



**Considerations for Policy Development and Scaling-Up Household  
Water Treatment and Safe Storage with Communicable Disease  
Prevention Efforts**

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## **Acknowledgements**

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In addition the discussions benefitted from presentations from Dr Thomas Clasen (London School of Hygiene & Tropical Medicine), Dr Elizabeth Marum (WHO/HIV), Prof James Kahn (University of California San Francisco) and Prof Judd Walson (University of Washington). Finally, Dr Annette Prüss-Ustun (WHO/Evidence and Policy on Emerging Environmental Health Issues) and several staff within WSH offered valuable inputs including Bruce Gordon, Jennifer De France, Dr Graham Alabaster, Dr Maggie Montgomery, and Tarik Hassan. Tarik Hassan served as the rapporteur.

## 1. Introduction and Background

An estimated 780 million people drink water from unimproved sources, and millions more drink contaminated water from improved sources<sup>1</sup>. Unsafe drinking-water, along with inadequate hygiene and sanitation contributes to more than a million deaths each year. While countries work to provide universal access to safe, reliable, piped-in water, WHO and UNICEF have called for targeted, interim approaches that will accelerate the health gains associated with safe drinking-water for those whose water supplies are unsafe. One such approach is household water treatment and safe storage (HWTS) to prevent contamination during collection, transport, and use in the home.

A growing body of evidence demonstrates that the use of household water treatment and safe storage (HWTS) methods improves the microbial quality of household water and reduces the burden of diarrhoeal disease in users. WHO specifically recognizes the health contribution that HWTS can make in the *Guidelines on Drinking-water Quality*<sup>2</sup>. It also recommends integration of HWTS along with other water, sanitation and hygiene interventions in prevention and treatment efforts among vulnerable groups including those with HIV<sup>3</sup> and children at risk for pneumonia and diarrhoea<sup>4</sup>, and safe storage, in particular, as a means to prevent dengue fever.

Upon recommendation of the Advisory Group of the WHO/UNICEF hosted International Network for Household Water Treatment and Safe Storage (the Network), the Water, Sanitation, Hygiene and Health Unit of the WHO convened a group of technical staff to discuss integration of HWTS with health efforts. The aim of the discussions was to inform HWTS scaling-up efforts with particular attention to vulnerable, at-risk populations and integrated approaches to delivering water, HIV, and other interventions. The group that met consisted of experts in child and maternal health, HIV, malaria and vector borne diseases. A background report which synthesised meta-analyses and recent studies on the health impact of HWTS was developed to inform the discussions (Appendix 1). The group met over two days to discuss HWTS scaling-up and provide recommendations on needed action to leverage HWTS benefits with other health efforts.

This document serves to share key outcomes from the discussion among the wider HWTS community, including the abovementioned Network. It begins by summarizing the main discussion outcomes, including the specific recommendations for integrating HWTS with key health efforts and supporting scaling-up efforts. It then provides a brief description of the presentations and discussions.

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<sup>1</sup> WHO/UNICEF (2012). UNICEF/WHO (2012). *Progress on drinking water and sanitation: 2012 update*. New York, NY, USA, UNICEF; Geneva, Switzerland. <http://www.unicef.org/media/files/JMPReport2012.pdf>

<sup>2</sup> WHO (2011). *Guidelines for Drinking-water Quality*, Fourth Edition. Geneva: World Health Organization.

<sup>3</sup> WHO (2008b). *Essential prevention and care interventions for adults and adolescents living with HIV in resource limited settings*. Geneva, Switzerland, World Health Organization.

<sup>4</sup> WHO/UNICEF (2013). *Ending preventable child deaths from pneumonia and diarrhoea by 2025*. Geneva: Switzerland; New York: USA.

## 2. Key discussion outcomes

The overall consensus from the group was that existing meta-analyses, individual research reports, and WHO Guidelines provide sufficient support for scaling-up HWTS. Participants thought more can and should be done to integrate HWTS into HIV, child and maternal health, dengue and vector control, and other targeted efforts. The three specific conclusions were:

- Correct and consistent use of proven household water treatment technologies and safe storage results in health gains;
- Optimal selection of household water treatment and safe storage should consider several contextual and performance factors; and
- Integration of HWTS with health efforts offers “quick wins” for reducing diarrhoea and co-morbidity, providing incentives to seek health services, and makes efficient use of health resources.

During the discussion, a statement articulating important opportunities for integration of HWTS with health efforts was drafted. Following the meeting the statement was revised with input from all meeting participants for publication in a peer-reviewed journal (*publication forthcoming*).

The recommendations from the discussion (provided in greater detail in the statement) include:

- Highlight linkages between HWTS and priority health programmes in WHO and national strategies;
- Link HWTS (and other public health goods) with efforts to rapidly expand HIV testing in order to reach the global HIV target of treating 15 million by 2015;
- Increase implementation of HWTS to end preventable child deaths from pneumonia and diarrhoea by 2025;
- Develop and implement preventive interventions that jointly address faecal contamination and vector breeding in household water storage containers;
- Select household water treatment technologies that meet WHO performance criteria and are most likely to be used correctly and consistently;
- Implement household water treatment in tandem with existing health interventions and channels;
- Monitor and track progress in effective implementation of HWTS alongside other health interventions (i.e. improvements in antenatal care, HIV care and counselling, etc);
- Invest in operational research on uptake of environmental health interventions;
- Establish straightforward and ambitious global HWTS targets to drive scaling-up efforts.

### 3. Discussion Summary

The discussion among WHO staff had three main objectives. These included:

- Offer perspective on the existing evidence and reviews of evidence regarding the health impact of HWTS among at-risk populations;
- Inform implementation of HWTS with particular attention to at-risk populations; and
- Discuss needed policies on safe drinking-water and disease prevention, integration and future collaborative work.

To address these objectives the discussion was divided into three main sessions. The first concerned an overview of HWTS and health including a detailed presentation on the background report (Annex 1). The second session sought feedback from each of the participants regarding the role of HWTS in their respective health areas and what could be learned from similar challenges in scaling-up public health interventions. Participants also heard from external researchers on health and economic gains in integrating HWTS with HIV efforts. Finally the last session provided an opportunity to summarize what should and could be done to scale-up HWTS and at the same time advance global health goals regarding HIV, childhood pneumonia and diarrhoea, dengue and malaria.

#### **Presentation: Background on International Network on HWTS and integration with health efforts-** Dr Maggie Montgomery, WHO

Dr Montgomery began by highlighting the high mortality due to diarrhoeal diseases and the role of drinking-water, sanitation and hygiene in preventing such diseases. She mentioned the global rise in cholera and noted that prevention and control requires a multi-pronged approach. HWTS is one "piece" of this puzzle. She highlighted how the WHO/UNICEF hosted International Network on HWTS (Network) is working to coordinate effective action on HWTS. The aims of the Network 2011-2016 strategy include: support national policy and framework development, strengthen the evidence base, evaluate and disseminate best practices, and realize tangible results in scaling-up. The Network has three global targets. These are: by 2015 there are effective and replicable HWTS programmatic approaches to achieve long-term widespread use and public health impact; by 2015, thirty countries should have established policies on household water treatment and storage; and by 2020 fifty countries have achieved country-wide scale-up of project-based HWTS.

The impetus for bringing together WHO staff from various departments resulted from questions concerning the third Network target on scaling-up. How and where should WHO and the Network, more generally, focus efforts on HWTS? What can be learned from the scaling up of other public health interventions in similar settings? In an attempt to help answer these questions the Network Advisory Group called upon WHO to bring together staff from various health areas where there are direct links to water, sanitation and hygiene (WASH).

#### **Presentation: Assessing the Strength of Evidence on HWTS among Target Populations-**Dr Thomas Clasen, London School of Hygiene and Tropical Medicine

Dr Clasen provided a comprehensive presentation which highlighted the key issues concerning HWTS and health. These are described in detail in his background report (refer to Annex 2).

He highlighted the burden of diarrhoeal disease which accounts for 11% of deaths in children. Much of this is associated with unsafe drinking-water and poor sanitation and hygiene. Based on systematic reviews, Thomas indicated that use of HWTS is protective against diarrhoea. He also noted that in a number of sub-populations, use of HWTS has shown to have a health impact. For example, in a recent review regarding HWTS and individuals living with HIV, a protective effect against reported diarrhoea was found where use of HWTS was high. Such findings are important given that individuals with HIV are more likely to suffer from diarrhoea and gastrointestinal infections may increase the progression of HIV. As such, current WHO policy and PEPFAR funding support HWTS as an element of preventive care packages in resource-limited studies. Tom also noted that in emergencies (outbreaks, floods, earthquakes, displacement) HWTS has served an important role in quickly reaching affected populations. However, he noted that a recent review of HWTS found that use (and thus impact) is limited unless a number of factors are met. These include selecting options based on user preferences and performance, providing appropriate training and behaviour support on use, establishing a supply chain of consumables and replacement parts, and engaging communities for longer-term coordination and support.

**Presentation: Global strategy for prevention and control of Dengue (2012-2012)-Dr Raman Velayudhan, WHO**

Dr Velayudhan presented the Global Strategy for Dengue Prevention and Control of Dengue which aims to reduce dengue mortality and estimate the true burden of the disease. He articulated that Dengue is currently on the rise with an estimated 300 million at risk. Due to various environmental factors, including water storage in the home, the mosquitoes vectors, *Aedes aegypti* and *Aedes albopictus* are increasing in range. The key components of the strategy include diagnosis and case management, integrated surveillance and outbreak preparedness, sustainable vector control, future vaccine implementation, and operational and implementation research. Household water storage containers with tightly sealed covers are a key intervention for vector control component. Other preventive methods include netting actions (such as window or door screening), insecticide-treated water storage container covers, and biocontrol methods to lower mosquito populations (with fishes or mesocyclops). Raman stressed that as households increasingly store water as a means to mitigate irregular water supplies and shortages, safe storage will become even more important as a vector control measure.

**Presentation: Prevention of endemic co-infections to delay HIV-1 disease progression-Prof. Judd Walsom, University of Washington**

Prof Walsom summarized the results of his study which assessed the impact of long-lasting insecticide-treated bed nets and point-of-use water filter on HIV disease progression in Kenya. The data demonstrated that a long lasting insecticide-treated bed net (LLIN) combined with a water filter intervention resulted in a 27% risk reduction in HIV disease progression. He stressed that study results further support integration of HWTS with HIV efforts and for the first time provides evidence of morbidity reductions. He cited many additional reasons why integration could be advantageous. First, existing program and research infrastructure for HIV may offer significant opportunity to leverage unique opportunities to strengthen both. Second, co-infection with other diseases (neglected tropical diseases, enteric pathogens, respiratory pathogens) may directly affect the health of individuals living with HIV/AIDS and could affect susceptibility to and progression of HIV/AIDS. Finally, engaging emerging researchers and program leaders may be facilitated by linking with HIV.

**Presentation: Integrated Prevention Campaigns (IPC) cost, health impact and cost effectiveness**-Prof. James Kahn, University of California, San Francisco

Prof Kahn described a diarrhoea, malaria and HIV IPC implemented in Lurambi district, Western Kenya in September 2008. Program costs were derived from empirical data from the implemented campaign. This cost was used to infer a Scaled-Up Replication cost (SUR). Health impact, measured by deaths and Disability-Adjusted Life Years (DALY) averted, was derived from published trials and meta-analyses and disease incidence modelling. The costs of medical care incurred/averted were taken from published studies and databases. The result was that per 1000 participants, projected reductions in cases of diarrhea, malaria, and HIV infection avert an estimated 16.3 deaths, 359 DALYs and \$85,113 in medical care costs. Accounting for the estimated campaign cost of \$32,000, the campaign saves an estimated \$16,015 per 1000 participants. These findings indicate that mass, rapidly implemented IPC for HIV, malaria and diarrhoea in a Western Kenya setting provides substantial health benefits in terms of deaths and DALY averted. The campaign was also economically attractive.

**Presentation: Water and Malaria: Common challenges, parallel paths**-Dr Michael Macdonald, WHO

Dr Macdonald highlighted similarities between HWTS and Malaria Vector Control (MVC) with the specific examples of Long Lasting Insecticidal Nets (LLIN) and integrated vector management. He noted that HWTS has the following challenges: moving from laboratory efficacy to community effectiveness, HWTS is a necessary but not sufficient intervention to interrupt diarrhoeal disease transmission, reaching vulnerable populations and providing them with effective and affordable HWTS solutions, and securing a correct and sustained use.

MVC has similar challenges to HWTS: reaching vulnerable population, providing LLIN, securing correct, consistent and sustained use, and favouring personal protection over community protection (less exposure reduces immunity). To overcome these challenges he noted that MVC has several strategic policies. These include:

- Universal coverage remains primary objective achieved through campaigns with routine distribution in-between;
- On-going efforts to look at other continuous distribution mechanisms to inform future strategy.
- Ensuring and improving upon the durability of nets;
- Prioritizing the most vulnerable populations and/or geographic areas; and
- Effecting disbursing resources to prevent delays in campaigns that might lead to resurgence.

In summary, Michael indicated that lessons from MVC can be applied to HTWS implementation for increasing demand, access and appropriate use. And strategic parallels exist between a comprehensive, sustained program for water safety and malaria vector control.

## **Presentation: Lessons from HIV Scale-up-Dr Elizabeth Marum, WHO**

In her presentation Elizabeth reflected on lessons learned from HIV services scale-up. She noted that early on in the effort to prevent HIV, testing was very rare, but in 2011, over 100 million tests were done resulting in millions on anti-retroviral treatment. Of the various avenues for integration in HIV programmes she felt prevention of mother to child transmission and home based ART presented the best platforms for reaching those most vulnerable to diarrhoeal disease associated with unsafe drinking-water. She also mentioned that effective scale-up requires cooperation within WHO and among UN agencies and partners. Finally she stressed the importance of ambitious targets, human rights based approach and engaging influential advocates both at the national and international level.

### **4. Conclusion**

It was agreed that more could and should be done to integrate HWTS with specific health programmes. Existing evidence indicates that use of HWTS can result in health improvements and can mutually profit from integration with other public health projects. The participants agreed to continue to work together on a statement for publication which will highlight key opportunities and work in their own capacities in furthering mutually beneficial health aims that have links to HWTS.

# Appendix 1. Assessing the Strength of Evidence on the Health Impact of Household Water Treatment and Safe Storage among Target Populations

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## 1. Introduction

Unsafe drinking water is a major killer, particularly of young children with undeveloped immune systems and for those whose immunity has been compromised due to malnutrition, HIV/AIDS or agedness. Diarrhoea represents a significant share of this burden. While recent estimates report significant declines in its contribution to the global burden of disease, diarrhoea is still a leading cause of morbidity and mortality in low-income settings (Lim 2012, Boschi-Pinto 2008). Diarrhoeal disease also contributes to decreased food intake and nutrient absorption leading to malnutrition, reduced resistance to infection, and impaired physical growth and cognitive development (Baqui 1993, Guerrant 1999). Repeated exposure to faecal pathogens is also associated with sub-clinical infections leading to environmental enteropathy (Humphrey 2009). Unsafe drinking water also contributes to more than 25 million cases and 250,000 deaths annually of enteric fevers (typhoid and paratyphoid) (Crump 2010), as well as to much of the disease burden from cholera, poliomyelitis and hepatitis A and E.

As part of its Millennium Development Goals (MDGs), the UN expressed its commitment by 2015 to reduce by half the proportion of people without “sustainable access to safe drinking water”. As of 2010, an estimated 850 million people worldwide lacked access to improved water sources (WHO/UNICEF 2012). While progress is being made, current trends will leave hundreds of millions unserved by the target date. Three quarters of these will live in rural areas where poverty is often most severe and where the cost and challenge of delivering safe water are greatest. Even improved water supplies, however, such as protected wells and communal stand posts often fail to deliver safe drinking water in setting with poor sanitation due to infusion of faecal contamination (WHO/UNICEF 2010). Moreover, water that is microbiologically safe at the source or other point of distribution is subject to frequent and extensive faecal contamination during collection, transport and storage in the home (Wright 2003). Thus, without an effective intervention, the potential health benefits of safe drinking water will remain elusive for vast populations for years to come.

Providing safe, reliable, piped-in water to every household is an essential goal, yielding optimal health gains while contributing to the MDG targets for poverty reduction, nutrition, childhood survival, school attendance, gender equity and environmental sustainability. While committed strongly to this goal, and to incremental improvements in water supplies wherever possible, the WHO and others have called for targeted, interim approaches that will accelerate the health gains associated with safe drinking water for those whose water supplies are unsafe (Sobsey 2002). While careful not to encourage diversion of resources away from increasing access to safe and reliable piped water, public health officials have called for other approaches that will provide some of the health benefits of safe drinking water while progress is

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<sup>5</sup>This background paper attempts to provide a balanced summary of the research concerning HWTS, particularly in respect of specified populations that may be most vulnerable. It relies heavily on systematic reviews and other papers by Fewtrell (2005), Clasen (2006), Arnold (2007), Waddington (2009), Peletz (submitted) and Lantagne (2012). Some of these reviews, and many of the other papers included in this summary were co-authored by me. Over the last ten years, I have also conducted research and consulting services on HWTS for a variety of governments, UN organizations, bilateral donors, NGOs and private commercial companies. In reviewing this background paper and the research cited herein, the Task Force should be mindful of the potential conflict of interest created by this prior work. The author gratefully acknowledges the comments and suggestions of Dr. M. Montgomery on a previous draft of this report.

being made in improving infrastructure (Mintz 2001, WHO 2005).

One such alternative is household water treatment and safe storage (HWTS) (WHO 2007). In many settings, both rural and urban, populations have access to sufficient quantities of water, but that water is unsafe for consumption as a result of microbial or chemical contamination. This is increasingly true even for piped-in water, since supplies are rarely provided on a 24-7 basis, forcing householders to store water in the home, thereby subjecting it to re-contamination through unsafe handling and storage practices. In addition, inconsistent flow results in pressure changes in the piped network which increase the risk of microbial infiltration (Besner 2010).. Effective treatment at the household level—often using the same basic approaches of filtration, disinfection and assisted sedimentation, as characterize conventional water treatment—can remove, kill or inactivate most microbial pathogens (Quick 1996, Luby 2001, Rangel 2003, Souter 2003). Moreover, by focusing at the point of use rather than the point of delivery, treating water at the household level minimizes the risk of recontamination that even improved water supplies can present (Wright 2003).

Although HWTS is not new, its promotion as a focused public health intervention strategy is just emerging. For centuries, householders have used a variety of methods for improving the appearance and taste of drinking-water, including filtering it through porous rock, sand and other media or using natural coagulants and flocculants to reduce suspended solids. Even before germ theory was well established, successive generations were taught to boil water, expose it to the sun or store it in metal containers with biocidal properties, all in an effort to make it safer to drink. Only in 2008, however, did the WHO acknowledge the potential contribution of HWTS in its *Guidelines for Drinking-Water Quality* (GDWQ): “HWT technology has the potential to have rapid and significant positive health impacts in situations where piped water systems are not possible and where people rely on source water that may be contaminated, or where stored water becomes contaminated because of unhygienic handling during transport or in the home” (WHO 2008). The WHO also recognized the contribution that HWTS can make among people living with HIV/AIDS, both in providing safe drinking water for those on drug therapy and for the preparation of replacement feeds for mothers who are HIV+ and choose not to breastfeed in order to prevent transmission of the virus in breastmilk (WHO 2009). In 2009, the WHO and UNICEF announced a seven-point strategy for the treatment and prevention of diarrhoea among children that includes HWTS, calling for the adoption of “household water treatment and safe storage systems, such as chlorination and filtration, in both development and emergency situations to support reductions in the number of diarrhoea cases” (WHO/ UNICEF 2009).

Despite this support for HWTS as a targeted intervention for preventing diarrhoea and other water borne diseases among vulnerable populations, the promise of the intervention has yet to be fully realized. This is due in part to three fundamental challenges that research has shown to be inherent to achieving any health gains from the intervention: (i) reaching a vulnerable population, (ii) providing them with effective and affordable HWTS solutions, and (iii) and securing their correct, consistent and sustained use.

While efforts are continuing in addressing these challenges, however, some have questioned the actual strength of the evidence on which HWTS promotion has been based. Schmidt and Cairncross (2009) have argued that efforts to scale up the intervention are premature given uncertainty about the health impact of the intervention and the potential for diversion of resources away from improved water supplies that can increase water quantity and access as well as quality. Others have responded to these assertions, citing studies showing an effect on objective health indicators, including stool samples, serology and mortality, and arguing that the evidence suggests the intervention can be protective even if estimates of effect are exaggerated due to reporting bias (Clasen 2009).

The WHO has convened an expert task force (the Task Force) to review the evidence on the health impact of HWTS to review and assess the strength of the evidence on the health impact of HWTS

in respect of four categories of potentially vulnerable populations: These populations include (i) general populations in low-income settings who may be exposed at times to untreated water, (ii) young children, (iii) people living with HIV, (iii) people affected by emergencies (natural disasters, conflicts and outbreaks), and (iv) people relying on surface and other unimproved water supplies. The purpose of this background paper is to summarize the relevant research.

Before addressing the evidence on health impact (Section 4), however, this paper summarizes certain factors that may be important in assessing the evidence concerning HWTS (Section 2). It then describes briefly the leading types of HWTS methods (Section 3).

## 2. Assessing the Evidence of the Health Impact

### 2.1 Assessing the Strength of the Evidence.

A threshold question in assessing the strength of the evidence on HWTS is the standard to be applied. One approach is a grading system developed by the World Cancer Research Fund (WCRF 2007) but applied broadly to other health sectors, most recently as part of the Global Burden of Disease 2010 (Lim 2012). That approach defines four categories of evidence:

**Convincing Evidence:** Evidence based on epidemiological studies showing consistent associations between exposure and disease, with little or no evidence to the contrary. The available evidence is based on a substantial number of studies including prospective observational studies and where relevant, randomised controlled trials of sufficient size, duration, and quality showing consistent effects. The association should be biologically plausible.

**Probable evidence:** Evidence based on epidemiological studies showing fairly consistent associations between exposure and disease, but for which there are perceived shortcomings in the available evidence or some evidence to the contrary, which precludes a more definite judgment. Shortcomings in the evidence may be any of the following: insufficient duration of trials (or studies); insufficient trials (or studies) available; inadequate sample sizes; or incomplete follow-up. Laboratory evidence is usually supportive. The association should be biologically plausible.

**Possible evidence:** Evidence based mainly on findings from case-control and cross-sectional studies. Insufficient randomised controlled trials, observational studies, or non-randomised controlled trials are available. Evidence based on non-epidemiological studies, such as clinical and laboratory investigations, is supportive. More trials are needed to support the tentative associations, which should be biologically plausible.

**Insufficient evidence:** Evidence based on findings of a few studies which are suggestive, but insufficient to establish an association between exposure and disease. Little or no evidence is available from randomised controlled trials. More well-designed research is needed to support the tentative associations.

There are other scales for categorizing the strength of epidemiological evidence. However, it may be helpful to keep these types of scales in mind and perhaps even use them in assessing the evidence on HWTS.

### 2.2 Types of Studies

The evidence around HWTS derives from six basic types of studies: laboratory studies, field studies of microbiological effectiveness, acceptability/uptake studies, efficacy studies, effectiveness studies and epidemiological modelling.

Several dozen laboratory studies have been conducted on the various methods for treating water at the household level. The primary purpose of these studies is to assess the microbiological performance of the methods. While these follow various approaches, many of the studies are based on a methodology prescribed by the US EPA *Guide Standard and Protocol for Testing Microbiological Water Purifiers* or, more recently, the WHO's *Evaluating household water treatment options: health-based targets and microbiological performance specifications* (WHO 2011). Laboratory studies also often assess dosing and filter flow rate/longevity under various chemical and physical conditions (TDS, temperature, pH, turbidity) that can affect POU water treatment performance. While there is some disagreement about testing methods or standards for HWTS methods, there is little controversy about the quality of the evidence from laboratory testing. WHO recognizes that the functional objective of HWTS is to reduce pathogens sufficiently to protect health and thus pathogen removal performance is a pre-requisite for realizing health gains from HWT (WHO 2011). This background paper cites only a few examples of these types of studies.

On the other hand, it should not be assumed that the microbiological performance that HWTS methods achieve in the laboratory would be transferred to the field. In a study in Ecuador, for example, McLaughlin and colleagues (2009) found that while point-of-use chlorination was substantially less effective in reducing levels of *E. coli* in households than it had been in controlled conditions in the laboratory. In three case studies in India, Zambia and Peru, Rosa (2012) also found that drinking water from households who reported treating it at home using microbiologically effective methods such as boiling, chlorination and filters was often still contaminated. Among the possible reasons for this disparity between laboratory and household results are (i) poor quality products, such as low potency chlorine or defects in filters, (ii) incorrect use of the methods by householders, and (iii) recontamination of the water after treatment. Inconsistent compliance, another possible reason why lab results fail to transfer to the field, is a separate issue discussed below.

A third class of HWTS studies focuses on acceptability and use (uptake) of the various methods of treating water at the household level and assessments of various strategies for improving uptake among vulnerable populations. Examples of the former are studies from Kenya and Bangladesh that compare acceptability and use of a variety of filtration and disinfection products (Albert 2010, Luoto 2011). Examples of the later are studies that evaluate uptake following promotion through schools, clinics, health care workers, and women's self-help groups (Freeman 2011, Patel 2012, Freeman 2012). In some cases, these studies rely on reported uptake, but in most cases they use objective indicators such as the presence of chlorine water stored in the home or water in filters.

In terms of health impact evaluations, the great majority of studies that employ an intervention (experimental) design, either on a randomized, quasi-randomized or non-randomised basis, consist of "efficacy" studies. These are usually research-driven studies under controlled conditions and in settings that are often carefully selected to meet the needs of the research (high prevalence of diarrhoea, poor water quality, etc.) rather than be representative of a broader population. Moreover, the intervention itself—and particularly the way it is promoted to the study population—is often more intensive than could be delivered at scale. Even the frequency of follow-up for research purposes is likely to influence the outcomes (Zwane 2009). As a result, there are questions about the external validity of these studies and good reasons to suspect that they exaggerate the results that are likely to be achieved in a similar intervention delivered to the general population at scale. Most of the research described in the systematic reviews presented below consists of these efficacy studies.

There are a few "effectiveness" studies in which the intervention is assessed in a real-world context. Two recent assessments of programmes by NGOs to introduce HWTS among vulnerable populations demonstrate the challenges of achieving uptake and the corresponding lack of any measurable

health impact. Arnold and colleagues (2009) assessed the uptake and health impact of a 3-year programme by NGOs in Guatemala to promote HWTS (boiling, Sodis and chlorination) and hand washing with soap. The six-month study used propensity scoring to match and compare 600 households in 30 villages (15 intervention/15 control). They found no statistically meaningful difference in adoption of intervention and control households for HWTS (9% vs. 3%) or hand washing. Consistent with the low sustained behaviour adoption, the investigators found no difference between intervention and control villages in child diarrhoea, respiratory infections or growth. Mausezahl and colleagues (2009) used a cluster-randomized controlled trial design in 22 rural communities in Bolivia to evaluate the effect of Sodis (solar disinfection) in reducing diarrhoea among children under the age of 5. A local NGO conducted a standardized interactive Sodis-promotion campaign in 11 villages targeting households, communities, and primary schools. Mothers completed a daily child health diary for 1 year. Despite this extensive promotion campaign, investigators found only 32% compliance with the intervention and no strong evidence for a substantive reduction in diarrhoea among children (RR 0.81 (95% CI 0.59–1.12)).

### **2.3 The Debate over Scaling up HWTS**

As noted above, there is increasing concern that the protective effect reported in many studies of HWTS interventions may be exaggerated due to reporting bias. Clasen and colleagues first observed that while more than two dozen studies of HWTS interventions reported a protective effect, none of the four studied that attempted to blind the intervention with a placebo found the effect to be statistically significant (Clasen 2006). In their review, however, they identified methodological issues in each of the blinded trials, including small sample sizes, low rates of disease, and similar water quality among the intervention and control groups that raised questions about their probity.

A subsequent editorial by Schmidt and Cairncross (2009) that included a blinded trial by Jain and colleagues (2010) argued that it was premature to promote scaling up HWTS interventions. The editorial cited the studies from the prior Cochrane review as well as a newer 12-week study among 240 households in Ghana that found no protective effect from a chlorine/safe storage intervention. However, even this blinded trial presented issues of interpretation as both the control and intervention groups used groundwater with little contamination compared to surface water, and the safe storage containers used by both groups were likely the important intervention (Clasen 2009). Nonetheless, this editorial launched a debate among researchers about the strength of the evidence and whether and under what circumstances HWTS should be promoted.

Two additional blinded studies conducted since 2009 also found a lack of health benefit though these also present issues that complicate interpretation. In a 12-month study in the Congo DRC, Boisson and colleagues (2010) found no significant impact on diarrhoea from a gravity filter. Investigators acknowledged that the “placebo” in that study was actually removing about 90% of faecal bacteria from drinking water (due to apparent biofilm action in an sham device that contained no actual filter media), a result that could have impacted the effect (Engler 2012). Moreover, while a large majority of householders used the filter, over 80% continued to drink untreated water, a result that the above cited modelling studies would predict to vitiate most of the potential health impact (Engler 2012, 2013). Most recently, in the largest scale blinded trial of an HWTS intervention to date, Boisson and colleagues (submitted) also found no protective effect on diarrhoea or weight-to-age (a possible objective proxy for recent diarrhoea) from NaDCC tablets provided free to both urban and rural populations over twelve months in India. Significantly, however, the investigators could not rule out the possibility that compliance was too low to realize a health impact.

The consistent discrepancy between the results from blinded versus open trial designs raises an important issue about the reliability of the estimates of effect from HWTS interventions. Clasen and

others (2009) have acknowledged the need for better evidence concerning whether and under what circumstances HWTS can be effective in preventing disease. However, they argue that it would be imprudent to abandon the intervention based on the current evidence base. Among other things, they note the following:

- The authors of each of the blinded trials of HWTS interventions conducted to date have themselves emphasized shortcomings in their studies and the generalizability of their findings. Accordingly, a superficial comparison of blinded versus open study designs that does not actually examine the underlying studies is misleading.
- There is compelling evidence of the health impact of improving microbiological water quality with no accompanying change in water quantity and access (Cutler 2005). In fact, much of the improvement in reduced child mortality and morbidity in developed countries over the last century is attributable to improvements in water quality. As improvements in water supplies do not always ensure improved water quality and are not likely to reach remote populations in the near future, interventions such as HWTS that specifically address water quality cannot be dismissed, even though they may not deliver all the gains associated with reliable piped water supplies.
- Wood and colleagues (2008) concluded that the absence of blinding and objective outcomes collectively inflated the actual effect by about 25%. Adjusting the pooled effect from the HWTS trials by this factor would still yield a substantial protective effect given the heavy burden of diarrhoeal disease and the comparatively low cost of some HWTS interventions.
- HWTS trials have shown effectiveness on objective health outcomes. Two studies that collected and analysed stool samples in addition to reported diarrhoea found both a lower prevalence of diarrhoeagenic agents among intervention group members and substantial reductions in reported diarrhoea (Mahfouz 1995, Quick 1999). In one of the few blinded trials of HWTS, anthropometrics showed that intervention group members were less likely to suffer from malnutrition than those in the control group (Austin, 1992). Crump et al. (2005) reported fewer deaths among intervention group members using HWTS (relative risk = 0.58,  $P = 0.036$ ) as well as reductions in reported diarrhoea when compared with a control group. Du Preez (2011) also reports an impact on child growth, though questions have been raised about their methods (Arnold 2012).
- The high level of heterogeneity among outcomes in HWTS is in fact consistent with a true, underlying effect that is not exclusively due to bias. Heterogeneity would be expected in view of the clinical and methodological heterogeneity among the studies (Thompson 2001). The differences include exposure (pathogens, transmission pathways, preventive measures, such as hygiene and sanitation), interventions (filters, disinfectants, hybrids), methods of delivery, levels of compliance and study methodologies (case definitions of diarrhoea, manner of disease surveillance, measures of disease frequency, measures of effect). The major factor influencing the effect in a specific situation is likely to be the extent to which water is the dominant pathway for transmission of diarrhoeagenic agents. If the protective effect in these studies were due exclusively to bias, one would in fact expect more homogeneity. The fact that the magnitude of an effect varies is not an argument against scaling up an intervention. Rather, it points towards the need to study these influences and learn how to best target the intervention to maximize public health benefit.

Those involved in HWTS have acknowledged in dozens of previous studies that there is a need to demonstrate that the intervention will be used correctly and consistently by vulnerable populations over the long term. However, there is no serious question about whether HWTS is acceptable at scale and sustainable over the long term; this is evident from the fact that boiling and other HWTS methods have been practiced by hundreds of millions of vulnerable householders for decades (Rosa 2010). Improving the microbiological performance and reducing the cost and environmental impact of these methods will themselves yield gains. However, the potential for HWTS will not be fully realized if the practice continues to be highly concentrated in some countries, such as Viet Nam and Indonesia, and not in other

countries, such as most of Africa.

There is a need for additional assessments of HWTS interventions using placebos (if possible) and objective outcomes in order to determine the actual protective effect of HWTS interventions to prevent diarrhoea (Clasen 2006, 2009a). Even so, the size of the effect, if any, is likely to depend largely on the prevailing conditions. The major factor influencing the effect is more likely to be the extent to which water is a significant pathway for transmission of diarrhoeagenic agents (Eisenberg 2007, 2012). Thus, any given trial, blinded or open, is unlikely deliver an estimate of effect that is fully generalizable, since the underlying effect will depend on transmission dynamics that vary according to settings, seasons and other factors. This is consistent with the large range of effect sizes and heterogeneity reported in the meta-analyses that accompanied each of these systematic reviews.

#### **2.4 HWTS: Necessary but Not Sufficient?**

There are two important reasons why even a microbiologically effective HWTS method may not actually prevent disease in under certain conditions. These reasons are (i) exposure through multiple pathways, only one of which is addressed by HWTS, and (ii) the need for high compliance. These are perhaps best demonstrated through epidemiological modelling.

The first reason is because HWTS only addresses the waterborne transmission route. Except perhaps in the context of an outbreak due to a waterborne agent such as cholera, water is rarely the sole transmission route to which people in low income countries are exposed to faecal pathogen; it may not even be the dominant pathway. The classic F-diagram reminds us that faecal pathogens can be transmitted through food, flies, fingers, fields and fomites, not just fluids such as water. Evidence from epidemiological modelling suggests that in most settings, an integrated, multi-barrier strategy that addresses these other pathways is necessary to achieve the kind of reduction in exposure to faecal pathogens that is necessary to actually prevent diarrhoea and enteric infection (Eisenberg 2007, Hunter 2009a). Eisenberg summarizes his conclusions about water quality interventions such as HWTS thus:

We found that the benefits of a water quality intervention depend on sanitation and hygiene conditions. When sanitation conditions are poor, water quality improvements may have minimal impact regardless of amount of water contamination. If each transmission pathway alone is sufficient to maintain diarrheal disease, single-pathway interventions will have minimal benefit, and ultimately an intervention will be successful only if all sufficient pathways are eliminated. However, when 1 pathway is critical to maintaining the disease, public health efforts should focus on this critical pathway.

As even advocates of HWTS have argued, safe drinking water is not a sufficient condition for preventing such disease, but it is a necessary condition (Clasen 2009). If the evidence on the health impact of HWTS is variable and uncertain, it may be because the actual extent to which water contributes to disease depends largely on the setting (and even the season in the setting) as well as other factors that science has not yet fully characterized (Clasen 2006).

#### **2.4 Need for Compliance (Adherence)**

The second reason why HWTS may not actually achieve optimal protection against waterborne pathogens is low compliance on the part of householders. Unlike vaccines and certain other interventions, HWTS requires householders to embrace and routinely use the intervention in order to provide protection; even occasional consumption of untreated water may neutralize the potential health benefits of the

intervention (Hunter 2009a). Using quantitative microbial risk assessment (QMRA), Brown and Clasen (2012) have shown that households relying on moderate water quality will realize only marginal reductions in episodes of diarrhoea unless they consume treated water almost exclusively. Engler and colleagues (2013) have also used modelling to demonstrate the need for correct, consistent use of HWTS methods.

Many interventions have been unable to achieve the levels of compliance that these modelling studies suggest necessary to achieve health benefits (Arnold 2007, Arnold 2009, Mausezahl 2009, Boisson submitted). There is also evidence that the health impact of some HWTS interventions diminishes over time, a factor that may be attributable to intervention fatigue (Arnold 2007, Waddington 2009, Hunter 2009). Both factors raise questions about the potential of the intervention to deliver on the promising results secured in many efficacy trials.

The Task Force will need to determine how these shortcomings in achieving correct, consistent and sustained use should be considered in its evaluation of the evidence and potential of HWTS. However, a shortcoming in compliance that impacts health outcomes may indicate a need for improved programming, not an inherent failure of the intervention.

## **2.5 Other Special Considerations in Assessing Evidence on HWTS.**

There are three additional points that the Task Force may want to consider in evaluating the evidence on HWTS.

First, as noted above, HWTS should be judged solely on its potential for advancing health (Clasen 2010). While improvements in health can yield other benefits, such as increased productivity and school attendance and savings in time and health care costs, these benefits can only be generated if the intervention is actual effective in preventing disease. This is in contrast to other environmental health interventions that may yield other benefits such as timesaving from improved water supplies and increased dignity from improved sanitation.

Second, the threshold of evidence necessary to support the promotion of HWTS in a given population should be determined in part by weighing the potential adverse consequences of the recommendation. Schmidt and Carincross (2009) have suggested, for example, that promotion of HWTS could divert government or other resources away from investments in infrastructure that could yield improvements in quantity, access and quality with fewer challenges to securing uptake. To date, there is little of any such diversion of public resources. However, from a societal perspective, expenditures by NGOs or other implementers—or by the householders themselves who must often pay for the cost of practicing HWTS by purchasing products or fuel for boiling water—do represent a genuine relinquishment of resources for other priorities.

At the same time, there is an important consideration that should urge caution in raising the evidentiary bar too high for HWTS: more than a billion people are treating their water at home now, many following a tradition that is almost universal in their culture and has been handed down for generations (Rosa 2010). This is not an intervention like a new drug or vaccine that governments and other implementers are contemplating anew, waiting for the evidence to come in before deciding whether to introduce and scale it up. There is evidence that large populations in Asia may already be benefiting from a cultural propensity to use boiled water in preparing food and beverages (Rudan 2010). The Task Force's recommendations regarding HWTS will not only impact future policy regarding the practice; it will also impact government policies regarding vast numbers of households that already practice HWTS.

## **3. HWTS Methods**

In 2000, the WHO commissioned a comprehensive study to review HWTS methods and practices. The review identified 37 different options for treating and safely storing water at the household level and assessed the available evidence on their microbiological effectiveness, health impact, acceptability, affordability, sustainability and scalability (Sobsey 2002). This section summarizes those options for which there is significant research on microbiological effectiveness and health impact. For additional details regarding these and other HWTS interventions, readers are referred to the websites on the intervention maintained by the WHO ([http://www.who.int/household\\_water/en/](http://www.who.int/household_water/en/)) and the US Centers for Disease Control and Prevention (CDC) ([www.cdc.gov/safewater](http://www.cdc.gov/safewater)) which both contain other useful links.

### 3.1 Boiling.

Boiling or heating with fuel is perhaps the oldest means of effectively disinfecting water at the household level. It is certainly the most common, with an estimated 600 million people in low and middle-income countries reporting that they usually boil their water before drinking it (Rosa 2010). If practiced correctly, boiling is also one of the most effective, killing or deactivating all classes of waterborne pathogens, including bacterial spores and protozoan cysts that have shown resistance to chemical disinfection and viruses that are too small to be mechanically removed by microfiltration. Moreover, while chemical disinfectants and filters are challenged by turbidity and certain dissolved constituents, boiling can be used effectively across a wide range of waters. While some authorities recommend boiling water for 10, 20 and even 25 minutes, the WHO GDWQ simply recommend bringing water to a rolling boil as an indication that a disinfection temperature has been achieved (WHO 2008). In fact, evidence indicates that enteric bacteria, protozoa and viruses in liquids are sensitive to inactivation at temperatures below 100°C and thus the recommendation to heat water to a rolling boil and then cool it to room temperature or below would provide more than enough time to inactivate pathogenic bacteria, viruses and protozoa (Fayer 1994, Spinks 2006)..

For decades, governments, NGOs and others have promoted boiling, both in developing countries where water is routinely of uncertain microbial quality and in developed countries when conventional water treatment fail or water supplies are interrupted due to disasters or other emergencies (Gilman 1985). Among householders who report that they “always” or “almost always” treat their water by boiling, the practice has been associated with reductions of faecal bacteria of 99% Vietnam (Clasen 2008), 97% in India (Clasen 2009b) and 86.2% in Guatemala (Rosa 2010a). In rural Kenya, pasteurization of water using a simple wax indicator to show householders when water reached 70° C increased the number of households whose drinking water was free of fecal indicator bacteria from 10.7% to 43.1% and significantly reduced the incidence of severe diarrhea compared to a control group (Iijima 2001). Given this evidence of microbiological effectiveness, and the widespread use of the practice, Clasen and colleagues (2008, 2009b) have argued that boiling is the benchmark against which all other HWTS methods should be measured.

### 3.2. Chlorination.

Chlorination is the most widely practised means of treating water at the community level; it has been used to continuously in the Europe and North America for more than 100 years (Sobsey 2002). Combined in most cases with some level of filtration to remove solids and reduce chlorine demand, community-based chlorination of drinking water has been credited with nearly half the total mortality reduction, three quarters of the infant mortality reduction, and nearly two thirds of the child mortality reduction in major cities in the early 20<sup>th</sup> century, the period which recorded the largest gains in childhood health (Cutler 2003).

Chlorination is also used increasingly at the household level. An estimated 5.6% of households in middle- and low-income countries, or 67 million people, report that they usually treat their water with bleach (sodium hypochlorite) or another source of chlorine at home before drinking it (Rosa 2010). Tablets formed from dichloroisocyanurate (NaDCC), a leading emergency treatment of drinking water, and novel systems for on-site generation of oxidants such as chlorine dioxide, also have a role in household water treatment. At doses of a few mg/l and contact time of about 30 minutes, free chlorine can inactivate more than 99.999% of enteric pathogens, the notable exceptions being *Cryptosporidium* and *Mycobacterium* species (WHO, 2011).

The Safe Water System (SWS) is a programmatic chlorination intervention developed by the US Centers for Disease Control and Prevention in response to a cholera outbreak in Latin America. It

combines bottles of dilute sodium hypochlorite with safe storage and behaviour change techniques ([www.cdc.gov/safewater](http://www.cdc.gov/safewater)). The microbiological efficacy of the SWS has been demonstrated (Quick 1996, Rangel 2003), and the effectiveness of the intervention in reducing diarrhoeal disease has been reported in a variety of settings (Semenza 1998, Quick 1999, 2002, Reller 2003, Luby 2004, Chiller 2006).

Despite impressive gains in coverage, the adoption and long-term use of chlorine-based HWTS options has been challenging. Follow-up studies on populations exposed to the intervention on a programmatic basis have reported mixed (Clasen 2009a). Though there is evidence of widespread uptake in Zambia and other countries, achieving correct, consistent use of the intervention by the target population is a significant challenge for all HWTS options. In an effort to address the deficiencies with respect to chlorine, investigators have begun experimenting with the placement of chlorine dispensers at protected springs and other water sources (Kremer 2010). After collecting a vessel of water, users turn a valve to deliver a measured dose of a stock solution of sodium hypochlorite directly into their water, starting the 30-minute contact time even before they reach home. There is some initial evidence that these chlorine dispensers have higher levels of consistent uptake than chlorine products that are purchased for household use (Kremer 2010). Research is underway to explore this alternative in greater scale and to investigate strategies for ensuring that the dispensers are filled when necessary. As most of the cost of the SWS and similar sodium hypochlorite solutions is in the packaging, bulk chlorine dispensers offer an alternative that is significantly lower in cost per litre or cost per household. Whether there is a way to recover the cost of treatment is not yet clear.

### **3.3 Solar Disinfection.**

Solar disinfection has been subject to rigorous efficacy testing, both in the laboratory and under field conditions, and evaluated for effectiveness in preventing diarrhoeal disease. The Sodis bottle system which simply involves filling 1-2L plastic PET bottles with water and exposing them to the sun for 6 or more hours, has been particularly well documented (McGuigan 2012). Testing in the laboratory has demonstrated the microbiological efficacy of the method against a variety of pathogens. As described below, a number of field studies have been conducted to assess the effectiveness of the intervention against diarrhoea and dysentery.

### **3.4 Filtration.**

Unlike boiling, chlorination and solar disinfection, household filtration encompasses a variety of different processes and products for improving the microbiological quality of drinking water. Mechanical filtration involves the physical removal of suspended solids (including microbes) from water by employing a porous media whose pore size is smaller than the target contaminant. Common media include cloth, sand, porous rock, unglazed ceramics. Advanced membranes for microfiltration, ultrafiltration, nanofiltration and reverse osmosis are also used, but must be specially configured for gravity-pressure applications common in low-income settings. Adsorption involves the retention of contaminants within the medium itself, much like a sponge retains water. Activated carbon, either in block or granulated form, is the most common adsorption media for treating water, but is rarely used in low-income settings because of the inability to determine when its adsorption capacity has been exhausted.

Slow-sand filters, which remove suspended solids and microbes by means of a slime layer (*schmutzdecke*) that develops within the top few centimetres of sand, are capable of removing 99% or more of enteric pathogens if properly constructed, operated and maintained (Hijnen 2004). A simpler but more advanced version, known as the “bio-sand” filter, was specifically designed for intermittent use and is more suitable for household applications. It has been tested both in the laboratory and the field (Stauber 2006, Tiwari 2009) and is being deployed widely in development settings by some non-governmental organizations (Clasen 2009a).

Ceramic filters have been used for treating drinking water for more than a century (Sobsey 2002). Higher quality ceramic filters treated with bacteriostatic silver have been shown effective in the lab at reducing waterborne protozoa by more than 99.9% and bacteria by more than 99.9999%; to date, however, they have not met targets for reducing waterborne viruses, though viral sorption and inactivation can be enhanced by special processing (Brown 2009). Commercial gravity filters are typically formed into hollow cylindrical “candles” which are mounted into the top of a two-compartment vessel; locally fabricated filters usually consist of a ceramic pot that serves as the upper chamber and is designed to fit directly into a lower plastic vessel. Pathogens are removed as contaminated water passes through the ceramic in the top compartment to the lower holding compartment. Because the filtered water can only be accessed from this lower compartment by a tap or spigot, it is protected from another significant risk--recontamination prior to consumption.

Larger commercial companies have also developed, tested and promoted the use of gravity filtration technologies. A hollow-fibre membrane filter has been shown to treat up to 18,000L (designed for a household of five for three years) (Clasen 2009). While a blinded study field study of the device in the Congo reported no effect (Boisson 2009), a smaller open trial using the filter combined with safe storage was effective in preventing reported diarrhoea (but not improving wasting) in children <2 with mothers that were HIV+ (Peletz 2012). A commercial table-top filter using multiple barriers has been shown to be effective in improving water quality in the laboratory and in the field (Clasen 2006, Freeman 2011), though no studies of the impact of the device on health have been published to date.

### **3.5. Combination Flocculation and Disinfection.**

Sachets combining flocculation and disinfection agents were developed in South Africa more than two decades ago. The original products, employ alum to reduce turbidity and chlorine-resistant protozoan cysts and dichloroisocyanurate to inactivate bacteria and viruses. In 2002, a large US consumer goods company began field testing its own flocculation/disinfectant sachets. The product uses ferric sulfate as the flocculant and calcium hypochlorite as the disinfectant, and was designed to address perceived deficiencies in other combination products. Users open the sachet, pour the contents into 10L of water, stir it repeatedly for several minutes until the floc settles out in the bottom of the vessel, pour the supernatant through a clean cloth into another vessel, then allow it to stand for 30 minutes.

Few HWTS technologies have been tested as extensively as coagulant-flocculant sachets, both in the laboratory and the field. Laboratory tests demonstrated that the product is highly efficacious, not only against bacteria (>99.99999% reduction), virus (>99.99%) and cysts (>99.95%), but also in reducing levels of arsenic, a significant chemical health hazard in many South Asian water supplies (Rangel 2003). Significantly, the sachets have also shown efficacy against arsenic, an important waterborne risk in many Asian countries (Souter 2003, Norton 2008). A series of rigorous field trials have been undertaken, mainly to assess the efficacy of the intervention in reducing diarrhoeal disease. Some of these studies also assessed the microbiological performance of the intervention (Reller 2003, Luby 2004, Crump 2005, Doocy 2006, Chiller 2007).

### **3.6 Safe Storage.**

Households without access to piped-in water are normally required to store water in the home. Research has consistently found that even water that is safe at the point of collection is subject to frequent and extensive microbial contamination during collection, transport and storage in the home, usually as a result of poor hand hygiene and the practices of drawing drinking water by dipping into a large-mouth vessel (Wright 2003). The microbiological quality of water from contaminated surface or other sources will be aggravated as a result of poor storage practices. While there is some debate over the pathogenicity

of microbes circulating in the household (domestic domain) as opposed to those outside the home (public domain) (Cairncross 1996), rigorous field trials have reported reductions in diarrheal disease in children from the distribution and use of improved vessels for storing water (Roberts 2001). Some of the key factors influencing the impact of storage vessels and conditions on household water quality are: (1) portability and ease of use, based on capacity, size, shape, weight, presence of handles, (2) durability, weight and other properties related to resistance and longevity, (3) presence of a coverable (preferably screw-cap) opening for filling and cleaning access but small enough to reduce the potential for introducing contaminants by contaminated hands, dipping utensils and other vehicles (e.g., airborne dust), vectors, or other sources, (4) ability to withdraw water in a sanitary manner, such as via a tap, spigot, spout or other narrow orifice, and (5) presence and accessibility of documentation describing how to properly use the container for water treatment and sanitary storage (Mintz 2001).

#### 4. Health Impact Evaluations

##### 4.1 General Populations in Low-Income Countries

Two decades ago, Esrey and colleagues reviewed previous studies on the impact of environmental interventions on diarrhoea, and found improvements in water quality to be considerably less effective than those aimed at water quantity, water availability and sanitation (Esrey 1985, 1991). Ubiquitously cited in both professional journals and practical guides, the reviews have led to the dominant paradigm respecting water supply and sanitation interventions: that to achieve broad health impact, greater attention should be given to safe excreta disposal and proper use of water for personal and domestic hygiene rather than to drinking-water quality. The corollary has become equally established: that interventions aimed solely at improving drinking water quality would have relatively little impact in reducing diarrhoeal disease.

Over the last two decades, however, efficacy trials on HWTS provided evidence that lead to a refinement of the dominant paradigm. Esrey's conclusions that water quality improvements could reduce diarrhoeal disease by 15%-17% were based exclusively on studies involving interventions at the point of distribution, such as protected wells and springs. Thus, it did not capture the potential additional health gains that could be achieved by ensuring water quality to the point of use by treating it at the household level or by preventing recontamination after collection, transport and storage in the home.

Table 1 summarizes the results of two more recent systematic reviews of water interventions to prevent diarrhoeal diseases. They suggest that improvements in water quality make substantial contributions to the prevention of diarrhoeal diseases. Among household-based interventions, filtration was associated with the largest reductions in diarrhoeal disease, perhaps because it also improves water aesthetics, which may increase use (compliance) with the intervention.

**Table 4.1: Pooled estimate of risk (and number of studies) of systematic reviews of water quality interventions to prevent diarrhoeal disease among all ages**

Intervention (Improvement)	Fewtrell & Colford 2005 (95% CI)	Clasen <i>et al.</i> 2006 (95% CI)
Source-based	0.89 (0.42-1.90)(3)	0.73 (0.53-1.01) (6)
Household-based	0.65 (0.48-0.88)(12)	0.53 (0.39-0.73)(32)
Chlorination		0.63 (0.52-0.75)(16)
Filtration		0.37 (0.28-0.49)(6)
Solar disinfection		0.69 (0.63-0.74) (2)
Floc-disinfection		0.69 (0.58-0.82)(6)

Fewtrell and Colford (2005) were the first to identify the apparent benefit of improving water quality at the household level over improvements at the source:

Improving the microbial safety of water immediately before consumption seems to be very effective in reducing diarrhoeal disease, especially when only good quality studies are examined (relative risk 0.61, 95%CI: 0.46–0.81). This result makes intuitive sense, and is important because many households in less developed countries do not have individual connections to treated, piped water, or 24 h access to water. Such households typically store water in the home, and this water is vulnerable to contamination (primarily from handling) during transport and storage, even if it is clean at source. The result suggests that a water quality intervention at the point of use should be considered for any water supply programme that does not provide 24 h access to a safe source of water.

Nevertheless, researchers identified certain shortcomings in the evidence, including the paucity of longer-term studies, heterogeneity, and the possible role of reporting and publication bias.

A year later, Clasen and colleagues were able to identify more than twice as many intervention studies, but came to a similar conclusion about the health advantage of ensuring water quality at the household level. At the same time, they cautioned about the need for more rigorous study designs, particularly blinded and longer-term studies:

Interventions to improve water quality are generally effective in preventing diarrhoea, and interventions to improve water quality at the household level are more effective than those at the source. Significant heterogeneity among the trials suggests that the actual level of effectiveness may depend on a variety of conditions that research to date cannot fully explain. Rigorous, blinded, multi-arm randomized controlled trials conducted over a longer duration in a variety of settings may help clarify the potential effectiveness.

Two more recent reviews used data from Clasen's Cochrane review to conduct further analysis. Hunter (2009) undertook a meta-regression analysis to explore the causes of the heterogeneity in the results to potentially identify factors associated with good health gains. The overall effect size of all unblinded studies was relative risk = 0.56 (95% confidence intervals 0.51-0.63), but after adjusting for bias due to lack of blinding the effect size was much lower (RR = 0.85, 95% CI = 0.76-0.97). Hunter found that four main variables were significant predictors of effectiveness of intervention in a multi-predictor meta regression model: Log duration of study follow-up (regression coefficient of log effect size = 0.186, standard error (SE) = 0.072), whether or not the study was blinded (coefficient 0.251, SE 0.066) and being conducted in an emergency setting (coefficient -0.351, SE 0.076) were all significant predictors of effect size in the final model. Compared to the ceramic filter all other interventions were much less effective (biosand 0.247, 0.073; chlorine and safe waste storage 0.295, 0.061; combined coagulant-chlorine 0.2349, 0.067; SODIS 0.302, 0.068). A Monte Carlo model predicted that over 12 months ceramic filters were likely to be still effective at reducing disease, whereas SODIS, chlorination, and coagulation-chlorination had little if any benefit; the actual benefit of these interventions was eliminated when adjusting for the apparent reporting bias from the lack of blinding.

Cairncross and colleagues (2010) also used data from the Clasen review, but concluded that the evidence did not support a departure from Esrey's 17% estimate of effect from water quality interventions (similar to Hunter's 15% estimate after adjusting for non-blinding). This was based on four factors: (i) biological plausibility ("a subject would have to ingest very large amounts of water in order to consume an infectious dose of a bacterial pathogen"), (ii) the anomaly that the reduction in diarrhoea seems to be independent of the quality of the ambient water before it is treated, (iii) the assertion that observational studies of drinking-water quality do not show such large effects as the point-of-use intervention trials, and

(iv) the fact that most of these trials were funded by manufacturers of water treatment chemicals or equipment.

Since these reviews were completed in 2008, there have been a number of health impact evaluations of HWTS interventions in low-income settings. Although these are currently being included in an update of Clasen's Cochrane review, the results are not yet available. The electronic search for such update, however, identified 18 newer studies (Appendix A). Most are randomized or quasi-randomized trials, though some follow a matched cohort or other observational study design. Thirteen studies found the interventions to be protective against diarrhoea (Brown 2008, Boisson 2009, Stauber 2009, Tiwari 2009, Harris 2009, DuPreez 2010, Opryszko 2010, DuPreez 2011, Islam 2011, McGuigan 2011, Peletz 2012, Fabiszewski 2012, Stauber 2012); five studies found no protective effect (Arnold 2009, Mausezahl 2009, Boisson 2010, Jain 2010, Boisson submitted). Notably, all the studies that found the intervention to be protective were open (non-blinded) efficacy trials, while all the studies that reported no protective effect were either effectiveness studies that evaluated programmatically delivered interventions (Arnold 2009, Mausezahl 2009) or blinded studies (Boisson 2010, Jain 2010, Boisson submitted). Two papers included in the Appendix A summarize the study protocols of these studies (Hartinger 2011, Overgaard 2012). Most newer studies also relied on subjective outcomes (self-reported diarrhoea) rendering them susceptible to reporting bias. The exceptions were Arnold (2009), Du Preez (2011), and Peletz (2012), all of which included anthropometrics as an outcome, though other questions have been raised about the analysis of data from the Du Preez study (Arnold 2012). Islam (2011) used clinical records and two studies (Du Preez 2010, McGuigan 2011) used bloody diarrhoea (dysentery), which may be less susceptible to recall bias.

Jain and colleagues also assessed NaDCC tablets in a blinded trial design, again with no evidence of an effect. Unlike the other studies, however, Jain reported high uptake, ranging from 74–89% in the intervention group compared to 0–7% in the control group. The investigators speculated that two possible reasons for the lack of an effect in their study were (i) the relatively low level of faecal contamination in the water, and (ii) the fact that the control arm received an improved vessel which may have prevented much of the potential recontamination (Jain 2010). The study was of short duration (12 weeks).

## 4.2 Young Children

Due to undeveloped immune systems, young children are particularly vulnerable to enteric infection. While recent figures indicate that the majority of diarrhoeal deaths are no longer among children <5 years, they still constitute a sizeable proportion of diarrhea mortality (WHO unpublished figures 2013, Liu, et. al., 2012).. Mortality curves show that the risk rises rapidly commencing at six months when exclusive breastfeeding ends, peaks between 6 and 11 months, and then drops slowly as children age (Kosek 2003). Overall, morbidity during the peak 6-12 month period is about 10 times greater than that of children 5-15 years; on the other hand, morbidity of children aged 4 is only about 2 times that of the 5-15 year olds (Snyder and Merson 1982). While deaths from diarrhoea have fallen dramatically over the past two decades it is likely due to advances in case management, improvements in water, sanitation and hygiene and overall economic development. (Kosek 2003).

Three systematic reviews have summarized the evidence on the impact of water quality interventions, including HWTS, on young children. In addition to the results reported above for the general population, Clasen and colleagues (2006) reported separately on the estimates of effect on children <5. Only a year after the Clasen review, Arnold and colleagues published another review that focused solely on household-based chlorination studies among young children (Arnold 2007). More recently, Waddington and colleagues (2009) conducted a review studies reporting on the impact of water, sanitation and hygiene interventions on children <6. The results of these reviews are presented in Table 4.2 below:

**Table 4.2: Pooled estimate of risk (and number of studies) of systematic reviews of water quality interventions to prevent diarrhoeal disease in young children**

<b>Intervention (Improvement)</b>	<b>Clasen <i>et al.</i> 2006 (95% CI)</b>	<b>Arnold <i>et al.</i> 2007 (95% CI)</b>	<b>Waddington <i>et al.</i> 2009 (95% CI)</b>
Source	0.85 (0.71-1.02) (4)		0.79 (0.62-1.02) (3)
Household	0.52 (0.32-0.83) (20)		0.56 (0.45-0.65) (28)
Filtration	0.36 (0.24-0.53) (5)		
Chlorination	0.74 (0.63-0.86) (12)	0.71 (0.58-0.87) (21)	
Solar disinfection	0.69 (0.63-0.74) (2)		
Floc-disinfection	0.52 (0.-2.46) (3)		

The conclusions and recommendations from Clasen’s Cochrane review have already been quoted above. Arnold reached a similar estimate of effect from chlorine interventions. He also noted the short duration of most trials, and was the first to identify a trend showing that longer-duration studies reported a lower level of protective effect:

A major finding from this review is that nearly all trials on this topic have been short (median length was 30 weeks). Although not statistically significant, we observed an attenuation of the intervention’s reduction of child diarrhea in longer trials. Future studies with multi-year follow-up are required to assess the long-term acceptability and sustainability of health impacts shown by the shorter trials identified in this review.

As part of a larger review on water, sanitation and hygiene interventions generally (to update Esrey), Waddington and colleagues (2009) also reported on HWTS interventions; they focused, however, only on results among children. Since they look at most of the same studies, it is not surprising that the Waddington and Clasen results are similar. Both found HWTS to be highly effective, but expressed some reservations about the quality of the evidence, particularly the need for longer term RCTs. Waddington also emphasized the need to evaluate the sustainability of the protective effect:

While point-of-use water quality interventions appear to be highly effective—and indeed, more effective than water supply or source treatment in reducing diarrhoea—much of the evidence is from trials conducted over small populations and short time periods. More evidence is needed on sustainability, as water quality interventions conducted over longer periods tend to show smaller effectiveness, while compliance rates, and therefore impact, appear to fall markedly over time.

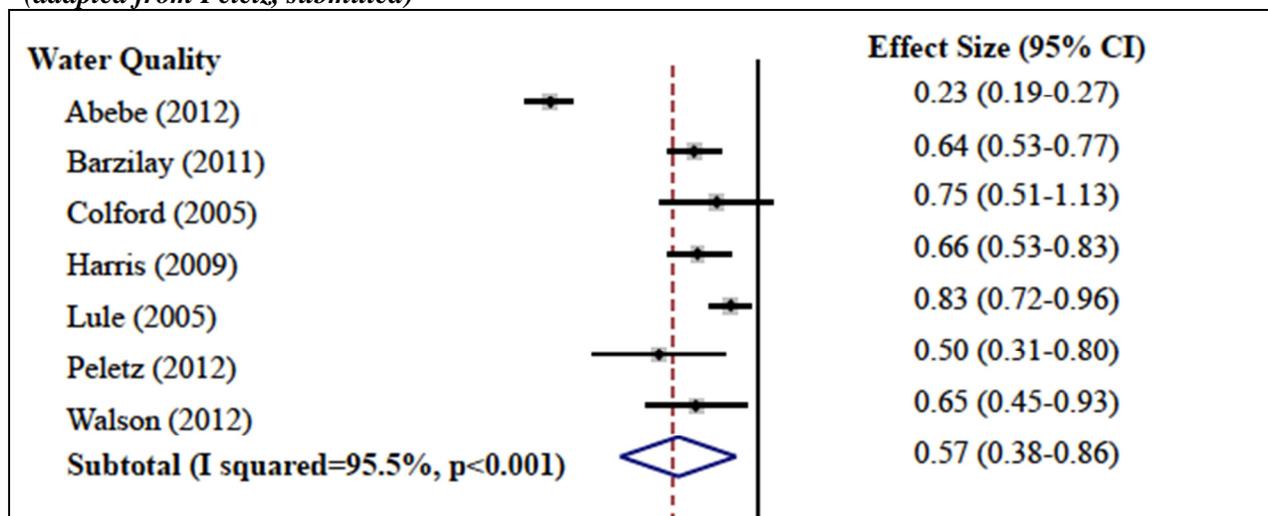
As noted above, a large number of health impact evaluations of HWTS interventions have been conducted since 2008 that are not included in the previous reviews (Appendix A). Some of these studies reported on health impacts among young children (mainly <5s). Ten studies found the interventions to be protective against diarrhoea in young children (Boisson 2009, Harris 2009, Tiwari 2009, DuPreez 2010, Opryszko 2010, DuPreez 2011, McGuigan 2011, Peletz 2012, Fabiszewski 2012, Stauber 2012); four studies found no statistically significant protective effect (Arnold 2009, Mausezahl 2009, Boisson 2010, Jain 2010, Boisson submitted). Again, only open-design efficacy studies found the intervention to be effective; the effectiveness studies or blinded trials found no protective effect.

### 4.3 People Living with HIV/AIDS<sup>6</sup>

A recent systematic review addressed the health impact of WASH interventions among people living with HIV/AIDS (PLHIV) (Peletz submitted). Eight studies were of household water treatment interventions, including five filtration studies [two ceramic pot filters (Abebe 2012, Potgieter 2008)), two LifeStraw® Family filters (Peletz 2012, Walson 2012), one filter combined with ultraviolet disinfection (Colford 2005)] and three household chlorination studies (Lule 2005, Barzilay 2011, Harris 2009). Four studies included safe water storage containers as part of the intervention (Lule 2005, Peletz 2012, Barzilay 2011, Harris 2009). The two ceramic pot filter studies included integrated water storage as part of the device (Abebe 2012, Potgieter 2008). In one study, the intervention was a combination of a long-lasting insecticide-treated bednet and LifeStraw® Family filter (Walson 2012); therefore the outcomes cannot be separated for the two interventions. One study examined the effect of cotrimoxazole prophylaxis in combination with household chlorination, after examining the effects of household chlorination alone for five months (Lule 2005); only the results for household chlorination alone are discussed below.

All studies reporting on diarrhoea found some reduction in morbidity, ranging from 17% to 77%, except that the 25% reduction reported by Colford was not statistically significant (Figure 4.3). All results are for PLHIV with the exception of Harris and Peletz that examined children born to HIV-positive mothers. The pooled estimate of effect from these studies reflects a 43% reduction overall (RR=0.57, 95% CI: 0.38-0.86) (Figure 4.3). However, there was substantial heterogeneity of studies (probability of heterogeneity,  $\chi^2 = p < 0.001$ ) and 95.1% consistency ( $I^2, p < 0.001$ ). Sub-grouping by these intervention type did not reduce heterogeneity or inconsistency.

**Figure 4.3: Forrest plot of studies of HWTS interventions to prevent diarrhoeal disease among PLHIV (adapted from Peletz, submitted)**



Only the Barzilay study stratified diarrhoea by intervention adherence; diarrhoea was

<sup>6</sup> This section draws heavily from Rachel Peletz, Thomas Mahin, Mark Elliott, Mamie Sackey Harris,, Ka Seen Chan, Myron Cohen, Jamie Bartram, and Thomas Clasen (submitted). Water, Sanitation, and Hygiene Interventions to Prevent Diarrhoeal Disease, Enteric Infection, Environmental Enteropathy, and the Progression of HIV or Malnutrition among People Living with HIV/AIDS: A Systematic Review. A copy of the manuscript is available upon request.

significantly reduced among high frequency users (46% reduction,  $p=0.04$ ) but not among low-frequency users (15% reduction,  $p=0.47$ ). Only two studies reported results for all members of households with an HIV-positive individual. When examining all household members in the Lule study, there were borderline significant reductions in diarrhoea episodes (adjusted RR=0.80, 95% CI 0.64-1.0,  $p=0.047$ ) and days with diarrhoea (adjusted RR=0.74, 95% CI: 0.54-1.01,  $p=0.055$ ). When examining all household members in the Peletz study, there was a significant reduction in diarrhoea (LPR=0.46, 95% CI: 0.30-0.70,  $p<0.001$ ) but not persistent diarrhoea (diarrhoea lasting at least 14 days) (LPR=0.75, 95% CI: 0.37-1.53,  $p=0.43$ ).

One HWTS study examined cryptosporidiosis as a primary outcome (Abebe 2012). Cryptosporidiosis was verified by stool samples. Abebe and colleagues found no significant difference in cryptosporidiosis prevalence at the end of the study (7% in the ceramic filter group and 22% in the control group,  $p=0.11$ ), though they did find a significant reduction between baseline and final collection in the intervention group (25% reduction,  $p=0.02$ ) and not in the control (4% reduction,  $p=0.74$ ). In the Lule and Huang studies, participants that had diarrhoea were tested for *Cryptosporidium* spp. in addition to other pathogens as secondary outcomes, though no significant difference was found between intervention and control groups.

Two studies of HWTS interventions examined other enteric infections of PLHIV as secondary outcomes, by collecting stool samples of participants with diarrhoea (Lule 2005, Potgieter 2008). Lule and colleagues tested for hookworms, *Strongyloides stercoralis*, enterotoxigenic *Escherichia coli*, enteropathogenic *E. coli*, *Aeromonas* spp., *Shigella* spp., *Salmonella* spp., *Campylobacter* spp., *Vibrio cholera*, and *Pleisiomonas* spp. In the study by Potgieter, samples were tested for pathogenic *E.coli* (five types) and *Salmonella* spp. (including *S. flexneri* and *S. typhimurium*). None of the studies assessed exposure for enteric infections specifically. Lule reported no significant differences between intervention and control groups in rates of the infection among PLHIV. For HIV-negative members of the household in the Lule study, the intervention group had lower rates of hookworm than the control (27% vs. 40%,  $p=0.0138$ ) and *Shigella* species (1% vs. 5%,  $p=0.0292$ ). In the Potgieter study, results were not stratified by intervention group for PLHIV; results were presented for intervention and control households though the majority of these households (63.4%, 158/248) did not include someone who was HIV-positive.

Progression of HIV/AIDS was examined in three studies of HWTS interventions. In the Walson study where disease progression was the primary outcome, individuals receiving bednets and water filters were 27% less likely to reach the endpoint of CD4 count of  $<350$  cells/mm<sup>3</sup> after controlling for baseline CD4 counts (HR=0.73, 95% CI: 0.57-0.95,  $p=0.02$ ) (Walson submitted). CD4 decline was significantly lower in the intervention group (-54 vs. -70 cells/mm<sup>3</sup>/year,  $p=0.03$ ).<sup>38</sup> The Lule and Potgieter studies also reported on the impact of household water treatment on progression of HIV/AIDS, though this was not the primary outcome in either study. Lule and colleagues found HWTS did not impact viral load, though diarrhoea episodes were significantly associated with viral load. HIV viral load increased by 0.40 log<sub>10</sub> per person-year for PLHIV using household chlorination compared with 0.71 log<sub>10</sub> per person-year in control (adjusted mean pairwise difference = -0.14 log<sub>10</sub> per person-year, 95% CI = -0.55 to 0.27,  $p=0.51$ ) (Lule 2005). Potgieter and colleagues found that HWTS did not significantly impact changes in CD4 counts ( $p=0.344$ ).

Two studies reported mortality results. In both studies, cause of death was determined by interviewing family members (verbal autopsy). Walson and colleagues reported that the intervention group that received filters and bednets was significantly less likely to die as a result of non-traumatic death or reach CD4  $<350$  cells/mm<sup>3</sup> during the surveillance period (HR 0.74, 95% CI: 0.58-0.95,  $p=0.02$ ) (Walson submitted). Peletz and colleagues reported fewer deaths of children  $<2$  years in the intervention group (3/61, 5%) that received filters than in the control group (6/60, 10%), but these results were not significant (RR=0.56; 95% CI: 0.13 – 2.37,  $p=0.43$ ).

Peltz and colleagues assessed the methodological quality of studies included in the review; this is included in the full copy of the review. Only one HWTS study was blinded (Colford 2005); significantly, this was the only study that did not find the intervention to be protective against diarrhoea, though the study was conducted in the United States where water supplies are generally of good quality. The Colford study was the only trial that met all the criteria for methodological quality of RCTs and the Harris study was the only trial that met all criteria for methodological quality for non-randomized controlled trials. Reported (subjective) outcomes were primary outcomes in five studies with non-blinded interventions, suggesting the potential of reporting bias. All studies reported on all outcomes with the exception of the Potgieter study; results on diarrhoeal disease were not available at the time of this review.

Evidence from the seven HWTS studies that reported on diarrhoea suggests that the intervention may be protective among PLHIV. The pooled reduction of 43% is similar to the pooled estimates for low-income populations generally (Section 4.1 above) and for young children (Section 4.2). Accordingly, there is no evidence that HWTS is more effective among PLHIV and their households in reducing the risk of diarrhoeal disease compared to the general population.

The pooled estimates must be qualified by differences among study interventions, populations, settings, durations, and methodologies. They included a variety of filtration and chlorination approaches that have different levels of efficacy against important opportunistic agents for PLHIV; specifically, chlorination does not inactivate *Cryptosporidium* spp. (White 1998) a pathogen of particular concern for PLHIV (Tzipori 2008). Other potential covariates with diarrhoea, including age, other demographics, access to sanitation and water supplies and hygiene practices, varied among studies. Populations also varied in terms of viral load and access to ARVs. Adherence with household water treatment, a major factor affecting exposure and potential health impact (Brown and Clasen 2012) also varied among studies or was not measured at all. Differences in study design, case definitions, the method and frequency of diarrhoea assessment also limit the potential utility of pooled estimates of effect. Because of the small number of studies, it was not possible to explore heterogeneity by conducting sub-analyses to stratify results by study design, intervention type, age, gender, intervention adherence, or other factors.

Results from studies on other outcomes provide only limited evidence of a protective effect from water quality interventions among PLHIV. Neither the single HWTS study reporting on cryptosporidiosis nor the three studies reporting on other enteric infections reported a statistically significant effect. However, only one of these studies investigated such infection in the primary analysis, and both it and the other studies could have been underpowered. Reductions in disease progression and non-traumatic were reported in only one study (Walson submitted), though since the intervention included provision of insecticide treated nets, it is not possible to ascribe these results solely to the water filter component.

Most studies included in the Peltz review presented issues of methodological quality. Only five of the eight studies employed randomization to allocate the intervention among the study population; the other three studies employed a non-randomized study design. Other methodological issues included failure to report on all study outcomes and on loss-to-follow up. In addition to the issues note above concerning self-reported outcomes (e.g., diarrhoeal disease) in non-blinded trials, some studies reporting on diarrhoea used longer diarrhoea recall periods that may be unreliable.

#### **4.4 Emergencies**

Safe drinking water is also an immediate priority in most emergencies. When normal water supplies are interrupted or compromised due to natural disasters, complex emergencies, or outbreaks, responders have often encouraged affected populations to boil or disinfect their drinking water to ensure its microbiological integrity. Because of increased risk from waterborne disease, HWTS could potentially be an effective emergency intervention, particularly in response to (i) flooding events or natural disasters

that lead to displacement, (ii) complex emergency settings when relief cannot progress to development, and (iii) outbreaks caused by untreated drinking water. HWTS may also be especially effective during the initial (acute) phase of an emergency when responders cannot yet reach the affected population with longer-term solutions.

However, differences between the emergency and development contexts may affect HWTS effectiveness, including higher crude mortality rates and the risk of outbreaks due to population migration; HWTS methods that are new to an affected population also require training which may be unavailable due to competing priorities for staff time. These differences raise questions about the generalizability of HWTS results from development into emergency situations.

A recent survey of emergency responders confirmed that promotion of HWTS methods is common in emergency response (Lantagne 2012). Forty survey respondents described 75 projects using one or more HWTS technologies in emergencies. That paper also describes the results of a literature review on HWTS in emergencies. However, the review revealed little rigorous evidence—particularly in the acute emergency context—on the effectiveness of efforts to promote HWTS among vulnerable populations to ensure correct use of the intervention that reduced their risk of diarrheal disease by rendering their water safe to drink.

Roberts (2001) and Doocy (2006) are the only RCTs of such interventions conducted in emergency settings. The improved bucket used by Roberts and colleagues in the Malawi refugee camp reduced the rate of episodes of diarrhoea among children under 5 years by 31% ( $P=0.06$ ); an 8.4% reduction recorded among all study participants, however, was not statistically significant ( $P=0.26$ ) (Roberts 2001). The combined flocculant-disinfectant used by Doocy in the Liberian camps, on the other hand, was associated with the largest reduction in diarrhoea among both all ages (longitudinal prevalence ratio of 0.12, 95% CI: 0.11 to 0.13) and under 5s (0.08, 95% CI: 0.07 to 0.09) of all trials of HWTS interventions to date. That level of effectiveness is an outlier for HWTS and may reflect an undetected outbreak of waterborne aetiology.

At least two other observational studies have shown POU water treatment in the home to be effective in preventing diarrhoea in emergency settings. Submicron filters used in Milwaukee following the massive outbreak of cryptosporidiosis were associated with a reduced rate of watery diarrhoea (Addiss 1996). Persons who reported boiling or chlorinating their water at home following the 1998 floods in Bangladesh also experienced lower rates of diarrhoea (Kunii 2002). Finally, in a small nested study of the impact of Sodis disinfection in the context of a cholera outbreak in Kenya, the intervention was protective 0.12 (95% CI 0.02 to 0.65,  $p = 0.014$ ). Several other unpublished reports of evaluations of HWTS interventions in emergencies have been summarized by Lantagne (2012).

A more recent paper summarized the results of four case studies of HWTS deployed in earthquakes, floods and a cholera outbreak (Lantagne 2012a). While the case studies did not assess the impact of the interventions on health—something that would be difficult in the context of an emergency response—they did go further than previous assessments by documenting “effective use”—the extent to which effective HWTS solutions actually reached a vulnerable population (i.e., relying on faecally contaminated drinking water) and used the products to improve their water by at least 1 log (90% reduction in faecal indicator bacteria). Chlorine-based methods were distributed in all four emergencies, and filters to small populations in Haiti. Effective use ranged widely, from 0%-67.5%, with only one pre-existing chlorine program in Haiti and unpromoted boiling use in Indonesia reaching >20% effective use. The investigators found that more successful programmes provided an effective HWTS method to households with contaminated water who were familiar with the method before the emergency, willing and trained in its use, and with necessary supplies provided. Despite that large variation in results, the authors concluded that HWTS can be effective at reducing risk of unsafe drinking water in the acute emergency context.

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## Recent Evaluations of the Health Impact of HWTS Interventions

Brown, J., M. D. Sobsey, et al. (2008). "Local drinking water filters reduce diarrheal disease in Cambodia: a randomized, controlled trial of the ceramic water purifier." The American journal of tropical medicine and hygiene **79**(3): 394-400.

A randomized, controlled intervention trial of two household-scale drinking water filters was conducted in a rural village in Cambodia. After collecting four weeks of baseline data on household water quality, diarrheal disease, and other data related to water use and handling practices, households were randomly assigned to one of three groups of 60 households: those receiving a ceramic water purifier (CWP), those receiving a second filter employing an iron-rich ceramic (CWP-Fe), and a control group receiving no intervention. Households were followed for 18 weeks post-baseline with biweekly follow-up. Households using either filter reported significantly less diarrheal disease during the study compared with a control group of households without filters as indicated by longitudinal prevalence ratios CWP: 0.51 (95% confidence interval [CI]: 0.41-0.63); CWP-Fe: 0.58 (95% CI: 0.47-0.71), an effect that was observed in all age groups and both sexes after controlling for clustering within households and within individuals over time.

Arnold, B., B. Arana, et al. (2009). "Evaluation of a pre-existing, 3-year household water treatment and handwashing intervention in rural Guatemala." Int J Epidemiol **38**(6): 1651-61.

**BACKGROUND:** The promotion of household water treatment and handwashing with soap has led to large reductions in child diarrhoea in randomized efficacy trials. Currently, we know little about the health effectiveness of behaviour-based water and hygiene interventions after the conclusion of intervention activities. **METHODS:** We present an extension of previously published design (propensity score matching) and analysis (targeted maximum likelihood estimation) methods to evaluate the behavioural and health impacts of a pre-existing but non-randomized intervention (a 3-year, combined household water treatment and handwashing campaign in rural Guatemala). Six months after the intervention, we conducted a cross-sectional cohort study in 30 villages (15 intervention and 15 control) that included 600 households, and 929 children <5 years of age. **RESULTS:** The study design created a sample of intervention and control villages that were comparable across more than 30 potentially confounding characteristics. The intervention led to modest gains in confirmed water treatment behaviour [risk difference = 0.05, 95% confidence interval (CI) 0.02-0.09]. We found, however, no difference between the intervention and control villages in self-reported handwashing behaviour, spot-check hygiene conditions, or the prevalence of child diarrhoea, clinical acute lower respiratory infections or child growth. **CONCLUSIONS:** To our knowledge this is the first post-intervention follow-up study of a combined household water treatment and handwashing behaviour change intervention, and the first post-intervention follow-up of either intervention type to include child health measurement. The lack of child health impacts is consistent with unsustainable behaviour adoption. Our findings highlight the difficulty of implementing behaviour-based household water treatment and handwashing outside of intensive efficacy trials.

Boisson, S., W. P. Schmidt, et al. (2009). "Randomized controlled trial in rural Ethiopia to assess a portable water treatment device." Environmental science & technology **43**(15): 5934-9.

We conducted a randomized controlled trial to assess the Lifestraw Personal pipe-style water treatment device among a rural population in Ethiopia. A total of 313 households (including 1516 persons) were randomly assigned either to an intervention group in which each householder received a Lifestraw Personal or a control. Households were visited fortnightly over a five-month intervention period and asked to report any episode

of diarrhea during the previous week. A random sample of 160 devices was tested each month to assess the presence of thermotolerant coliforms (TTC) and residual iodine in treated water and to measure flow rate under simulated use. Members of the intervention group had 25% fewer weeks with diarrhea than those of the control group (longitudinal prevalence ratio = 0.75; 95% CI 0.60; 0.95). All 718 filtered water samples were free of TTC, were free of detectable iodine disinfectant, and showed a constant flow rate over time. After the five-month intervention period, 34% of participants reported use of device in the preceding week and 13% reported consistent use. While the device was associated with a 25% reduction in longitudinal prevalence of diarrhea, low levels of use suggest that much of this effect is likely to be attributable to reporting bias that is common in open trials with nonobjective outcomes.

Mäusezahl, D., A. Christen, et al. (2009). "Solar drinking water disinfection (SODIS) to reduce childhood diarrhoea in rural Bolivia: a cluster-randomized, controlled trial." *PLoS medicine* 6(8): e1000125.

**BACKGROUND:** Solar drinking water disinfection (SODIS) is a low-cost, point-of-use water purification method that has been disseminated globally. Laboratory studies suggest that SODIS is highly efficacious in inactivating waterborne pathogens. Previous field studies provided limited evidence for its effectiveness in reducing diarrhoea. **METHODS AND FINDINGS:** We conducted a cluster-randomized controlled trial in 22 rural communities in Bolivia to evaluate the effect of SODIS in reducing diarrhoea among children under the age of 5 y. A local nongovernmental organisation conducted a standardised interactive SODIS-promotion campaign in 11 communities targeting households, communities, and primary schools. Mothers completed a daily child health diary for 1 y. Within the intervention arm 225 households (376 children) were trained to expose water-filled polyethyleneteraphtalate bottles to sunlight. Eleven communities (200 households, 349 children) served as a control. We recorded 166,971 person-days of observation during the trial representing 79.9% and 78.9% of the total possible person-days of child observation in intervention and control arms, respectively. Mean compliance with SODIS was 32.1%. The reported incidence rate of gastrointestinal illness in children in the intervention arm was 3.6 compared to 4.3 episodes/year at risk in the control arm. The relative rate of diarrhoea adjusted for intracluster correlation was 0.81 (95% confidence interval 0.59-1.12). The median length of diarrhoea was 3 d in both groups. **CONCLUSIONS:** Despite an extensive SODIS promotion campaign we found only moderate compliance with the intervention and no strong evidence for a substantive reduction in diarrhoea among children. These results suggest that there is a need for better evidence of how the well-established laboratory efficacy of this home-based water treatment method translates into field effectiveness under various cultural settings and intervention intensities. Further global promotion of SODIS for general use should be undertaken with care until such evidence is available.

Harris J.R. Greene S.K. Thomas T.K. Ndivo R. Okanda J. Masaba R. Nyangau I. Thigpen M.C. Hoekstra R.M. Quick R.E (2009). "Effect of a point-of-use water treatment and safe water storage intervention on diarrhea in infants of HIV-infected mothers." *Journal of Infectious Diseases* 200(8): 1186-1193.

To reduce mother-to-child transmission of human immunodeficiency virus (HIV) in resource-poor settings, the World Health Organization recommends exclusive breastfeeding for 6 months, followed by rapid weaning if replacement feeding is affordable, feasible, available, safe, and sustainable. In the Kisumu Breastfeeding Study (trial registration: Clinicaltrials.gov identifier NCT00146380), infants of HIV-infected mothers who received antiretroviral therapy experienced high rates of diarrhea at weaning. To address this problem, mothers in the Kisumu Breastfeeding Study were given safe water storage vessels, hygiene education, and bleach for household water treatment. We

compared the incidence of diarrhea in infants enrolled before (cohort A) and after (cohort B) implementation of the intervention. Cohort B infants experienced less diarrhea than cohort A infants, before and after weaning ( $P < .001$  and  $P = .047$ , respectively); however, during the weaning period, there were no differences in the frequency of diarrhea between cohorts ( $P = 0.89$ ). Testing of stored water in cohort B homes indicated high adherence (monthly range, 80%-95%) to recommended chlorination practices. Among infants who were weaned early, provision of safe water may be insufficient to prevent weaning-associated diarrhea.

Stauber, C. E., G. M. Ortiz, et al. (2009). "A randomized controlled trial of the concrete biosand filter and its impact on diarrheal disease in Bonao, Dominican Republic." The American journal of tropical medicine and hygiene **80**(2): 286-93.

A number of household water treatment and safe storage technologies, such as chlorine disinfection, solar disinfection, and ceramic filtration, have been documented for their ability to reduce diarrheal disease and improve microbial water quality. The biosand filter (BSF) is a promising household water treatment technology in use by > 500,000 people globally. The purpose of this research was to document the ability of BSFs to improve water quality and to reduce diarrheal disease in user compared with non-user households in a randomized controlled trial in Bonao, Dominican Republic, during 2005-2006. During the 6-month intervention period, 75 BSF households had significantly improved drinking water quality on average compared with 79 control households ( $P < 0.001$ ). Based on random intercepts logistic regression, BSF households had 0.53 times the odds of diarrheal disease as control households, indicating a significant protective effect of the BSF against waterborne diarrheal disease.

Tiwari, S. S., W. P. Schmidt, et al. (2009). "Intermittent slow sand filtration for preventing diarrhoea among children in Kenyan households using unimproved water sources: randomized controlled trial." Tropical medicine & international health : TM & IH **14**(11): 1374-82.

**OBJECTIVE:** Measure effectiveness of intermittent slow sand filtration for reducing child diarrhoea among households using unimproved water sources in rural Kenya. **METHODS:** A randomized controlled trial was conducted among populations meeting a high-risk profile for child diarrhoea from drinking river water in the River Njoro watershed. Intervention households (30) were provided the concrete BioSand Filter and instructed on filter use and maintenance. Control households (29) continued normal practices. Longitudinal monthly monitoring of diarrhoea (seven-day daily prevalence recall) and of influent, effluent, and drinking water quality for fecal coliform was conducted for 6 months. **RESULTS:** Intervention households had better drinking water quality than control households (fecal coliform geometric mean, 30.0 CFU vs. 89.0 CFU/100 ml,  $P < 0.001$ ) and reported significantly fewer diarrhoea days (86 days over 626 child-weeks) compared to controls (203 days over 558 child-weeks) among children up to 15 (age-adjusted RR 0.46; 95 % CI = 0.22, 0.96). Greater child diarrhoea reduction due to the intervention (age-adjusted RR 0.23, 95 % CI = 0.10, 0.51) was observed among the sub-group using unimproved water sources all of the time. **CONCLUSION:** Intermittent slow sand filtration, a non-commercial technology, produces similar observed effects on child diarrhoea as commercial POU products, adding to the range of effective options for poor populations (chlorination, ceramic filtration, solar disinfection, flocculation/disinfection).

Boisson, S., Kiyombo, M., Sthresley, L., Tumba, S., Makambo, J., Clasen, T. (2010) Field assessment of a novel household-based water filtration device: a randomised, placebo-controlled trial in the Democratic Republic of Congo. PLoS One e12613 DOI:

**BACKGROUND:** Household water treatment can improve the microbiological quality of drinking water and may prevent diarrheal diseases. However, current methods of treating

water at home have certain shortcomings, and there is evidence of bias in the reported health impact of the intervention in open trial designs. METHODS AND FINDINGS: We undertook a randomised, double-blinded, placebo-controlled trial among 240 households (1,144 persons) in rural Democratic Republic of Congo to assess the field performance, use and effectiveness of a novel filtration device in preventing diarrhoea. Households were followed up monthly for 12 months. Filters and placebos were monitored for longevity and for microbiological performance by comparing thermotolerant coliform (TTC) levels in influent and effluent water samples. Mean longitudinal prevalence of diarrhoea was estimated among participants of all ages. Compliance was assessed through self-reported use and presence of water in the top vessel of the device at the time of visit. Over the 12-month follow-up period, data were collected for 11,236 person-weeks of observation (81.8% total possible). After adjusting for clustering within the household, the longitudinal prevalence ratio of diarrhoea was 0.85 (95% confidence interval: 0.61-1.20). The filters achieved a 2.98 log reduction in TTC levels while, for reasons that are unclear, the placebos achieved a 1.05 log reduction ( $p < 0.0001$ ). After 8 months, 68% of intervention households met the study's definition of current users, though most (73% of adults and 95% of children) also reported drinking untreated water the previous day. The filter maintained a constant flow rate over time, though 12.4% of filters were damaged during the course of the study. CONCLUSIONS: While the filter was effective in improving water quality, our results provide little evidence that it was protective against diarrhoea. The moderate reduction observed nevertheless supports the need for larger studies that measure impact against a neutral placebo.

Du Preez, M., K. G. McGuigan, et al. (2010). "Solar disinfection of drinking water in the prevention of dysentery in South African children aged under 5 years: the role of participant motivation." *Environ Sci Technol* **44**(22): 8744-9.

Solar disinfection (SODIS) effectively improves the microbial quality of drinking water for preventing diarrhoea; however, the effect of participant motivation has not been studied. This 1-year randomized controlled trial investigated the effect of SODIS of drinking water and motivation on the incidence of dysentery and nondysentery diarrhoea among children of age 6 months to 5 years living in periurban communities in South Africa. We compared 383 children in 297 households using SODIS with 335 children in 267 households with no intervention. At baseline 62.4% of the study households had stored water which met World Health Organization guidelines for zero thermotolerant coliforms per 100 mL. Dysentery was recorded using a pictorial diary. Incidence of dysentery was significantly associated with higher motivation, defined as 75% or better completion of diarrhoea data. Incidence rates were lower in those drinking solar disinfected water (incidence rate ratio 0.64, 95% CI 0.39 - 1.0,  $P = 0.071$ ) but not statistically significant. Compared with the control, participants with higher motivation achieved a significant reduction in dysentery (incidence rate ratio 0.36, 95% CI 0.16 - 0.81,  $P = 0.014$ ). However, there was no significant reduction in risk at lower levels of motivation. Solar disinfection was not significantly associated with nondysentery diarrhoea risk overall ( $P = 0.419$ ). A statistically significant reduction in dysentery was achieved only in households with higher motivation, showing that motivation is a significant determinant for measurable health gains. Failure of three-quarters of participants to achieve a significant reduction in dysentery suggests that research into effective implementation is required.

Jain, S., O. K. Sahanoon, et al. (2010) Sodium dichloroisocyanurate tablets for routine treatment of household drinking water in periurban Ghana: a randomized controlled trial. *The American journal of tropical medicine and hygiene* **Volume**, 16-22 DOI:

We conducted a randomized, placebo-controlled, triple-blinded trial to determine the health impact of daily use of sodium dichloroisocyanurate (NaDCC) tablets for household drinking water treatment in periurban Ghana. We randomized 240 households

(3,240 individuals) to receive either NaDCC or placebo tablets. All households received a 20-liter safe water storage vessel. Over 12 weeks, 446 diarrhea episodes (2.2%) occurred in intervention and 404 (2.0%) in control households ( $P = 0.38$ ). Residual free chlorine levels indicated appropriate tablet use. *Escherichia coli* was found in stored water at baseline in 96% of intervention and 88% of control households and at final evaluation in 8% of intervention and 54% of control households ( $P = 0.002$ ). NaDCC use did not prevent diarrhea but improved water quality. Diarrhea rates were low and water quality improved in both groups. Safe water storage vessels may have been protective. A follow-up health impact study of NaDCC tablets is warranted.

Opryszko, M. C., S. W. Majeed, et al. (2010). "Water and hygiene interventions to reduce diarrhoea in rural Afghanistan: a randomized controlled study." *J Water Health* 8(4): 687-702.

A randomized controlled trial of four interventions was conducted using tubewells ( $n=2,486$ ), liquid sodium hypochlorite ('Clorin') distributed with an improved water vessel ( $n=2,305$ ), hygiene promotion ( $n=1,877$ ), and a combination of the three ( $n=2,040$ ) to create an evidence-base for water policy in Afghanistan. A fifth group served as a control ( $n=2,377$ ). Interventions were randomized across 32 villages in Wardak province. Outcomes were measured through two household surveys separated by one year and twice-weekly household surveillance conducted over 16 months. The households receiving all three interventions showed reduction in diarrhoea compared with the control group, through both longitudinal surveillance data (IRR [95% CI]=0.61 [0.47-0.81]) and cross-sectional survey data (AOR [95% CI]=0.53 [0.30-0.93]). This reduction was significant when all household members were included, but did not reach significance when only children under five were considered. These results suggest multi-barrier methods are necessary where there are many opportunities for water contamination. Surveillance data suggested a greater impact of interventions on reducing diarrhoeal diseases than data from the surveys. Higher economic status as measured through household assets was associated with lower rates of diarrhoea and greater intervention uptake, excepting Clorin. Use of soap was also associated with lower prevalence of diarrhoea.

Du Preez, M., R. M. Conroy, et al. (2011). "Randomized intervention study of solar disinfection of drinking water in the prevention of dysentery in Kenyan children aged under 5 years." *Environ Sci Technol* 45(21): 9315-23.

We report the results of a randomized controlled intervention study (September 2007 to March 2009) investigating the effect of solar disinfection (SODIS) of drinking water on the incidence of dysentery, nondysentery diarrhea, and anthropometric measurements of height and weight among children of age 6 months to 5 years living in peri-urban and rural communities in Nakuru, Kenya. We compared 555 children in 404 households using SODIS with 534 children in 361 households with no intervention. Dysentery was recorded using a pictorial diary. Incidence rate ratios (IRR) for both number of days and episodes of dysentery and nondysentery diarrhea were significantly ( $P < 0.001$ ) reduced by use of solar disinfection: dysentery days IRR = 0.56 (95% CI 0.40 to 0.79); dysentery episodes IRR = 0.55 (95% CI 0.42 to 0.73); nondysentery days IRR = 0.70 (95% CI 0.59 to 0.84); nondysentery episodes IRR = 0.73 (95% CI 0.63 to 0.84). Anthropometry measurements of weight and height showed median height-for-age was significantly increased in those on SODIS, corresponding to an average of 0.8 cm over a 1-year period over the group as a whole (95% CI 0.7 to 1.6 cm,  $P = 0.031$ ). Median weight-for-age was higher in those on SODIS, corresponding to a 0.23 kg difference in weight over the same period; however, the confidence interval spanned zero and the effect fell short of statistical significance (95% CI -0.02 to 0.47 kg,  $P = 0.068$ ). SODIS and control households did not differ in the microbial quality of their untreated household water over the follow-up period ( $P = 0.119$ ), but *E. coli* concentrations in SODIS bottles

were significantly lower than those in storage containers over all follow-up visits ( $P < 0.001$ ). This is the first trial to show evidence of the effect of SODIS on childhood anthropometry, compared with children in the control group and should alleviate concerns expressed by some commentators that the lower rates of dysentery associated with SODIS are the product of biased reporting rather than reflective of genuinely decreased incidence.

Hartinger, S. M., C. F. Lanata, et al. (2011). "A community randomised controlled trial evaluating a home-based environmental intervention package of improved stoves, solar water disinfection and kitchen sinks in rural Peru: rationale, trial design and baseline findings." *Contemp Clin Trials* **32**(6): 864-73.

**INTRODUCTION:** Pneumonia and diarrhoea are leading causes of death in children. There is a need to develop effective interventions. **OBJECTIVE:** We present the design and baseline findings of a community-randomised controlled trial in rural Peru to evaluate the health impact of an Integrated Home-based Intervention Package in children aged 6 to 35 months. **METHODS:** We randomised 51 communities. The intervention was developed through a community-participatory approach prior to the trial. They comprised the construction of improved stoves and kitchen sinks, the promotion of hand washing, and solar drinking water disinfection (SODIS). To reduce the potential impact of non-blinding bias, a psychomotor stimulation intervention was implemented in the control arm. The baseline survey included anthropometric and socio-economic characteristics. In a sub-sample we determined the level of faecal contamination of drinking water, hands and kitchen utensils and the prevalence of diarrhoeagenic *Escherichia coli* in stool specimen. **RESULTS:** We enrolled 534 children. At baseline all households used open fires and 77% had access to piped water supplies. *E. coli* was found in drinking water in 68% and 64% of the intervention and control households. Diarrhoeagenic *E. coli* strains were isolated from 45/139 stool samples. The proportion of stunted children was 54%. **CONCLUSIONS:** Randomization resulted in comparable study arms. Recently, several critical reviews raised major concerns on the reliability of open health intervention trials, because of uncertain sustainability and non-blinding bias. In this regard, the presented trial featuring objective outcome measures, a simultaneous intervention in the control communities and a 12-month follow up period will provide valuable evidence.

Islam, M. S., Z. H. Mahmud, et al. (2011). "Purification of household water using a novel mixture reduces diarrhoeal disease in Matlab, Bangladesh." *Trans R Soc Trop Med Hyg* **105**(6): 341-5.

In Bangladesh, one of the main causes of waterborne diseases is related to the use of contaminated surface water. This pilot study was conducted to determine the acceptability and effectiveness of a recently developed surface water purifying mixture to prevent diarrhoeal diseases in a rural community in Bangladesh. The mixture, using a combination of alum potash, bleaching powder and lime, is added to 15 l of surface water and mixed; the water becomes suitable for drinking after 30 min. A total of 420 households from 15 villages were provided with the mixture and were taught how to use it. Episodes of diarrhoeal disease from study families were determined from hospital records of the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) in Matlab and were compared with diarrhoea episodes among 1613 control families who were not provided with the mixture. A total of 83 diarrhoeal patients were treated at Matlab Hospital from 1613 control families, but only one patient was treated for diarrhoea from among the intervention families. Among the intervention families, 73 families decided to shift from using tube well water to surface water using the mixture. The mixture could be used as a cheaper, easier and simpler point-of-use water treatment strategy in Bangladesh.

McGuigan, K. G., P. Samaiyar, et al. (2011). "High compliance randomized controlled field trial

of solar disinfection of drinking water and its impact on childhood diarrhea in rural Cambodia." *Environ Sci Technol* **45**(18): 7862-7.

Recent solar disinfection (SODIS) studies in Bolivia and South Africa have reported compliance rates below 35% resulting in no overall statistically significant benefit associated with disease rates. In this study, we report the results of a 1 year randomized controlled trial investigating the effect of SODIS of drinking water on the incidence of dysentery and nondysentery diarrhea among children of age 6 months to 5 years living in rural communities in Cambodia. We compared 426 children in 375 households using SODIS with 502 children in 407 households with no intervention. Study compliance was greater than 90% with only 5% of children having less than 10 months of follow-up and 2.3% having less than 6 months. Adjusted for water source type, children in the SODIS group had a reduced incidence of dysentery, with an incidence rate ratio (IRR) of 0.50 (95% CI 0.27-0.93,  $p = 0.029$ ). SODIS also had a protective effect against nondysentery diarrhea, with an IRR of 0.37 (95% CI 0.29-0.48,  $p < 0.001$ ). This study suggests strongly that SODIS is an effective and culturally acceptable point-of-use water treatment method in the culture of rural Cambodia and may be of benefit among similar communities in neighboring South East Asian countries.

Fabiszewski de Aceituno, A. M., C. E. Stauber, et al. (2012). "A randomized controlled trial of the plastic-housing BioSand filter and its impact on diarrheal disease in Copan, Honduras." *Am J Trop Med Hyg* **86**(6): 913-21.

Point of use drinking water treatment with the BioSand filter (BSF) allows people to treat their water in the home. The purpose of this research was to document the ability of the Hydraid plastic-housing BSF to reduce diarrheal disease in households who received a BSF in a randomized controlled trial. The trial of the Hydraid plastic-housing BSF was carried out in rural, mountainous communities in Copan, Honduras during April of 2008 to February of 2009. A logistic regression adjusting for clustering showed that the incidence of diarrheal disease in children under 5 years was reduced by approximately 45% (odds ratio = 0.55, 95% confidence interval = 0.28, 1.10) in households that had a BSF compared with those households without a BSF, but this finding fluctuated depending on season and was not statistically significant. Households with a BSF had significantly better drinking water quality regardless of water source or season.

Overgaard, H. J., N. Alexander, et al. (2012). "Diarrhea and dengue control in rural primary schools in Colombia: study protocol for a randomized controlled trial." *Trials* **13**(1): 182.

**BACKGROUND:** Diarrheal diseases and dengue fever are major global health problems. Where provision of clean water is inadequate, water storage is crucial. Fecal contamination of stored water is a common source of diarrheal illness, but stored water also provides breeding sites for dengue vector mosquitoes. Poor household water management and sanitation are therefore potential determinants of both diseases. Little is known of the role of stored water for the combined risk of diarrhea and dengue, yet a joint role would be important for developing integrated control and management efforts. Even less is known of the effect of integrating control of these diseases in school settings. The objective of this trial was to investigate whether interventions against diarrhea and dengue will significantly reduce diarrheal disease and dengue entomological risk factors in rural primary schools. **Methods/design** This is a 2x2 factorial cluster randomized controlled trial. Eligible schools were rural primary schools in La Mesa and Anapoima municipalities, Cundinamarca, Colombia. Eligible pupils were school children in grades 0 to 5. Schools were randomized to one of four study arms: diarrhea interventions (DIA); dengue interventions (DEN); combined diarrhea and dengue interventions (DIADEN); and control (C). Schools were allocated publicly in each municipality (strata) at the start of the trial, obviating the need for allocation concealment. The primary outcome for diarrhea is incidence rate of diarrhea in school children and for dengue it is density of

adult female *Aedes aegypti* per school. Approximately 800 pupils from 34 schools were enrolled in the trial with eight schools in the DIA arm, nine in the DEN, eight in the DIADEN, and nine in the control arms. The trial status as of June 2012 was: completed baseline data collections; enrollment, randomization, and allocation of schools. The trial was funded by the Research Council of Norway and the Lazos de Calandaima Foundation. DISCUSSION: This is the first trial investigating the effect of a set of integrated interventions to control both dengue and diarrhea. This is also the first trial to study the combination of diarrhea-dengue disease control in school settings.

Peletz, R., M. Simunyama, et al. (2012). "Assessing Water Filtration and Safe Storage in Households with Young Children of HIV-Positive Mothers: A Randomized, Controlled Trial in Zambia." *PLoS One* 7(10): e46548.

**BACKGROUND:** Unsafe drinking water presents a particular threat to people living with HIV/AIDS (PLHIV) due to the increased risk of opportunistic infections, diarrhea-associated malabsorption of essential nutrients, and increased exposure to untreated water for children of HIV-positive mothers who use replacement feeding to reduce the risk of HIV transmission. This population may particularly benefit from an intervention to improve water quality in the home. **METHODS AND FINDINGS:** We conducted a 12-month randomized, controlled field trial in Zambia among 120 households with children <2 years (100 with HIV-positive mothers and 20 with HIV-negative mothers to reduce stigma of participation) to assess a high-performance water filter and jerry cans for safe storage. Households were followed up monthly to assess use, drinking water quality (thermotolerant coliforms (TTC), an indicator of fecal contamination) and reported diarrhea (7-day recall) among children <2 years and all members of the household. Because previous attempts to blind the filter have been unsuccessful, we also assessed weight-for-age Z-scores (WAZ) as an objective measure of diarrhea impact. Filter use was high, with 96% (596/620) of household visits meeting the criteria for users. The quality of water stored in intervention households was significantly better than in control households (3 vs. 181 TTC/100 mL, respectively,  $p < 0.001$ ). The intervention was associated with reductions in the longitudinal prevalence of reported diarrhea of 53% among children <2 years (LPR = 0.47, 95% CI: 0.30-0.73,  $p = 0.001$ ) and 54% among all household members (LPR = 0.46, 95% CI: 0.30-0.70,  $p < 0.001$ ). While reduced WAZ was associated with reported diarrhea (-0.26; 95% CI: -0.37 to -0.14,  $p < 0.001$ ), there was no difference in WAZ between intervention and control groups. **CONCLUSION:** In this population living with HIV/AIDS, a water filter combined with safe storage was used correctly and consistently, was highly effective in improving drinking water quality, and was protective against diarrhea.

Stauber, C. E., E. R. Printy, et al. (2012). "Cluster randomized controlled trial of the plastic BioSand Water filter in Cambodia." *Environ Sci Technol* 46(2): 722-8.

About half of the rural population of Cambodia lacks access to improved water; an even higher percentage lacks access to latrines. More than 35,000 concrete BioSand Water filters (BSF) have been installed in the country. However, the concrete BSF takes time to produce and weighs hundreds of pounds. A plastic BSF has been developed but may not perform to the same benchmarks established by its predecessor. To evaluate plastic BSF performance and health impact, we performed a cluster randomized controlled trial in 13 communities including 189 households and 1147 participants in the Angk Snoul district of Kandal Province from May to December 2008. The results suggest that villages with plastic BSFs had significantly lower concentrations of *E. coli* in drinking water and lower diarrheal disease (incidence rate ratio 0.41, 95% confidence interval: 0.24-0.69) compared to control villages. As one of the first studies on the plastic BSF in Cambodia, these are important findings, especially in a setting where the concrete BSF has seen high rates of continued use years after installation. The study suggests the plastic BSF may

play an important role in scaling up the distribution/implementation of the BSF, potentially improving water quality and health in the region.

Sophie Boisson, Matthew Stevenson, Lily Shapiro, Vinod Kumar, Lakhminder P Singh, Dana Ward and Thomas Clasen (submitted). Effect of household-based drinking water chlorination on diarrhoea among children under five in Orissa, India: a double-blind randomised placebo-controlled trial.

**Background** Most evidence on the health impact of household water treatment is based on open-trial designs and subjective outcomes that are subject to bias. We undertook a double blind randomised controlled trial to measure the effect of in-home water disinfection on diarrhea among children under five.

**Methods and findings** The study was conducted among 2163 households comprising 2986 children under five in rural and urban communities of Orissa, India. The intervention consisted of an intensive promotion campaign and free distribution of sodium dichloroisocyanurate (NaDCC) tablets during bi-monthly household visits. An independent evaluation team visited households monthly for one year to collect health data and water samples. The primary outcome was the mean longitudinal prevalence of diarrhea (3-day point prevalence) among children under five. We also measured weight-for-age Z scores (WAZ) at each visit to assess its potential as proxy marker for diarrhoea. Compliance was monitored each month through caregiver's reports and presence of residual free chlorine in the child's drinking water at the time of visit. On 20% of the total household visits, children's drinking water was assayed for thermotolerant coliforms (TTC), an indicator of faecal contamination. Over the follow-up period, 84391 child-days of observations were recorded, representing 87% of total possible child-days of observation. The longitudinal prevalence of diarrhoea among intervention children was 1.69% compared to 1.74% among controls. After adjusting for clustering within household, the longitudinal prevalence ratio was 0.95 (95%CI 0.79; 1.13). The mean WAZ score was similar among children of the intervention and control groups (-1.586 versus -1.589 respectively). Among intervention households, 51% reported their child's drinking water to be treated with the tablets at the time of visit, though only 32% of water samples tested positive for residual chlorine. Faecal contamination of drinking water was lower among intervention households than controls [geometric mean TTC count of 50 (95% CI 44; 57) per 100ml compared to 122 (95% CI 107; 139) per 100ml among controls ( $p < 0.001$ ) (N=4546)].

**Conclusions:** These results provide no evidence that the intervention was protective against diarrhoea. Low compliance and modest reduction in water contamination may have contributed to the lack of effect. However, our findings are consistent with other blinded studies of similar interventions and provide additional evidence that the protective effect of household water treatment, and perhaps other environmental interventions, may be exaggerated due to reporting bias.