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Sustained Uptake of a Hospital-Based Handwashing with Soap and Water Treatment Intervention (Cholera-Hospital-Based Intervention for 7 Days [CHoBI7]): A Randomized Controlled Trial

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Abstract. Diarrhea is the second leading cause of death in children under 5 years of age globally. The time patients and caregivers spend at a health facility for severe diarrhea presents the opportunity to deliver water, sanitation, and hygiene (WASH) interventions. We recently developed Cholera-Hospital-Based Intervention for 7 days (CHoBI7), a 1-week hospital-based handwashing with soap and water treatment intervention, for household members of cholera patients. To investigate if this intervention could lead to sustained WASH practices, we conducted a follow-up evaluation of 196 intervention household members and 205 control household members enrolled in a randomized controlled trial of the CHoBI7 intervention 6 to 12 months post-intervention. Compared with the control arm, the intervention arm had four times higher odds of household members' handwashing with soap at a key time during 5-hour structured observation (odds ratio [OR]: 4.71, 95% confidence interval [CI]: 2.61, 8.49) (18% versus 50%) and a 41% reduction in households in the World Health Organization very high-risk category for stored drinking water (OR: 0.38, 95% CI: 0.15, 0.96) (58% versus 34%) 6 to 12 months post-intervention. Furthemore, 71% of observed handwashing with soap events in the intervention arm involved the preparation and use of soapy water, which was promoted during the intervention, compared to 9% of control households. These findings demonstrate that the hospital-based CHoBI7 intervention can lead to significant increases in handwashing with soap practices and improved stored drinking water quality 6 to 12 months post-intervention.

INTRODUCTION

Diarrhea is the second leading cause of death in children under 5 years of age globally, causing an estimated 800,000 deaths annually.[1] Previous studies have identified lack of caregiver handwashing with soap and drinking water treatment, poor water storage practices, and lack of caregiver knowledge of diarrhea prevention as important risk factors for diarrheal disease in pediatric populations.[2–8] Water, sanitation, and hygiene (WASH) interventions promoting household chlorination of drinking water and handwashing with soap have the potential to reduce diarrheal disease incidence in children less than 5 years of age by an estimated rate of 20–40%.[9–11] However, in many low-income countries, community-based WASH interventions are often difficult to implement in urban settings because of limited community health work infrastructure. In 2014, the World Health Organization (WHO) estimated that the urban population accounted for over half of the population globally.[12] Therefore, WASH interventions are urgently needed that can be implemented in urban settings to reduce diarrheal disease in susceptible pediatric populations.

The current standard of care for diarrhea patients at the time of discharge from health facilities in Bangladesh is to provide instructions on the proper use of oral rehydration solution (ORS). There is no standard of care for the household members of patients, who are often at very high risk of developing a subsequent enteric infection.[13–20] A study in urban Dhaka, Bangladesh, found that household members of cholera patients had more than a 100 times higher risk of a cholera infection than the general population during the 1-week period after the presentation of the index cholera patient at the hospital.[21,22] Consistent with this finding, a recent study in rural Bangladesh found that the odds of a *Shigella* infection were 44 times higher for household members of pediatric shigellosis patient during this 1-week window.[23] Similar findings have also been observed for enterotoxigenic *Escherichia coli*.[20,24] This high rate of enteric infections among household members of diarrhea patients is likely attributed to a shared contaminated environmental source or secondary transmission within the household through poor hygiene practices.

The time patients and their caregivers spend at a health facility for the treatment of severe diarrhea episodes presents the opportunity to deliver WASH interventions when perceived severity of diarrheal disease and perceived benefits of water treatment and handwashing with soap is likely the highest.[25] Previous studies have found that at the time of severe illness such as cholera outbreaks, households have higher perceived disease severity and perceived benefits of water treatment.[25–27] In Madagascar, an intervention promoting the use of chlorine reached peak sales during the high season for cholera.[26] Consistent with this findings, in Dhaka, in 2013, community-level point-of-use (POU) chlorine dispenser usage peaked after cholera deaths in a slum area of the city (L. Unicomb, personal communication). However, there are very few published studies that have evaluated the impact of health facility–based WASH interventions for households, and none, to our knowledge, that have evaluated the impact this form of intervention focused on household members of diarrhea patients.[28–35]

In an effort to develop a low-cost standard of care for the household members of cholera patients, we recently developed a hospital-based handwashing with soap and water treatment intervention entitled Cholera-Hospital-Based Intervention for 7 days (CHoBI7). In our recent randomized controlled trial (RCT) of this intervention where CHoBI7 was compared with the standard message given in Bangladesh to diarrhea patients

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at discharge on ORS use, we observed a 47% reduction in the incidence of overall cholera infections (symptomatic and asymptomatic), and a significant reduction in symptomatic cholera infections among household members of cholera cases in the intervention compared with the control arm during the 1 week intervention period.[36] These findings demonstrated the effectiveness of the hospital-based CHoBI7 intervention in reducing cholera infections among highly susceptible household members of cholera cases.

To investigate if the CHoBI7 intervention could lead to sustained improvements in handwashing with soap and water treatment practices over time, we conducted a follow-up of households that received the 1-week CHoBI7 intervention and control households 6 to 12 months post-intervention.

METHODS

Ethical approval. Informed consent was obtained from all study participants, and study procedures were approved by the research Ethical Review Committee of the International Center for Diarrheal Disease Research, Bangladesh (icddr,b) and the Institutional Review Board of the Johns Hopkins Bloomberg School of Public Health.

Study site. This study was conducted at icddr,b Hospital in Dhaka, Bangladesh.

Enrollment. A cluster RCT of the sustained uptake of the CHoBI7 intervention was conducted from August 2014 to January 2015. This evaluation was nested within the larger main RCT that investigated the efficacy of the CHoBI7 intervention in reducing cholera infections among household members of cholera cases during the 1-week intervention period. To be eligible for our trial, households had to have been recruited for the main CHoBI7 intervention trial at least 6 months prior. Because of budgetary constraints, the sample size was based on the number of households eligible during the 6-month study period (August 2014 to January 2015). A household was defined as the household of the baseline index cholera case and their corresponding household members. Household member was defined as those individuals sharing the same cooking pot with the index case. Index cholera cases at baseline were defined as diarrhea patients presenting at Dhaka icddr,b Hospital with WHO defined moderate to severe dehydration and a stool sample culture positive for *Vibrio cholerae*.[37] The exclusion criteria for cholera cases were if they had received cholera vaccine or if they already had a household member enrolled in our trial.

Intervention. The CHoBI7 intervention includes 1) a diarrhea prevention package containing a 3-month supply of Aquatabs® chlorine tablets (sodium dichloroisocyanurate; Medentech, Wexford, Ireland) for water treatment, two week supply of soapy water bottles (prepared using diluted liquid soap), a handwashing station, and a sealed water vessel with cover to ensure safe water storage (Figure 1) and 2) a pictorial ("Chobi" in Bangla) module disseminated by a health worker promoting handwashing with soap at critical times and water treatment (Figure 2). The pictorial module includes messages on how diarrheal diseases spread through the environment (e.g., contamination of household drinking water sources and stored water), and how people can spread diarrheal diseases to each other through contaminating food and water in their home. The health worker delivers this diarrheal prevention package and pictorial module to cholera cases and their accompanying family members during a consultation session in the hospital. During this session, instructions are provided on how to treat household water using chlorine tablets, how to properly wash hands with soap, how to prepare soapy water, and how to set up the handwashing station provided in the diarrhea prevention package. The messages in the CHoBI7 module are then reinforced through daily visits by a health worker for the 1-week intervention period. On day 7 of the CHoBI7 intervention, the health promoter provided instructions on how to prepare soapy water using detergent powder (a low-cost alternative to liquid soap), and encouraged intervention households to boil their stored drinking water once their Aquatab supply was depleted.

Randomization. The control arm received the standard message given at health facilities in Bangladesh at discharge on the use of ORS for the treatment of diarrhea and the intervention arm received this standard message and the CHoBI7 intervention. Study recruitment at Dhaka icddr,b Hospital occurred from Saturday to Thursday each week. Each week, half of surveillance days were randomly selected to be intervention days and half were randomly assigned to be control days using a random number generator. Randomization was assigned by the study principal investigator. This randomization scheme was used to limit the likelihood of seasonal variations in study arm assignment and selection bias. Two separate field teams implemented the intervention and evaluation activities.

Assessment of intervention uptake indicators. To investigate if the CHoBI7 intervention could lead to sustained impacts on handwashing with soap and water treatment behaviors over time, we followed up with households enrolled in our main RCT of CHoBI7 6 to 12 months post-intervention. During unannounced household visits, drinking water source and stored drinking water (water to be used for immediate consumption) samples were tested for the presence of fecal coliform, an indicator of water quality, and free available chlorine, a proxy indicator of household water treatment. Free available chlorine was measured using a digital colorimeter (Hach, Loveland, CO). The Center for Disease Control (CDC) recommended cutoff for free available chlorine of a minimum of 0.2 mg/L present in household stored drinking water was used.[38] To assess water quality, two cutoffs were used: the WHO guideline of less than 1 colony forming units (CFU)/100 mL of *E. coli* in drinking water and the WHO classification of "very high risk: urgent action required" for drinking water supplies cutoff of 100 CFU/100 mL *E. coli*.[39] Spot checks were also performed to check for the presence of intervention hardware and soap or soapy water in the cooking and latrine areas (within 10 steps) as a proxy measure of handwashing with soap behavior.[40] Three attempts were made to follow-up with study households. To observe actual household handwashing with soap practices, a visit was scheduled to perform 5-hour structured observation of handwashing with soap at the following key times promoted in the CHoBI7 intervention: 1) after using the toilet, 2) after cleaning a child's anus, 3) before eating, and 4) before preparing food. The percentage of household members with a handwashing with soap event at a key time was compared between the control and intervention arms. Information was also collected on the percentage of water treatment events (boiling and the use of chlorine tablets) during water collection and storage events during the 5-hour structured observation

FIGURE 1. Intervention hardware: water vessel with cover, chlorine tablets, handwashing station, and bottle of soapy water.

period. Households were informed that the 5-hour structured observation was being conducted as a sub-study to evaluate their day-to-day activities.

Laboratory analysis. All water samples were processed at the Enteric Microbiology Laboratory at icddr,b. For *E. coli* measurements, 100 mL water was filtered through a 0.22-μm membrane filter, and the filter was placed on fecal coliform agar plates for culturing, according to previously published methods.[41] The maximum *E. coli* value recorded was 300 CFU/100 mL.

FIGURE 2. Photos of promotional flipbook and cue cards on handwashing with soap and water treatment. Cue cards are placed next to intervention hardware as a cue to action on hygiene and water treatment–related behaviors.

Statistical analysis. For a comparison of the household-level characteristics by study arm a χ^2 test was performed for categorical variables, a two sample *t* tests for continuous variables, and a Fisher exact test when five values or less were in a category. To compare individual-level variables by study arm, *P* values were calculated by performing logistic regression models using generalized estimating equations (GEE) to account for clustering at the household level. *Escherichia coli* counts were divided into the following categories for comparison by study arm: < 1 CFU/100 mL, 1–10 CFU/100 mL, 10–100 CFU/100 mL, and 100–300 CFU/100 mL. To assess our intervention fidelity indicators, we conducted logistic regression models with study arm as the predictor. For structured observation, we conducted logistic regression models using GEE to account for clustering within households. All analyses were performed using SAS, version 9.3 (SAS Institute Inc., Cary, NC).

RESULTS

A total of 135 households had been enrolled in the CHoBI7 intervention trial at least 6 months before our follow-up visit and were therefore eligible for our evaluation. Among these households 103 (52 control and 51 intervention) (76%) were enrolled, four (3%) refused to participate, eight (6%) could not be located, and 20 (15%) moved outside our study area (Dhaka, Bangladesh) (Figure 3). A total of 401 household members were enrolled from these households (205 control arm and 196 intervention arm). All household members (401/401) present during our structured observation visit agreed to participate in the study. There were no significant differences in the number of months since baseline recruitment of study households or household member characteristics between the intervention and control arms (Table 1).

Spot check of intervention hardware (intervention households only). Ninety four percent of intervention households (48/51) had the drinking vessel provided by CHoBI7 present during the follow-up spot check visit. Of these vessels, 88% (42/48) were at least halfway full with water, and none had items other than water present in them. Eighteen percent of intervention households reported that their water vessel tap was broken at least once during the post-intervention period. Seventy seven percent of these households repaired their broken water vessels, and all these repaired water vessels were found to be at least halfway full with water at the follow-up visit. Eighty eight percent of intervention households (45/51) had a handwashing station provided by CHoBI7 at the follow-up check visit. Of these handwashing stations, 83% had water present, 78% had soap or soapy water present adjacent to them, and 11% had items other than water present in them. Fifty-seven percent of intervention households had soapy water present next to their handwashing station during spot checks. Eighteen percent of households reported that their handwashing stations broke at least once during the post-intervention period, and 44% of these households repaired their handwashing stations, and all these repaired hand washing stations were found to have water inside at the follow-up visit. Five households reported that the tap on their handwashing station was broken and four reported that the lid on their handwashing station was broken.

Intervention uptake indicators. The intervention arm had a four times higher odds of household members handwashing with soap at a key time compared with the control arm (odds ratio [OR]: 4.71, 95% confidence interval [CI]: 2.61, 8.49) (50% versus 18%) during structured observation (Table 2). Seventy-one percent of observed handwashing with soap events (98/139) in the intervention arm involved the use of soapy water; this was followed by the use of bar soap at 23% (32/139). For the control arm, 9% (3/34) of handwashing with soap events involved the use of soapy water and 82% (28/34) of handwashing with soap events involved the use of bar soap during the structured observation period. Household members handwashing with soap at a key

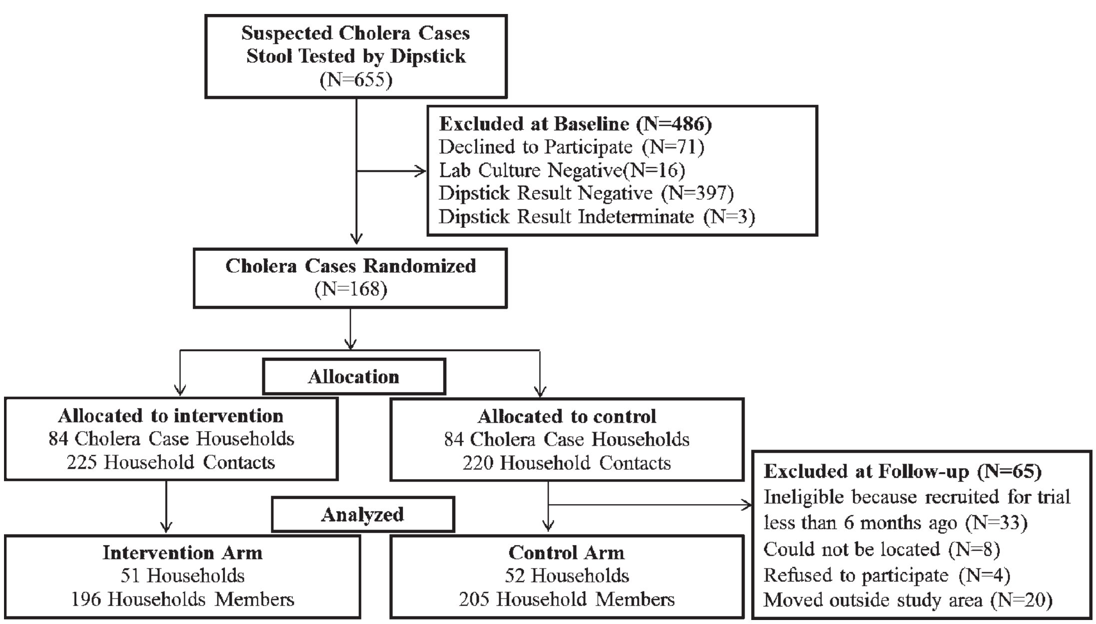

FIGURE 3. Flowchart of study participation.

Table 1
Household characteristics by study arm

	Control arm		Intervention arm		
	%	N	%	N	P value*
Number of households	–	52	–	51	–
Number of household members present during the structured observation visit	–	205	–	196	–
Age of household members (years) median (interquartile range)†	18 (0.8–80)	205	18 (0.3–90)	196	0.12
Female†	53	108	47	93	0.21
Television ownership	56	29	61	31	0.60
Electricity	100	52	100	51	–
Refrigerator ownership	19	10	17	8	0.73
Water source type					
Groundwater	50	26	53	27	0.76
Piped water supply	50	26	47	24	
A household member can read and write	83	43	92	47	0.10
Educational level of person responsible for primary drinking water collection					
No formal education	48	25	49	25	0.24
Primary school	38	20	25	13	
Secondary school	12	6	24	12	
Higher secondary school	2	1	0	0	
Bachelor degree	0	0	2	1	
Time since baseline recruitment (month) median (interquartile range)	9 (6–12)		9 (6–12)		0.49

*χ^2 test for categorical variable, two sample *t* tests for continuous variables, and a Fisher exact test when five values or less were in a category.
†*P* values were calculated using generalized estimating equations to account for the clustering of the data at the household level.

time in the intervention arm was 52% (38/73) for household visited 6 to 8 months after baseline recruitment and 49% (35/72) for household members visited 9 months or greater after baseline recruitment (P = 0.68) (Figure 4). Intervention households when compared with control households had significantly higher presence of any type of soap at latrine (57% versus 33%, P = 0.01) and cooking areas (59% versus 29%, P = 0.002). For "source water," there was no significant difference between the intervention and control arms relative to the WHO safe drinking water guideline or the WHO very high-risk category for household drinking water (Figure 5). For "household stored water," there was no significant difference observed for households complying with the WHO safe drinking water guideline (OR: 1.76, 95% CI: 0.52, 5.97) (21% versus 13%) between intervention and control households (Figure 6). However, there was a significant 41% reduction in the number of households in the WHO very high-risk category in the intervention compared with the control arm (OR: 0.38, 95% CI: 0.15, 0.96) (34% versus 58%). Only one household in the control arm had free available chlorine in stored drinking water greater than the CDC cutoff of 0.2 mg/L compared with none of the intervention households (P = 0.32). The elevated chlorine in the stored water of this control household is likely due to chlorination from the municipal water supply, since this household did not report treating their stored drinking water with chlorine during the previous 48 hours. There were no self-reported or observed water treatment events using Aquatabs or chlorine products during the 6 to 12 month follow-up period. Intervention households boiled their household stored water at 52% (17/33) of water collection and storage events, compared with only 26% (6/23) of control households (P = 0.10) during the structured observation period.

DISCUSSION

Our hospital-based CHoBI7 intervention led to significant increases in handwashing with soap practices and improved water quality 6 to 12 months post-intervention. The majority of intervention household members were observed handwashing with soap at a key time and boiling their household drinking water during water collection and storage events. In addition, the majority of intervention household continued to use their intervention hardware and prepare soapy water

Table 2
Odds ratio for intervention fidelity indicators at 6–12 months post-intervention

	Control arm			Intervention arm			
Outcome	%	N	Total	%	N	Total	OR (95% CI)
Household members with a handwashing with soap event at a key time during the observation period†	18	25	142	50	73	145	4.71 (2.61, 8.49)*
Household members with a handwashing with soap event after using the toilet during the observation period†	16	11	69	36	23	64	2.76 (1.16, 6.53)*
Presence of any type of soap in latrine area	33	17	52	57	29	51	2.71 (1.21, 6.05)*
Presence of any type of soap in cooking area	29	15	52	59	30	51	3.52 (1.55, 7.99)*
Household drinking water complies with WHO safe drinking water guideline‡	13	5	38	21	8	38	1.76 (0.52, 5.97)
Household drinking water in WHO very high-risk category§	58	22	38	34	13	38	0.38 (0.15, 0.96)*

CI = confidence interval; OR = odds ratio; WHO = World Health Organization.
*P < 0.05.
†*P* values were calculated using generalized estimating equations to account for the clustering of the data at the household level.
‡WHO guideline for safe drinking water: *Escherichia coli* counts < 1 CFU/100 mL.
§WHO cutoff of "very high risk: urgent action required" for drinking water supplies is 100 CFU/100 mL *E. coli*.

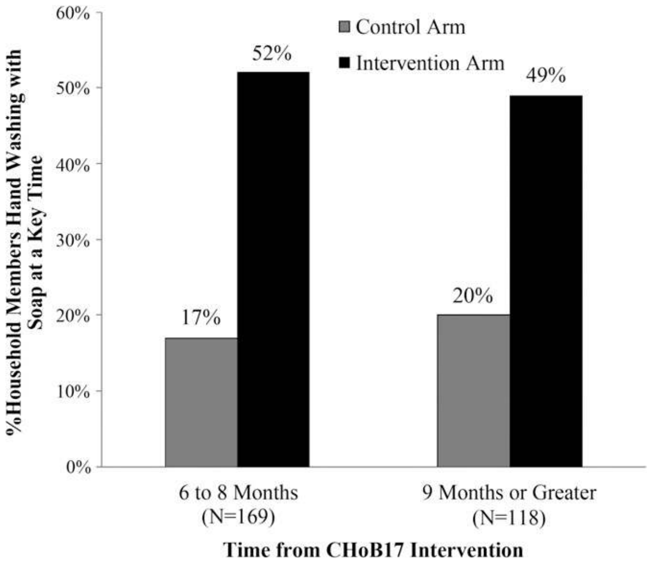

FIGURE 4. Household member handwashing with soap practices over time.

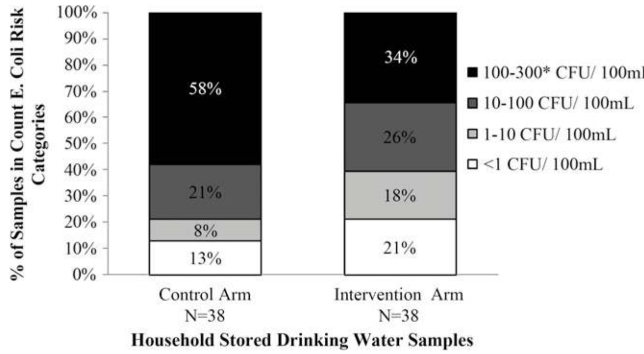

FIGURE 6. Categories of *Escherichia coli* counts in household stored water at 6–12 months post-intervention. *300 CFU/100 mL was the maximum value recorded.

6 to 12 months post-intervention. Furthermore, there was a significant reduction in the number of households in the intervention arm in the WHO very high-risk category for stored household drinking water. These findings demonstrate that the CHoBI7 intervention is not only effective in significantly reducing symptomatic cholera infections during the 1-week intervention period, but can also lead to sustained handwashing with soap practices and improved household stored water quality over time.

There was no significant difference in handwashing with soap at a key time between intervention households followed up 6 to 8 months after receiving the CHoBI7 intervention compared with those followed up 9 months or greater. This promising finding suggests that intervention households have adopted the handwashing with soap practices promoted in the CHoBI7 intervention and have sustained these practices over time.

The significant reduction in the number of intervention households in the WHO very high-risk category for stored household drinking water was striking considering that these households were only given a 3-month supply of Aquatabs, and no intervention households had free available chlorine concentrations exceeding the CDC recommend cutoff of 0.2 mg/L at follow-up. This finding is likely attributed to the majority of intervention households boiling their household stored drinking water during water storage and collection events and the high usage of the CHoBI7-sealed drinking water vessel for water storage.

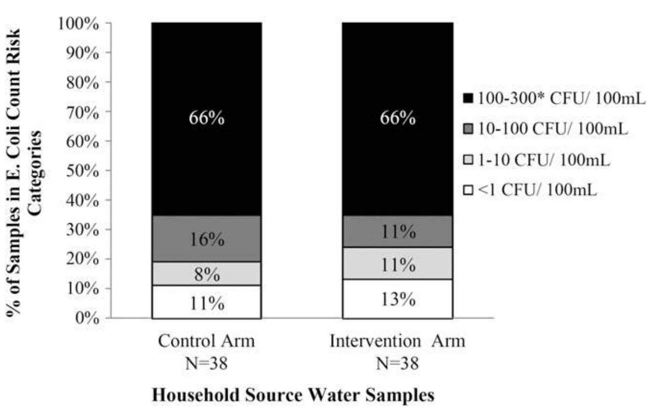

FIGURE 5. Categories of *Escherichia coli* counts in household source water at 6–12 months post-intervention. *300 CFU/100 mL was the maximum value recorded.

Very few intervention households were able to comply with the WHO safe drinking water guideline. This is likely due to lack of access to a POU water treatment options post-intervention. Currently, Aquatabs are not locally available in Bangladesh. There are a few locally available POU water treatment options that were found previously to have a high efficacy in reducing microbial contamination such as Halotabs (Halazone), Zeoline®-200 (sodium hypochlorite solution), and bleaching powder (calcium hypochlorite).[45] However, these products are almost exclusively used in Bangladesh during natural disasters such as flood events.[43] Future studies should determine through formative research the feasibility and social acceptability of incorporating locally available POU chlorine products in the CHoBI7 intervention.

We attribute the sustained high uptake of the CHoBI7 intervention 6 to 12 months post-intervention to the following factors. First, CHoBI7 was delivered at a time of severe illness in these households when previous studies have reported perceived severity of diarrheal disease and uptake of WASH interventions to be high.[25–27,44] Consistent with this, during the 1-week CHoBI7 intervention period, we observed 55% handwashing with soap events at key times in the intervention arm compared with 8% in the control arm.[36] This high uptake of the promoted behaviors during the week-long CHoBI7 intervention was likely sufficient for households to become habituated with these practices and sustain them over time. Second, the study hardware likely facilitated the promoted behaviors included in the CHoBI7 intervention. This hardware was selected because of previous formative research that showed high user acceptance in our study site of urban Dhaka, Bangladesh.[46] Consistent with high user acceptance, we observed that more than 80% of intervention households continued to use the hardware provided by the CHoBI7 intervention 6 to 12 months post-intervention. Furthermore, when intervention hardware failed, it was repaired by the majority of households and usage continued, suggesting high perceived value of the hardware provided in the CHoBI7 intervention.

In addition, more than 70% of hand washing with soap events in intervention households involved the use of soapy water, demonstrating high user acceptance and the ability of intervention household members to prepare soapy water 6 to 12 months post intervention. Third, the communication messages disseminated in the CHoBI7 module were likely a key motivator in encouraging households to boil their household drinking water and wash their hands with soap at key times. During our formative research and piloting phase, we found that many household members were surprised to learn that fecal matter from others could contaminate their food and water (C. M. George, personal communication). Therefore, consistent with previous studies, we suspect disgust was an important factor in intervention adoption.[47,48] We plan to evaluate this construct in a subsequent article.

Our water quality findings are consistent with a recent community-based intervention in rural Bangladesh, which found that safe water storage alone resulted in only marginal improvements in household water quality relative to the WHO safe drinking water guideline (30% safe water storage arm versus 10% control arm). Safe water storage alone in this previously published trial did however lead to a significant 31% reduction in pediatric diarrhea prevalence compared with the control arm.[49] This finding demonstrates that safe water storage alone, although not sufficient to remove all fecal contamination in drinking water this setting, was sufficient to significantly reduce pediatric diarrheal disease. Future studies should evaluate the efficacy of the CHoBI7 intervention in reducing diarrheal disease prevalence in susceptible pediatric populations.

This is the first published study, to our knowledge, to evaluate the uptake of a health facility–based WASH intervention focused on households of diarrhea patients. Previous health facility–based WASH intervention studies have mostly focused on integrating WASH into clinic-based antenatal services.[28–35] In Kenya, a child and maternal health clinic–based intervention that promoted chlorination of household drinking water as part of regular nursing practice resulted in 71% of households having detectable chlorine in stored drinking water 1 year later.[29] Consistent with this, in Malawi, a health facility–based water treatment and hygiene intervention integrated into a antenatal program, resulted in 71% of households having detectable chlorine in stored drinking water at the 10-month follow-up, compared with only 9% of households at baseline.[28] These studies demonstrate the ability of health facility–based WASH interventions to lead to sustained water treatment practices over time.

This study has a few limitations. First, we did not collect information on health outcomes. Therefore, we cannot determine if the observed uptake of handwashing with soap or improvements in stored water quality confers a health benefit. Future studies should assess the effectiveness of this form of intervention in reducing diarrheal disease and other hygiene-related diseases such as respiratory infections. Second, our small sample size prevented us from being able to observe the impact of the CHoBI7 intervention at individual time points for household-level variables during the follow-up period. Future studies should determine how the uptake of the CHoBI7 intervention varies over time using a larger sample size and for a longer duration. Third, we did not investigate potential spill-over effects of the CHoBI7 intervention to neighboring households. This should be evaluated in future studies. Finally, we focused on households of cholera cases and therefore cannot conclude on the impact of this form of intervention on households of other diarrhea patients. Future studies should evaluate the sustained impact of the CHoBI7 intervention in households of all types of diarrhea patients rather than focusing on a particular enteric pathogen.

Our study has several strengths. First, the RCT study design that allowed us to account for secular trends in intervention uptake. Second, the use of previously validated measures to assess handwashing with soap practices such as structured observation to assess hand washing with soap events and spot checks of the presence of soap at latrine and cooking areas as proxy measures of household hand washing with soap behavior.[39,42] Finally, the use of WHO measures to assess water quality and the use of the CDC cutoff for the presence of free available chlorine in household stored drinking water.[38,39]

CONCLUSION

These findings demonstrate that the hospital-based CHoBI7 intervention can lead to sustained handwashing with soap practices and improved household stored water quality, and therefore presents a promising approach for WASH program delivery. Future studies should evaluate the efficacy of this intervention in reducing diarrhea prevalence over time and assess low-cost strategies to integrate CHoBI7 into health facility settings.

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