dosage, product pH, and composition - but suggested a contact time of 1-4 hours may be required to meet WHO-recommended bacterial removal (virus and protozoa data unavailable) (Hoogewerf & Johnson, 2011).

The SAFI sample copper concentration was 68% more than expected, and zinc concentration was >99% less than expected (Table 7-1). Small amounts of aluminum and iron were identified (<150 mg/L).

Water treated with SAFI at the recommended dose would meet EPA, WHO, and EU guidelines for copper ingestion, and applicable EPA and EU guidelines for zinc, iron, and aluminum content (no WHO guidelines exist) (Table 7-2).

SAFI usage directions and dose were listed in English, and the bottle contained a dropper to deliver the recommended dose. Product contents, manufacturing lot number, and dates of manufacture and expiration were not provided.

Table 7-1: Composition verification of primary chemical constituents of all products.

HWT Product	Chemical Constituent	Target Concentration (mg/L)	Tested Concentration (mg/L)	% Diff
SAFI	Copper	36,000	60,300	67.5%
	Zinc	24,000	113	99.5%
SCI-62®	Copper	50,290	61,500	22.3%
SilverDYNE®	Silver	3,600	2,640	26.7%
Antinfek™ 10H	Silver	0.00001	9	>100 %
	PHMB	140,000	Not tested	Not tested

7.4.2 SCI-62®

SCI-62 is a copper sulfate pentahydrate solution manufactured by Chem-A-Co Inc. (Monticello, Indiana, USA), and marketed by SMG Global Partners, LLC. This algicide/bactericide is promoted in the US to control odor and algae growth in wastewater treatment (Chem-A-Co Inc., n.d.), and (although not MSPP-approved) in Haiti for drinking water treatment to prevent and eradicate cholera ("SMG Global, Haiti," n.d.). The product manufacturer provided no HWT instructions; however, the most conservative dose in product literature was one gallon per 60,000 gallons of water (approximately 1 drop/3 liters), with no contact time given.

SCI-62 complies with NSF/ANSI Standard 60 as an algicide and bactericide (NSF International, n.d.-a). It has been EPA-registered since 1990 as a pesticide for controlling odors, bacteria, and algae in ponds, flooded rice fields, reservoirs, swimming pools, and wastewater applications. Its registration is for non-public health claims, and the approved label states that "for applications in waters destined for use as drinking water, those waters must receive additional and separate potable water treatment” (US EPA, 2012b).

The SCI-62 manufacturer did not provide MSPP with efficacy test data. Copper is a known bactericide, and a literature review identified two studies of HWT with uncharged copper documenting bacterial reduction; however, in these studies, water was left in contact with copper storage containers for 8-24 hours (Sharan, Chhibber, & Reed, 2011; Sudha, Singh, Prasad, & Venkatasubramanian, 2009). No additional data were identified to demonstrate this product’s efficacy for HWT.

The SCI-62 sample had 22% higher copper concentration than expected (Table 7-1), and small amounts of iron, zinc, and aluminum (<150 mg/L).

Water treated with SCI-62 would meet EPA, WHO, and EU drinking water guidelines for copper, and applicable EPA and EU guidelines for zinc, iron, and aluminum content (no WHO guidelines exist) when dosed with 1 drop/3 liters (Table 7-2).

SCI-62 was labeled in English. The bottle had a dropper; however, directions, recommended dosage, product contents, manufacturing lot number, and dates of manufacture and expiration were not listed.

Table 7-2: Summary of expected chemical concentrations in water treated with each product, and corresponding international, United States, and European Union drinking water guidelines.

HWT Product	Chemical Constituent	Drinking water concentration (mg/L)	WHO Guideline (mg/L)	US EPA Standard[b] (mg/L)	EU Standard (mg/L)
SAFI	Copper	0.8	2	1.3	2
	Zinc	0.001	-	5	-
	Aluminum	0.001	-	(0.05-0.2)	0.2
	Iron	0.002	-	0.3	0.2
SCI-62®	Copper	1.03	2	1.3	2
	Zinc	0.002	-	5	-
	Aluminum	0.001	-	(0.05-0.2)	0.2
	Iron	0.002	-	0.3	0.2
SilverDYNE® [c]	Silver	0.07	0.1 [d]	0.1	-
Antinfek™ 10H [e]	PHMB	0.056	-	7 [f]	-

Notes:

a. Calculated from recommended dose and tested sample concentration (except PHMB, which is expected concentration).
b. Primary, but non-enforceable, maximum contaminant level goal (MCLG) for copper. Secondary, non-enforceable maximum contaminant level (MCL) for zinc, aluminum, iron, and silver.
c. Negligible amounts of copper, zinc, and boron.
d. Non health-based guideline for average adult, based on 10g / lifetime recommended limit.
e. Negligible amounts of copper, silver, zinc, and boron.
f. Adult average based on dietary recommendation of 0.2 mg per kg body mass per day, and 2 L/day drinking water.

7.4.3 SilverDYNE®

SilverDYNE is a liquid colloidal silver suspension distributed by World Health Alliance International, Inc. (Las Vegas, NV, USA) and marketed in Mexico, Africa, Asia, and (although not MSPP-approved) Haiti to disinfect household drinking water and prevent cholera (World Health Alliance International, n.d.-a, 2009). Instructions on the bottle were to add 1 drop/2 liters of water (or 2 drops for “very contaminated” water), and wait 30 minutes before drinking. The manufacturer's website offered a conflicting dose of 2 drops/liter of "disaster quality" water (World Health Alliance International, n.d.-a).

SilverDYNE is not registered with NSF or EPA. It is approved to disinfect drinking water for human consumption under Mexican Norm NOM 127 SSA1 of 1994, which lists allowable limits of bacteriological contamination, physical characteristics, chemical components, and radioactive materials, but does not discuss HWT or silver ingestion guidelines (El Director General de Salud Ambiental, 1994).

The SilverDYNE manufacturer provided efficacy data from five laboratories. Four sets of data were not considered: three provided no contact time, and one tested silver-treated earthenware jars with unknown dosage and contact time. A fifth test used six times the recommended dose, and while results indicated 5-log removal of four bacteria types, they lacked virus or protozoa data (World Health Alliance International, n.d.-b). A literature review identified an independent study demonstrating that SilverDYNE could meet the WHO *limited protection* target at a dose of 3 drops/liter (six times the recommended dose) and 90-minute contact time (three times that recommended); protozoa removal would require longer contact time at that dose (Gerba & Maxwell, 2012).

The tested SilverDYNE sample had 27% less silver than expected (Table 7-1), and small copper, zinc, and boron concentrations (<30 mg/L).

Water treated with SilverDYNE would meet WHO guidelines and EPA secondary standard for silver when used at the recommended dose (Table 7-2). However, twice the dose is recommended for "very contaminated" water, which would surpass those limits. No EU guideline exists for silver.

The SilverDYNE sample bottle listed product contents and usage directions in French, and provided a dropper to deliver the listed dose. Lot number, manufacture date, and expiration date were not listed.

7.4.4 Antinfek ™ 10H

Antinfek 10H is a liquid disinfectant manufactured by Dove Biotech (Bangkok, Thailand). This product, with active ingredient Poly(hexamethylene biguanide) Hydrochloride (PHMB), is marketed for eliminating bacteria and fungi in drinking water, natural waters, pools, sewage, and industrial water; and treating drinking water to prevent waterborne diseases (Dove Biotech, n.d.). Antinfek 10H drinking water dosage is 0.4 mg/L (no contact time provided), although product literature also listed a conflicting dose of 0.2 mg/L (Dove Biotech, 2012).

Antinfek 10H is not registered with NSF or EPA; however, other PHMB products are EPA-registered as antimicrobial pesticides for swimming pools, oil field injection water, cut flower preservation, and hard surface disinfectants (US EPA, 2004). Antinfek is registered with the Thai FDA (FDA Thailand, n.d.-b), but we were unable to verify the 10H formulation is the one registered. Registration under the Thai Hazardous Substances Control Group as an antimicrobial disinfectant requires antimicrobial efficacy data (FDA Thailand, n.d.-a); however, we were unable to determine if registration indicates safety for human consumption.

The Antinfek manufacturer provided MSPP with five sets of laboratory test data. Results demonstrated bacterial removal, but none exhibited the product's efficacy at the recommended dose, as: 1) one test used Antinfek 30P, a different product; 2) one test reported the microbiological content of packaged drinking water, without treatment process information; 3) one test dosed at 1,500 mg/L (3,750 times the recommended dose) and contact time of 6 hours; 4) one test dosed at 10 mg/L (25 times the recommended dose); and 5) one test reported bacteria removal in one sample, in a water treatment plant with 700 L/hr throughput and 1.0 mg/L dose (2.5 times the recommended dose).

The Antinfek 10H sample PHMB concentration was unverified, but at 9 mg/L, silver concentration was substantially higher than the 0.00001 mg/L target concentration (Table 7-1). Small concentrations of copper, zinc, and boron were identified (<30 mg/L).

There is no recommended PHMB drinking water limit, but EPA recommends a maximum dietary ingestion of 0.2 mg per kg body mass per day (14 mg/day for average adults) (US EPA, 2004). Expected daily PHMB ingestion from treated water is 0.11 mg, assuming two liters consumed at 0.4 mg/L product dose. Neither WHO nor EU guidelines for PHMB exist (Table 7-2).

The Antinfek 10H bottle was labeled in English. It provided no usage directions, but listed product contents, manufacturing lot number, expiration and manufacturing dates, and recommended dosage. The listed dose presents three problems: 1) users would not know what volume to add, because dose is given in mg/L; 2) users would need to add one drop to 125 liters of water to obtain the recommended dose, and would be unlikely to have a vessel that size; and 3) product packaging provides no way to measure drops.

7.4.5 Results Summary

None of the four products was recommended for approval for HWT distribution in Haiti (Table 7-3), as: 1) only SCI-62 had NSF certification for drinking water use, but not as a final treatment chemical, and none was registered with EPA for treating drinking water; 2) no product demonstrated its ability to meet the WHO *limited protection* microbiological performance target at the recommended dosage and contact time; 3) no tested sample composition was within 20% of labeled product composition; 4) dosages were not easily attainable on Antinfek 10H and SCI-62 due to missing instructions or dispensing method; and 5) no product was labeled in Haitian Creole or with complete information (contents, usage instructions, dosage, lot number, manufacturing date, and expiration date).

Table 7-3: Results summary

Certification Criteria	Products Reviewed			
	SAFI	**SCI-62®**	**SilverDYNE®**	**Antinfek™ 10H**
National certifications for drinking water	No	Yes	No	No
Could meet WHO limited protection target at recommended dose	No	No	No	No
Composition verification (within 20%)	No	No	No	Not tested
Treated effluent meets chemical contaminant guidelines	Yes	Yes	Yes	Yes
Achievable dosage by user	Yes	No	Yes	No
Appropriate labeling	No	No	No	No
Recommend approval	**No**	**No**	**No**	**No**

7.5 Discussion

This work established country-level HWT certification requirements and evaluated chemical treatment products based on efficacy (ability to remove reference pathogens when used according to product instructions); toxicity (compliance with drinking water chemical content recommendations); manufacturing consistency and accountability (availability of product contents, lot numbers, and expiration dates); and usability (appropriate language, dosing ability). In this review of four HWT products seeking approval for distribution in Haiti, none fulfilled prescribed requirements, and products were not recommended for approval.

Further, misleading product information proved difficult to distinguish from pertinent information. Manufacturers gave MSPP documentation of irrelevant product certifications (that had expired, were for a different product, were not for drinking water applications, or simply unrelated) and non-applicable laboratory test results (tests performed on a different product, with a different use, or at higher dose or contact time). Conflicting dosing information was identified between manufacturer websites, product literature, and product bottles; and unsubstantiated claims were recognized.

Because of the complex nature of existing international certification processes, regulatory officials in many countries may not be equipped to evaluate the validity of provided information, which is often: 1) not written in their native language, 2) pertaining to unfamiliar regulations, and 3) provided as "official-looking" documentation. Country regulators may be presented with limited staffing and financial resources, limited laboratory facilities, language barriers, and time constraints to develop both the minimum submission requirements for product certification requests, and to review the provided information.

The availability of a clear, international process for HWT product evaluation, such as the WHO microbiological performance based evaluation scheme, would lessen the decision-making burden for country regulators, particularly with regard to evaluating product efficacy. There is additional opportunity for inclusion of toxicity and manufacturing consistency requirements in an international process. However, country-level approval processes may remain necessary to evaluate context-specific product usability - considering language, cultural norms, and domestic habits.

Further technical assistance may be beneficial as countries build capacity to objectively evaluate HWT products. This assistance could including training in: 1) understanding international drinking water quality and product efficacy standards and certifications, 2) performing online product database searches, 3) instituting laboratory test procedures to verify product composition locally, and 4) establishing metrics to evaluate product usability. Some countries may have higher capacity to do more locally, and others may require more assistance and reliance on internationally facilitated processes.

Limitations to this work include: only the one sample provided to MSPP was analyzed for composition and packaging, and manufacturers were not explicitly contacted to provide additional data and validation information. As such, data are not comprehensive, and may not inform potential future certifications of evaluated products as more information becomes available.

While Haiti's post-emergency setting may currently represent an outlier in terms of novel HWT product promotion, these results are more generally applicable to other contexts as: 1) at least two products described herein are currently available in other countries; 2) locally-produced HWT products, such as flocculant/disinfectants and ceramic filters, could have similar efficacy and quality challenges to those presented here; and 3) there is intense interest in developing novel HWT products for emergency response, and new options may be promoted in future emergencies.

Additional work may be needed to advise similar schemes in other countries using HWT products, and in Haiti to apply this evaluation method to other HWT products and ensure the sustainability of the certification process. Dissemination of information contained herein about currently available HWT products may benefit the public and encourage the use of safe and efficacious household water treatment products.

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7.7 Disclaimer

The findings and conclusions in this report are the findings and conclusions of the authors and do not necessarily represent the official position of the Ministère de la Santé Publique et de la Population (MSPP) or the Centers for Disease Control and Prevention (CDC). Use of trade names and commercial sources is for identification only and does not imply endorsement by the Office of Workforce and Career Development, Centers for Disease Control and Prevention, or the U.S. Department of Health and Human Services.

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8 Conclusions and Recommendations

8.1 Research summary

The laboratory, field, and policy research comprising this dissertation explored many facets of evaluating HWT technology performance for both technology improvement and regulatory decision-making.

The laboratory research contained in Chapters 2 and 3 confirmed field laboratory methods often used to evaluate HWT technologies. Appropriate chlorine field test methods were recommended for use in low resource settings, considering accuracy, precision, usability, and cost. A low-cost test tube kit was recommended if results are only required within a general range, and a more expensive but accurate electronic colorimeter was recommended if more specific measurements are needed (Chapter 2). Research also confirmed the importance of dechlorinating drinking water samples when conducting microbiological water quality testing. Results from both *E. coli* spiked water and field-collected samples highlighted the risk of underestimating bacteria counts, and therefore disease risk, if chlorinated supplies are not dechlorinated before analysis (Chapter 3). FCR and microbiological analysis are commonly conducted field tests. Confirming these laboratory methods was important for both subsequent research presented here, and for researchers and practitioners throughout the sector.

Next, field research presented in Chapters 4, 5, and 6 investigated use, performance, and failure mechanisms of HWT technologies in realistic household settings.

In the research presented in Chapter 4, Sawyer PointONE™ filters removed from households were found to have membranes severely fouled by organic and inorganic constituents and biofouling. Results highlighted the need for better understanding household performance of these filters, improving filter cleaning recommendations, and the recognition of a realistic life span and end-of-life indictor.

A follow-up investigation of Sawyer PointONE™ filters (presented in Chapter 5) compared laboratory efficacy, field efficacy with natural waters, and household microbiological effectiveness. Filters demonstrated >9-log *E. coli* reduction in the laboratory, >2-log reduction in natural water efficacy tests, and 1-log reduction in households, where 70% of filtered samples had *E. coli* present. Additional field effectiveness research to understand failure mechanisms and performance disparity was recommended.

The research presented in Chapter 6 evaluated consistent use, barriers to use, and microbiological effectiveness of three pilot HWT technologies in realistic household settings. Consistent HWT use varied, where 2-78% of households in different evaluations had confirmed use at all four follow-up visits. Barriers to use included behavioral challenges like respondents forgetting or not being home to drink treated water, and also a high rate of technological failures. Microbiological effectiveness ranged from 68-96% *E. coli* reductions, although results were limited by low pre-treatment concentrations. This research identified the importance of realistic use trials to within the technology design cycle to identify design flaws and other barriers to use prior to conducting health impact trials or widely distributing technologies. It also recognized the need for standard field evaluation metrics of consistent use and microbiological effectiveness. Finally, this research identified the challenge of achieving both consistent HWT use and microbiological effectiveness, and highlighted the need for clearer understanding of tradeoffs in terms of health impacts.

Finally, policy research presented in Chapter 7 described the implementation of the first known country-level regulation process to evaluate HWT products based on efficacy, toxicity, manufacturing consistency and accountability, and usability. None of four evaluated chemical treatment products was recommended for approval in Haiti. This research demonstrated the use of a relatively simple process to identify HWT technologies that are ineffective, unsafe, or inappropriate for use. Results also highlighted the challenge of HWT manufacturers providing impertinent or misleading information to regulators who may be unfamiliar with relevant international standards, guidelines, and regulations.

8.2 General conclusions

Six common themes were identified across the breadth of this work, which encompassed laboratory, field, and policy research relevant to verifying HWT technology performance. These six themes are:

- Evaluations in realistic settings are important
- There is a need to refine HWT field evaluation methods
- Determining HWT "success" remains difficult
- HWT regulation must begin with basic parameters
- Technology is important, but behavior change cannot be ignored

- Household water treatment is a complex public health intervention

Each theme is presented and further discussed below.

Evaluations in realistic settings are important

It is important to conduct evaluations – both of laboratory methods and HWT technologies – in realistic use settings.

The laboratory research described in Chapters 2 and 3 each included components incorporating practical methods in addition to ideal laboratory conditions. This included volunteer testing of FCR test kits, and microbiological analysis performed by field monitoring partners to evaluate dechlorination recommendations.

HWT technologies are generally evaluated by controlled laboratory efficacy tests immediately followed by diarrheal disease reduction trials. Research described in Chapters 4-6 provides evidence that HWT field trials in realistic use settings should be conducted prior to health impact trials or wide distributions. Manufacturers of HWT prototypes described in Chapter 6 believed the technologies were market-ready, and were surprised by the number of device failures. Fortunately, they were able to address these before sales and distributions, unlike the filter described in Chapters 4 and 5, which had already been widely promoted for household use.

We know HWT technologies will not work indefinitely. When included in the technology design cycle, these evaluations can help designers identify and address design flaws, understand technology limitations and maintenance requirements, set realistic lifespans, and inform programmatic decisions to help technologies succeed.

There is a need to refine HWT field evaluation methods

WHO has worked since 2011 to establish microbiological efficacy targets, laboratory protocols, and conduct efficacy testing for HWT technologies, which has successfully standardized HWT efficacy test methods (WHO, 2011a). Methodologies for health impact trials are somewhat consistent, although variability in study length, and frequency and methods of measuring diarrheal disease outcomes still exists (W.-P. Schmidt et al., 2011).

Methodologies vary more widely in HWT field evaluations measuring consistent use and microbiological effectiveness, among other metrics, despite attempts to standardize methodologies in monitoring and evaluating HWT programs (WHO, 2012). Research presented in Chapters 2 and 3 aimed to standardize field laboratory methods for FCR testing and microbiological sample collection. In Chapter 6, we proposed standard metrics for consistent use and microbiological effectiveness in HWT field evaluations. Consistent use should be based on percentage of confirmed/observed use over several follow-ups, and microbiological effectiveness should be described by reporting results in several ways – as percent reductions and categorized in risk levels.

Determining HWT "success" remains difficult

Results across this dissertation highlight the complexities of determining success in HWT use trials, particularly for consistent use and microbiological effectiveness metrics.

Consistent use is infrequently and inconsistently measured in the literature, so there are few benchmarks to compare against. QMRA models conclude that HWT needs almost exclusive use to see health improvement (Joe Brown & Clasen, 2012; Kyle S Enger et al., 2013), but is 78% of users treating water at four follow-ups throughout a year good enough? What about 50% of users? Should that be called a success or a failure? Additional comparative evidence would be helpful to judge whether consistent use metrics are on target.

Household microbiological effectiveness results are similarly difficult to interpret. Results in Chapters 5 in 6 documented overall reductions in indicator bacteria by HWT technologies, although many treated samples were still contaminated. While not comparable to laboratory performance, is that modest improvement acceptable? Some health impact trials have documented health gains with similar performance (Christine E Stauber et al., 2009), yet QMRA models suggest higher effectiveness is needed. This leaves results open to interpretation.

Additionally, microbiological effectiveness is typically reported as a percent reduction in indicator organisms, which is highly dependent on pre-treatment water quality. Variability in water quality both within and between study settings makes comparison of HWT technology performance very challenging. There is a need for standard guidelines for interpreting effectiveness results, considering pre-treatment water quality.

HWT regulation must begin with basic parameters

As demonstrated in Chapter 7, basic regulation of HWT technologies is possible with a simple framework of well-defined, objective indicators. Application of a simple methodology with little laboratory capacity is possible as an interim measure to identify under-performing technologies until a more sophisticated framework is available.

Country regulators may need assistance in establishing guidelines, and encouragement to maintain a simple framework to quickly identify technologies that are not efficacious, are unsafe, or are unable to be used by target populations.

Given the complexity of interpreting field evaluation results in disparate settings (even in controlled studies), HWT regulation should exclude field results until better-defined, standard metrics are established internationally. Regulation decisions should be based on test results obtained under controlled, comparable situations, such as laboratory testing.

Technology is important, but behavior change cannot be ignored

A multitude of HWT technologies currently exist (CAWST, 2017b), and more continue to be developed. In 2014-2016 alone, manufacturers submitted over 60 technologies for efficacy evaluation under the WHO Scheme (Majuru, 2017). Recent HWT research, innovation, and policy work has focused on establishing HWT efficacy guidelines (WHO, 2011a) and developing microbiologically efficacious technologies. Yet research continues to demonstrate that, in order to achieve health gains, consistently drinking treated water is as important as attaining high microbiological reductions (Joe Brown & Clasen, 2012).

Behavior change was outside of the scope of the research presented here, which primarily evaluated HWT technology performance in realistic household settings. Nevertheless, inexorably linked to technology performance is user behavior. A household intervention like HWT is almost entirely dependent on individuals' decisions to use, and continue to use, the technology.

In the evaluations presented in Chapter 6, we worked with local implementing partners, hired community health workers to follow up with households on a monthly basis, and provided access to spare and replacement parts; all strategies shown to be associated with sustained HWT use (Hulland et al., 2015). Still, only 2-78% of households were using the technologies at all four follow-up visits, and households were more likely to use the HWT technology if they had practiced HWT prior to the study. This shows that, despite best efforts, behaviors were not substantially changed.

HWT can be complex overall. While some technology improvements and verification are still necessary, there is also a need to focus on understanding behavior change and factors associated with HWT adoption. After all, the most efficacious technology in the world cannot be effective if it is never used.

Household water treatment is a complex public health intervention

The overall use of HWT technologies is highly complex and dependent on many actors along the way, including: product designers and manufacturers; country regulators; sales agents, health promoters, and NGO implementers; researchers; and of course, users who must be motivated to correctly and consistently use a HWT technology.

Each step of this process is difficult: designing technologies to be microbiologically efficacious in the laboratory, easy to use, culturally appropriate across wide global regions, and durable in developing country households; regulating technologies so ineffective products do not supplant effective technologies where they are needed; ensuring technologies reach appropriate populations who need them; and sustaining behavior change so HWT methods are consistently used.

It is known that plastic pieces break, filters clog, and individuals decide not to treat their water. Amid this complexity, and no matter what your role in this complex framework, it is critical to:

- Be realistic about the expectations and limitations of HWT in terms of appropriate lifespans and recommended usage conditions
- Understand that not everything is within your control, but consider that HWT technologies must be both microbiologically effective *and* consistently used
- Use regulation as a tool to prevent unsafe or ineffective products, but do not create a system so complicated it cannot be implemented

8.3 Contribution to science

Throughout this work, my contribution to science is the development of methods to evaluate and regulate household water treatment technologies for use in developing countries - namely the development of a method for conducting field effectiveness and acceptability evaluations of prototype HWT technologies. These methodological contributions are discussed below, by chapter, along with recommendations for methodological improvement, further research that was completed using these methods, and future research recommended.

A secondary contribution of the work presented is recommendations for the WHO International Scheme to Evaluate HWT Technologies, which are described after the methodological contributions.

8.3.1 Methodological contributions

Study 1: Accuracy, precision, usability, and cost of free chlorine residual testing methods

Methodological contribution

The main methodological contribution was the use of both volunteer testing to evaluate ease of use and accuracy of the chlorine test kits, and considering cost as a decision-making factor. Accuracy and precision of similar test kits has been evaluated before, but this was new, more holistic review of kits specific for use in developing countries.

Recommendations for improvement

For this work, the main methodological improvement would be blinding the chlorine solution concentrations in both laboratory testing and in volunteer testing. This would reduce potential bias, as many of the test kits rely on user judgement to match a color to a comparator card. In laboratory testing, I made chlorine solutions daily, and then tested that one concentration repeatedly with different test kits. A better way would be to have another person make the chlorine solutions and provide them to me without knowledge of what they were. In addition to accuracy, this would be particularly beneficial for evaluating test kit precision, as the same concentrations would not be measured repeatedly.

In volunteer testing, only three concentrations were tested. Although volunteer testers were not told what the concentrations were, they continued to test the same solutions with different test kits, so they would have a good idea of the concentrations after repeated testing, which could potentially bias their readings. In a later study done with a similar protocol to evaluate silver solution test kits, a variety of solution concentrations were provided to the volunteer testers. In this case, the concentrations were blinded to both the volunteers and researcher coordinating the testing, to minimize bias.

Another improvement to the methodology would be to evaluate test kit accuracy by measuring only concentrations that are identified on test kit comparator cards. While the electronic colorimeter has a resolution of 0.01 mg/L, the pool test kit only had five total readings between 0-3 mg/L with which to compare. This resulted in higher percent error readings for test kits with fewer possible comparison values.

Further research completed

A variation of this methodology, with some improvements, was used to evaluate chlorine test kits used for higher concentration samples, and test kits to quantify silver in solutions used for ceramic pot filter manufacturing. These have both been published, as:

Wells, E., Wolfe, M. K., Murray, A., & Lantagne, D. (2016). Accuracy, precision, ease-of-use, and cost of methods to test ebola-relevant chlorine solutions. PLoS ONE, 11(5), 1–14.

Meade, R. D., Murray, A. L., Mittelman, A. M., Rayner, J., & Lantagne, D. S. (2017). Accuracy, precision, usability, and cost of portable silver test methods for ceramic filter factories. Journal of Water and Health, 15(1), 72–82.

I also used the results of this research to decide which test kit to use for subsequent HWT field evaluations. I conducted most with the Lamotte test tube kit, which was one of the options which was identified by this research to be accurate, fairly easy to use, and low cost.

Additionally, because all of the visual color judgement tests are prone to user error, in field testing I always took time to train the survey enumerators by calibrating their visual judgement. Each individual would test a low, medium, and high concentration sample, and then compare their readings to those of others in the group, and also compare to the reading obtained by a colorimeter. This was particularly useful for low readings with the Lamotte test tube kit, which does not have a zero reading on the card.

Further research recommended

This methodology could be used to test other field test kits used to conduct water quality testing, such as arsenic, fluoride, turbidity, and iron concentrations.

Study 2: The effect of sodium thiosulfate dechlorination on bacteria enumeration: laboratory and field data

Contribution

This work used standard laboratory methods to confirm dechlorination recommendations that had been developed before these current standard laboratory methods had been developed.

Recommendations for improvement

Methodological improvements for the sodium thiosulfate laboratory study mainly apply to the testing done by water suppliers in sub-Saharan Africa. Some of the suppliers did not record free chlorine residual values with the testing, and it would have been better to have these readings corresponding to all tested samples. Additionally, more details about holding time and quality control like blank samples would have been beneficial.

Additional statistical analysis of the laboratory data is also possible. We considered performing a Poisson regression on the laboratory data with outcome of final E. coli counts, and explanatory variables of sodium thiosulfate presence, chlorine dose, and holding time, and an offset variable of initial E. coli concentration. However, because the primary research question was whether counts differed in samples collected with and without dechlorination, and this could be answered by the analysis presented here. Additionally, prediction of E. coli counts, which would be possible with regression results, would not be particularly useful, because the laboratory results are not directly comparable to E. coli concentrations seen in actual drinking water supplies.

Further research recommended

With this work, potential future research would be to conduct additional testing with natural waters with higher chlorine demand, to potentially slow disinfection rates. It would also be interesting to measure E. coli concentrations at varying holding times, to better understand if the effects of dechlorination are altered when samples are held for shorter amounts of time.

Study 3: Fouling in hollow fiber membrane microfilters used for household water treatment, and Study 4: Laboratory efficacy and field effectiveness of hollow fiber membrane microfilters used for household water treatment in Honduras

Methodological contribution

The primary methodological contribution of the work presented in Chapter 4 was the assessment of failure mechanisms of filters used in developing countries. This was done largely through the use of scanning electron microscopy to image membrane surfaces. Follow-up research to better understand laboratory and field microbiological performance was conducted as a result of this work, and is presented in Chapter 5. This work had few novel methods, but combined methods to present a more holistic view of filter performance.

Recommendations for improvement

Methodological improvements for the field study include visiting all of the known filter users or randomly selecting households visited, to eliminate any potential bias that may have been present as a result of convenience sampling. It would have also been preferable to test with consistent methods in both laboratory testing and field testing.

Also, for the controlled field testing with natural waters, the testing was done with the same filter both in Maine and in Honduras. If two new filters were available, it would have been interesting to test the water in Honduras with both this slightly-used filter and a brand new filter. I think there are two possible reasons that total coliform removal was incomplete in testing with Honduran river water. One potential reason is that the coliform species were smaller than the effective pore size of the filter, so the cells passed through the membrane. Another potential explanation is that coliform grew on the filter surface in the time between using it to test water in Maine and then in Honduras. If another new filter had been available to use alongside the already-used filter in Honduras, this would have indicated which of these two theories is more likely.

Further research completed

As a result of this work presented here, a third study evaluating this same filter type was conducted in a refugee camp in South Sudan in 2016. In this study, water quality samples were analyzed from filters monthly over the course of one year, to better understand if and when performance declined during household use. This manuscript is currently in preparation. Results indicate that household microbiological performance was initially good, but declined after approximately four months of use, and then was recovered slightly after filters were washed with a chlorine solution.

Further research recommended

Several future studies are possible to answer specific membrane fouling and filter microbiological effectiveness questions that arose throughout the work presented in Chapters 4 and 5.

First, to better understand filter fouling mechanisms, I would recommend controlled laboratory testing with both laboratory-prepared water and natural waters. To do this, I would create several different test waters with different water quality parameters, varying in hardness, total organic carbon, and natural organic matter such as humic acids, and also identify a local natural water source to test the filters. I would test three filters with each influent water type, running water through regularly with a pre-determined cleaning procedure, such as backwashing after every 100 liters (five buckets) of water filtered. I would record average filter flow rates for each bucket of water filtered throughout the testing. I would plan to open one filter from each water type halfway through the protocol to image the membrane and perform elemental analysis on the membrane surface, and do the same with the remaining two filters per influent water type at the completion of testing. I would compare the analysis done on each set of filters to better determine which water quality parameters most affect membrane fouling.

Next, to better understand when household microbiological effectiveness starts declining, and what the causal mechanisms are, I would recommend some additions to the longitudinal study design described above. I recommend collecting all the filters, opening each to look for evidence of burst membrane fibers, and performing similar SEM imaging and elemental analysis on a subset of filters, including ones that performed well and did not perform well. This would be useful to document: 1) the incidence of burst membrane fibers as a failure mechanism, 2) associations of filter microbiological performance with evidence of burst fibers, and 3) associations of filter microbiological performance with evidence of membrane fouling.

Finally, the use of field efficacy, or controlled testing in settings where the filters are typically used, is not often used alongside field trials. I think there is opportunity to do more “controlled” testing within typical operating environments of these technologies, and with natural waters. This would help separate whether failures or poor performance can be attributed to user error (a commonly-cited problem) or difficulty treating natural waters in household environments.

Study 5: Evaluation of consistent use, barriers to use, and microbiological effectiveness of three new household water treatment technologies in Haiti, Kenya, and Nicaragua

Methodological contribution

This evaluation methodology was developed to fill a gap in the academic literature about evaluating HWT technologies in household settings and focusing on metrics other than laboratory efficacy or health impact. This methodology specifically addresses a metric – consistent HWT use – which has not been reliably measured or reported to this point.

The overall method consists of enrolling a minimum of 60 households, conducting a baseline evaluation, training users on HWT technology use and distributing technologies, and then following up with households four times over the course of one year (at approximately one week, three months, six months, and 12 months after distribution). Household surveys and water quality testing on paired treated and untreated water samples were conducted at each visit. Two of the primary metrics, confirmed use and consistent use, are each described in detail below.

<u>Confirmed use metric</u>

Confirmed use was defined in these evaluations as households that provided a drinking water sample reported to have been treated with the particular HWT technology, and had water in their filter (for filter technologies) or had treated water with positive FCR (for the electrochlorinator). Other measures of confirmed use were considered including the following:

- Treated samples with lower microbiological contamination than untreated samples, indicating that the technology had been used.
    - There are three potential troubles with this measure: 1) If untreated samples had undetectable *E. coli*, there was no way to also use water quality to demonstrate use. 2) It potentially conflates two metrics: HWT use and microbiological effectiveness. It is possible that microbiological quality is worse in treated water than untreated water, which has nothing to do with whether the technology was used or not. 3) Additionally, with many technologies, untreated and treated samples are not exactly the same water before and after treatment. Filter flow rates are often slow for ceramic filters, biosand filters have a large standing water volume, and chemical disinfection technologies require a contact time to act, which all make the sampling of household exact treated and untreated pairs infeasible. Therefore, untreated samples are taken from stored household water from the same source, but microbiological quality is not always directly comparable.
- Self-reported HWT use
    - This is not a good metric of actual use, as demonstrated by the difference between "reported use" and "confirmed use." Household surveys are often affected by courtesy bias, which then requires observations to confirm more realistic estimates of true use.
- Enumerator judgement of whether the household was using the HWT technology.
    - In the ceramic filter evaluations in Haiti and Kenya, the funder was concerned about courtesy bias in filter use metrics, and requested that enumerators make a judgement at the completion of the interview whether they believed the family was using the technology or not. This method is also ridden with potential data collection bias, and more often than not, the enumerator observation aligned with the other observed metrics of use.

Consistent use metric

Consistent use was defined in these evaluations as the proportion of total visits in which households demonstrated confirmed use of the HWT technology. Other measures of consistent use, including the following, were also considered:

- Reported frequency of use and/or reported drinking of untreated water
    - Reported use or non-use is, as previously discussed, subject to courtesy bias in household surveys, so it is not a preferable metric for objective measures.
- More frequent household visits to observe use, such as weekly
    - Besides resource constraints that would render this frequency of data collection difficult, these evaluations also sought to emulate "realistic use" as much as possible while still being within a study setting. Weekly data collection would have given more frequent and regular measurements, but may have also further changed user behavior in a way that is not indicative of what it would have been with less frequent data collection (i.e. the Hawthorne effect).
- For the ceramic filter / bromine disinfection technology, the bromine beads fade in color as bromine elutes from them. Consistency of use could have been quantified by the observed color of the bromine beads after a given time.
    - The trouble with this as a measure of use is that technical issues with the filter system meant that water did not always flow though the bromine cartridge at it was designed. Bromine levels in treated water were lower than expected in many cases, and in several filter systems, the bromine beads did not change color at all, even though the filter appeared to be used. Because of this, and also because it was not something available with the other technologies, bromine bead color was discounted as metric for consistent use.

I decided upon the final consistent use metric because it was based on an observed (mostly objective) measure, comparable between all studies, and easy to measure and replicate in future evaluations with a similar methodology. Weaknesses of this metric are that it dependent on infrequent measurements to extrapolate to consistent use, and prone to measurement error in two possible ways: 1) it is still subject to courtesy bias, if users treat their water immediately before completing the survey, but conversely 2) users may use the HWT a majority of the time, but actually not have water available at the time of the unannounced visit.

Another possible way to quantify confirmed and / or consistent HWT use is to employ a remote sensing technology on filters to measure the volume of treated water by a household. This is potentially one of the most objective measures available, as it considers consistent use at all times, not just when data collection teams arrive at the household to check on use. However, it could be problematic because it may not be able to be used with every single technology type. Additionally, sensors are very expensive and fragile. Additional sensor design development is needed before this can be an ideal solution as a methodology for many researchers to apply across many studies.

Recommendations for improvement

Some methodological improvements were made along the way, as I learned lessons from earlier evaluations and could apply that to later evaluations. Perhaps the most notable is that in later evaluations, more care was taken to enroll households with drinking water with higher E. coli contamination levels, in order to demonstrate household microbiological effectiveness. For filters, treated samples were also taken from the users' cup, as well as directly from the filter, to disaggregate filter effectiveness from actual drinking water quality.

As mentioned above, another potential improvement to these evaluations would be field efficacy testing, where the technologies would also be evaluated by using them regularly in a controlled environment with typical community water sources. This type of testing would help identify if HWT technology performance is associated with user error, or with influent water quality.

Future work is possible to further analyze this data set collected from four country evaluations with baseline and four follow-up surveys and water quality testing. While the four different program evaluations were not intended to be directly compared, as they were conducted in variable study settings, the data sets could be merged and analyzed together to assess longitudinal outcomes such as confirmed use with a variety of factors and interaction terms. In place of mixed effects models, which were used in this research as presented, generalized estimating equations could potentially be used. However, the limits of other multivariate analysis are fairly small sample sizes and missing data points for some households at some follow-up visits.

Further research completed

This methodology, with minor adjustments, has been used to evaluate two other household water filters, in the Dominican Republic and India, within the past year.

Also, as a result of lower-than-expected bromine results seen throughout the field evaluations of the ceramic filter / bromine disinfection technology, I designed a laboratory study to evaluate influent water quality parameters, usage characteristics, and design parameters on bromine elution from the brominated resin used in this HWT technology. The results of this were used by the manufacturer to redesign this component of the treatment device.

Further research recommended

Given the wide range of existing HWT field evaluation methodologies, a systematic review of these methodologies is recommended to identify common metrics for HWT use and microbiological effectiveness.

Additionally, future research is recommended to establish guidelines for interpreting microbiological field effectiveness results, considering variable pre-treatment water quality, to judge if results are sufficient to provide health impact.

Study 6: Need for certification of household water treatment products: examples from Haiti

Methodological contribution

The methodological contribution of this work was the assembly of simple metrics that represent primary aspects most important to ensuring HWT product safety and efficacy.

Recommendations for improvement

This research could have been improved by requesting more product samples from the four HWT manufacturers to conduct concentration testing, an indicator of product quality. Microbiological efficacy testing could have also been conducted to verify performance of the samples in the laboratory. However, one goal of this certification framework was to keep testing and analysis simple and fairly fast to complete, so a desk review of literature and test results were determined to be the most appropriate method in this case.

Further research or work completed

Some additional work as a result of this research has already been performed. A set of other HWT technologies, both chemical treatment and filter technologies available in Haiti, were evaluated by the same process. Some of these passed and some did not, which demonstrated that the presented certification scheme is able to differentiate technologies, and it is not possible for some technologies to pass, although the initial four did not.

Additionally, I worked with WHO to facilitate workshops for country-level HWT regulators in Ethiopia and Ghana. Throughout these workshops, representatives from government ministries, regulation bureaus, standards agencies, product manufacturers, national laboratories, and international agencies like WHO and UNICEF convened to learn about HWT, how products are tested and regulated in other countries, and to discuss options for which government agencies would oversee what parts of a possible regulation framework, and what that might look like.

Further research recommended

More specific recommendations for further development of this certification scheme, including adaptation to durable treatment products and how the certification framework could fit into a larger HWT evaluations and regulation scheme, is presented in the section below.

8.3.2 Recommendations to the WHO Scheme to Evaluate HWT Technologies

HWT technology and program evaluations

HWT can be complicated to evaluate and regulate because at the core, there are two aspects to evaluate: the HWT technology, and the HWT program. HWT "technology" refers to factors that are constant for the device or process itself, such as microbiological performance under controlled laboratory conditions or the materials used to make the device. HWT "program" refers to factors that may vary such as location (region, country, urban or rural settings), distribution approach (free distributions versus sales in the market), additional program features (education, technical assistance, supply chain availability), and individual user factors (socioeconomic status, prior experience, etc.).

Some HWT evaluation metrics target one aspect, some target the other, and some metrics actually evaluate a combination of both technology and program aspects (see Table 8-1). The tension is that HWT regulation should focus on the constant technology factors in order to be independent and consistent across technologies, yet the actual success of HWT depends equally, or more so, on program factors that may determine if people actually use the technology and derive a health impact. This was the topic of much discussion in workshops in both Ethiopia and Ghana, where many participants were very interested in including field performance as part of a certification or regulation scheme.

But, again, I feel governments should regulate the technology, and not regulate the program.

Table 8-1:HWT evaluation types, metrics, and aspect targeted (technology or program)

Evaluation type	**Metric(s)**	**Primary aspect targeted (technology or program)**
Laboratory effectiveness testing	Log reduction of bacteria, viruses, protozoa in the laboratory	Technology
Field effectiveness testing	Log reduction of fecal indicator bacteria in household water by intended users	Technology & program
Health impact	Odds ratio, incidence rate ratio, longitudinal prevalence ratio comparing diarrheal disease between control and intervention groups	Technology & program
HWT use evaluation	Reported use, correct use, confirmed use, consistent use, acceptability	Program
Quality control check	Existence of manufacturing production processes, samples meet manufacturer standards	Technology
Chemical safety verification	Chemical concentrations in treated water, materials in contact with water	Technology
Ability to use verification	Packaging and sufficient information provided to use	Technology

Recommended overall evaluation and regulation scheme for HWT Technologies

A schematic illustrating the recommended HWT technology evaluation and regulation process is included in Figure 8-1, and further discussed below.

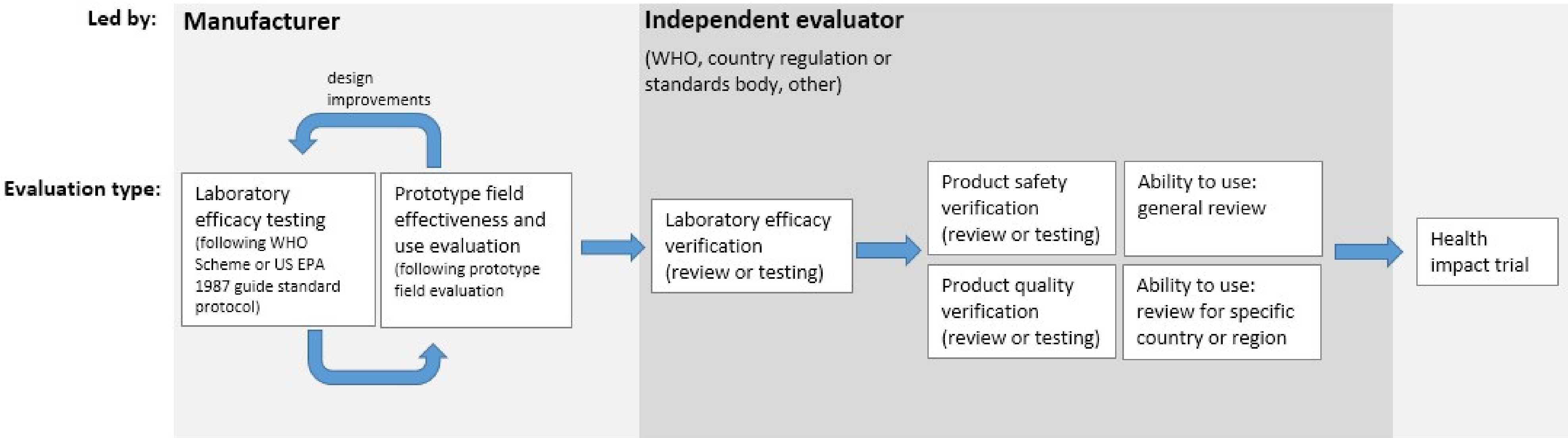

Figure 8-1: Schematic of recommended HWT technology evaluation and regulation process

Manufacturer-led design and testing for product development

First, HWT technology manufacturers should test laboratory efficacy (LRVs of bacteria, viruses, and protozoa) as part of the product development process. The target for this metric is based on a minimum 1-star performance classification by the WHO Scheme to Evaluate HWT technologies.

Next, manufacturers should have an independent evaluation of technology use in households. This evaluation should follow the protocol described above, and that which was employed in Study 5 in this document. Briefly, the study should enroll a minimum of 60 participants, should include a baseline evaluation to determine fecal indicator contamination levels in typical drinking water, and then should have a minimum of three follow-up visits over 6 months with household surveys and water quality testing. Trained local health workers should visit all households once per month throughout the evaluation to answer questions or provide technical assistance or replacement parts, as needed.

Outcome metrics from this evaluation should be log reductions of E. coli or thermotolerant coliforms (microbiological effectiveness), and use metrics of reported use, confirmed use, consistent use, primary barriers to use, and HWT technology problems reported by households and observed by study personnel.

Results from this prototype field evaluation will inform any design improvements. At that point, laboratory efficacy and/or prototype field effectiveness and use should be evaluated again if any major changes were made.

At the completion of this stage, the following three metrics should be demonstrated: 1) laboratory efficacy to WHO Scheme guidelines, 2) demonstrated ability to statistically significantly reduce indicator bacteria from drinking water in household settings, and 3) demonstrated ability to use in households. At this point, the HWT technology is ready to undergo a regulation review process.

Independent evaluator product verification

Next, the product can evaluated by one or more independent evaluation or regulation bodies, such as the WHO or a national HWT regulatory authority. This body or bodies will evaluate whether the product meets minimum microbiological efficacy, product safety, product quality, and ability to use metrics (Table 8-2). These metrics will vary based on whether the HWT technology is a chemical treatment technology such as chlorine, or a durable treatment technology such as filters or UV devices. Additionally, a minimum of one metric, the ability to use in a specific country or region, should be evaluated by officials in that country or region, based on the language provided on the product packaging.

A risk in this certification stage is that regulatory authorities may be apt to develop a framework that is too complex, metrics that are too stringent, or one that requires complicated testing. This was seen in both country workshops I conducted in Ethiopia and Ghana. We recommended that evaluations be based on requirements for consumer products or health devices, rather than based on similar requirements for pharmaceuticals, which are often complicated and time-consuming to complete.

Table 8-2: Metrics for an independent evaluator (WHO, country regulation or standards body, other)

<table>
<tr><th></th><th>Chemical treatment products</th><th>Durable treatment products</th></tr>
<tr><td>Laboratory efficacy</td><td colspan="2">LRV of bacteria, viruses, protozoa to meet WHO Scheme recommendations</td></tr>
<tr><td>Product safety</td><td>Treated water meets WHO chemical guidelines</td><td>Materials are food grade, safe for use</td></tr>
<tr><td rowspan="2">Product quality</td><td colspan="2">Manufacturing process review: ISO 9001 certified, or other quality control measures in place</td></tr>
<tr><td>Sample meets chemical concentration specifications</td><td>Sample meets flow rate (for filters) or other relevant specification</td></tr>
<tr><td rowspan="3">Ability to use, general</td><td colspan="2">Use instructions are provided</td></tr>
<tr><td>Has packaging that allows proper dosing (e.g. dropper bottle)</td><td rowspan="2">Can treat sufficient volume per day</td></tr>
<tr><td>Lists manufacture and expiration dates, product contents</td></tr>
<tr><td>Ability to use, specific</td><td colspan="2">Instructions are in the correct language</td></tr>
</table>

Health impact trials

Finally, it is appropriate to conduct health impact trials, such as diarrheal disease reduction, following the verification of efficacy, quality, safety, and ability to use by the independent evaluator or regulator.

8.4 Recommendations and future research

Based on overall conclusions drawn from the breadth of laboratory, field, and policy research related to evaluating and regulating HWT in developing countries, the following recommendations and future research have been identified.

First, HWT technology developers should continue to evaluate consistent use, barriers to use, and microbiological effectiveness of prototype HWT technologies in realistic household settings. This should be done following laboratory efficacy trials, and prior to health impact trials or large distributions. These trials will help identify design flaws and technological limitations and allow for iterative design before technologies are widely distributed.

Second, given the wide range of existing HWT field evaluation methodologies, a systematic review of these methodologies should be conducted to identify common metrics for HWT use and microbiological effectiveness.

Third, researchers should more consistently measure and report consistent use and microbiological effectiveness together with diarrheal disease reduction results to better understand the interrelationship of these metrics empirically.

Fourth, future research is recommended to establish guidelines for interpreting microbiological field effectiveness results, considering variable pre-treatment water quality, to judge if results are sufficient to provide health impact.

Finally, future work is recommended to develop an international process for HWT product evaluation that incorporates microbiological efficacy, but is expanded to include toxicity, manufacturing consistency and accountability, and usability. Country-level approval processes may remain necessary to evaluate context-specific product usability, and technical assistance should be provided if country governments do not have the capacity to objectively evaluate HWT products.

8.5 Closing

Household water treatment is a household-level intervention used to reduce diarrheal disease among users without access to safe drinking water. Many proven HWT methods exist, although there is ongoing interest in developing new HWT technologies. Technologies are typically evaluated through laboratory microbiological efficacy testing and diarrheal disease reduction measured through randomized controlled trials. Regulation of HWT products is limited both globally and nationally.

The overall research objective of this dissertation was to investigate methodologies of evaluating HWT technology performance for both technology improvement and regulatory decision-making. The primary contributions of this research were: confirmation of field water quality testing protocols, recommendation of standard HWT evaluation metrics and evaluations in realistic settings prior to health impact trials, and the demonstration of a simple national HWT regulation framework.

Future work remains to ensure the use of HWT continues to provide health improvements to those who need it most.

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