Adherence to point-of-use water treatment over short-term implementation: parallel crossover trials of flocculation-disinfection sachets in Pakistan and Zambia

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ABSTRACT

The health benefits of point-of-use (POU) water treatment can only be realized through high adherence: correct, consistent, and sustained use. We conducted parallel randomized, longitudinal crossover trials measuring short-term adherence to two single-use flocculant-disinfectant sachets in Pakistan and Zambia. In both trials, adherence declined sharply for both products over the eight-week surveillance periods, with overall lower adherence to both products in Zambia. There was no significant difference in adherence between the two products. Estimated median daily production of treated water dropped over the crossover period from 2.5 to 1.4 l person^{-1} day^{-1} (46% decline) in Pakistan, and from 1.4 to 1.1 l person^{-1} day^{-1} (21% decline) in Zambia. The percentage of surveillance points with detectable total chlorine in household drinking water declined from 70% to 49% in Pakistan and rose marginally from 28 to 30% in Zambia. The relatively low and decreasing adherence observed in this study suggests that these products would have provided little protection from waterborne disease risk in these settings. Our findings underscore the challenge of achieving high adherence to POU water treatment, even under conditions of short-term adoption with intensive follow-up.

INTRODUCTION

Water quality improvements, including point-of-use (POU) water treatment, are intended to deliver health benefits by reducing exposure to waterborne pathogens[1-3]. POU water treatment is often recommended for short-term deployment, such as in emergency response, where interim strategies are required to reduce potentially elevated waterborne disease risks when safe water supplies are unavailable[4-6]. The degree to which POU methods provide protection against disease depends on several factors, including (i) whether drinking water is an important source of pathogen exposure and (ii) effectiveness of the technology in reducing the presence or viability of waterborne pathogens under real-world use conditions.

Protective effects are also a function of the consistency of treatment over time, since even brief periods of exposure to high risk water can control overall risk[7-9]. POU *compliance* or *adherence* has been defined as the correct and consistent adoption of a given method[10 10], or the percentage of total water consumed that is treated[7, 8]. Previous studies have explored the relationship between POU adherence and health outcomes using Quantitative Microbial Risk Assessment (QMRA), modeling probabilities of infection and estimating the resulting burden of disease[7-9]. Under most modeling scenarios where waterborne disease risk is high, POU interventions require exclusive or nearly exclusive use to deliver substantial health benefits.

Despite the critical role of adherence in achieving health gains via water quality interventions, adherence has not been consistently measured in field trials[2, 3, 11, 12]. Where measured, adherence ranges from very low (<30%) to nearly exclusive use[13-15] . Reviews have found relatively greater disease reductions in studies reporting higher adherence[3, 11], lower health impact in longer-term studies,[16] and declining adherence overall in longitudinal trials[17-20]. The effects of adherence on the health impact of water quality interventions are unclear from the epidemiological evidence base, however. Various methods for measuring adherence have been used across a relatively small number of studies.

Achieving high adherence to POU interventions can be challenging, often requiring substantial changes to individual or collective behaviors and strategies[2] that can exert a burden on users; changes may be difficult to implement over short-term periods, such as in humanitarian response. These settings may represent the most compelling contexts for POU treatment, however[21].

In this study, we examined short-term adherence to POU flocculant-disinfectant sachets, as commonly recommended options for improving drinking-water quality in short-term implementation. Products were a previously characterized flocculant-disinfectant sachet[15] and a new product intended to be more acceptable to users by reducing treatment time, streamlining treatment steps, and producing water expected to have a less pronounced chlorine taste, developed because taste and treatment effort may be key barriers to adherence for this type of intervention[22, 23]. We conducted randomized, longitudinal crossover trials at two sites: flood-prone, rural Sindh, Pakistan, and a cholera-impacted urban area of Lusaka, Zambia. Each trial – using an identical design – was intended to replicate typical short-term deployment in terms of setting and support provided to users. We hypothesized that both treatment options would attain high adherence during short-term, intensive implementation in both settings. We further hypothesized that the taste-improved flocculant-disinfectant sachet would result in increased adherence as potentially more acceptable to users.

METHODS

Study setting and population. We conducted trials of the two products at two sites: urban Lusaka, Zambia (2012) and rural Sindh, Pakistan (2013). Study site criteria were (1) primary use of water sources lacking adequate disinfection, (2) high prevalence of household-level water storage, (3) recent (but not current) water-related emergencies, and (4) community-level support for the project. We worked with Oxfam country offices to identify potential study sites as typical of those where short-term implementation of POU treatment would be considered. The Zambian trial site was a low-income settlement in Lusaka of over 100,000 inhabitants with a history of inadequate sanitation, water, solid waste management, and seasonal cholera outbreaks in the rainy season[24, 25]. No cholera cases were reported during the trial period, which included the end of the dry season and the onset of the rainy season. The Pakistan trial was located in a community situated on the edge of a small rural town adjacent to two industrial sites in Sindh province. More than 98% of households reported experiencing one or both of the two major floods that affected the area in 2010[26] and Sindh in 2011[27].

At each site, we randomly selected households to determine eligibility for participation in the study. Eligible households were any living in the study area who stated an expectation that the household would be present in the community for the duration of the eight week study. We enrolled all eligible, consenting households until the *a priori* sample size criterion was met, intended to detect a difference of 20% in outcomes of adherence, accounting for clustering, loss to follow-up, and missing data. We used standard formulae for sample size calculations;[28-30] further details on sample size calculations are provided in Supporting Information. The primary respondent for households was an adult (usually female) with responsibility for household water management, including collection, storage, and treatment.

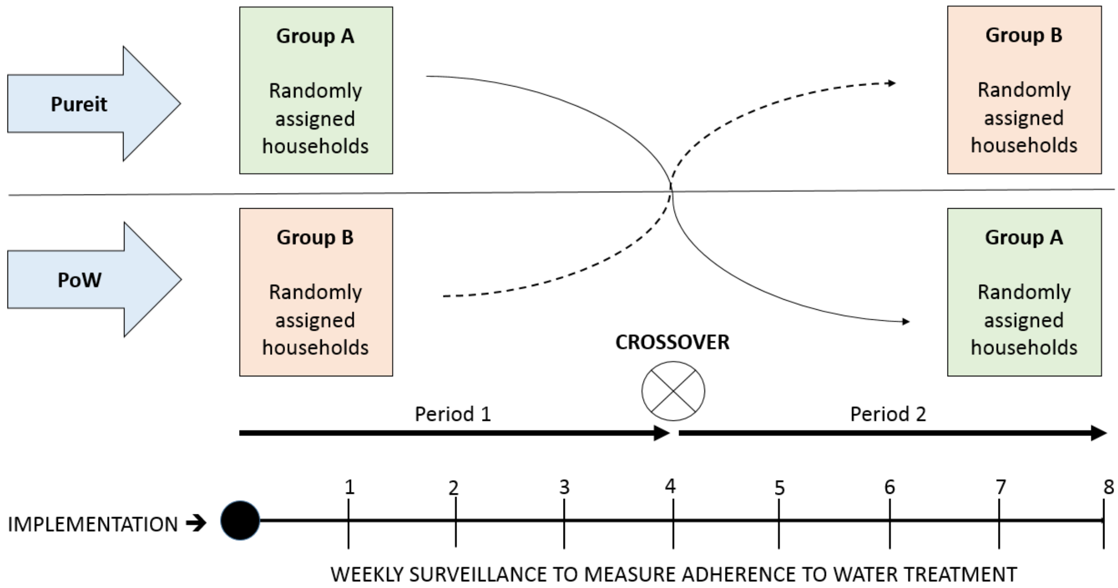
Interventions. We tested two single-use flocculant-disinfectant sachets intended for batch POU treatment of 10 liter volumes: the Purifier of Water (PoW), which has been previously studied under field use conditions[13, 31-33] and a new flocculant-disinfection sachet, Pureit, developed with the intention of reducing treatment effort and a less pronounced "chlorine taste" in treated water[34]. Both products are used similarly. Users add sachet contents to 10 liter volumes of untreated water. Flocs form and settle as chlorine is released; treated water is decanted through a cotton cloth filter into a storage container. Differences in use are described in Supporting Information. Total time needed for batch treatment per manufacturer recommendations was 27 minutes for PoW and 22 minutes for Pureit. The proprietary Pureit formulation was intended to result in less noticeable chlorine taste in post-treatment water, an innovation designed to promote increased uptake and adherence (Supporting Information). Pureit contains the same coagulant (ferric sulfate) and chlorine-based disinfectant (calcium hypochlorite) as PoW. Its performance under controlled laboratory conditions has been previously characterized[34]. We supplied all households with sufficient sachets to treat all household drinking water for the duration of the study period, along with the other required materials: a 10 liter bucket, a safe water storage container fitted with a tap and lid, a stirring utensil, and a cotton cloth of the type recommended for use with the products. We informed all participating households that additional sachets were available for any reason throughout the trial, according to households' needs and preferences, at no cost. We asked that households retain all used and unused sachets throughout the study, and provided each household with containers for this purpose. We recorded the number of sachets provided and the number of used and unused sachets at each household visit.

The study implementation team aimed to provide guidance to users consistent with Oxfam practice recommendations for POU deployment in emergency response (Supporting Information). The study team trained groups of households in use of the methods before distribution, holding structured training sessions for this purpose. Trainings included step-by-step instructions, demonstrations, and dialogue with participants about the project and the POU methods. Enumeration team members were also available to answer questions and provide further instructions to users at weekly follow-up visits throughout the study. No specific, intensive behavior change component was included in the intervention; we conveyed simple messaging about water risks, available water treatment options, and explicitly described the intent of the study to measure adherence to these interventions over time under actual household use conditions.

Study design. We conducted randomized, longitudinal crossover trials of the two products over eight week periods using identical methods at both study sites (Figure 1). Crossover trials, where all households receive each technology in randomized order, minimize the possibility that an observed effect would be attributable to between-arm differences[35-37]. This study design has been used previously in comparing technology use *in situ*[38], allowing for households to serve as their own control[39], and enabling within and between-group comparisons on study outcomes. Briefly, we randomly allocated products to half of participating households for four weeks ("Period 1"), after which they were switched to the alternate product for another four weeks ("Period 2"). Pre-defined primary measures of adherence were: (i) self-reported daily use of the product, measured via weekly surveys; (ii) per-capita daily sachet use, measured by counting households' used sachets at each follow-up visit (also used to calculate the volume of water treated per person per day by the household); and (iii) detection of total chlorine in household drinking water samples.

At weekly, unannounced visits, enumerators administered surveys collecting information on the household and its water management practices, adherence outcomes, and observations on household hygiene. The survey team collected samples of any water respondents indicated as having been treated. We tested household drinking water at the point of sampling in duplicate for free and total chlorine using a colorimetric *N*,*N*-diethyl-*p*-phenylenediamine (DPD) method with a detection limit of 0.2 mg l^{-1} (Palintest Standard Comparator Kit ® PT 220).

Figure 1. Crossover trial design.



The enumerator team double entered all data in Epidata 3.1 (Epidata Association, Denmark). After cleaning and checking for internal consistency of data, we conducted all statistical analyses in Stata 12 (StataCorp, TX, USA). We obtained ethical clearance from the London School of Hygiene & Tropical Medicine, and No Objection certifications from the Lusaka City Council and the Office of the Deputy Commissioner in our study district in Sindh.

Statistical analysis. All outcome data were characterized by non-normal distributions and required non-parametric statistical methods for hypothesis testing appropriate to crossover trials.[40-42] All analyses accounted for clustering of repeat visits within households on adherence outcomes. We used Somer's D non-parametric analysis of variance for estimating two-way and stratified differences in usage measures across categories such as product, crossover period, and weekly visits[24]. We used ordered and generalized ordered logistic regression to assess trends in *per capita* consumption over time and between products, with consumption calculated from counts of used sachets and household size; we considered 2.5 l person^{-1} day^{-1} the minimum target for meeting household safe water needs.[43] We also used logistic regression to test binary outcomes including the presence of detectable total chlorine in water samples and further regression methods for additional analyses (Supporting Information). *A priori* covariates included in models were: crossover period, order of product allocation, reported use of untreated water, household size, and days between visits.

RESULTS

Cohort characteristics varied between sites (Table 1), reflecting differences around water access and sources, sanitation, reported education and literacy, and other variables. In Zambia, approximately 8% of recruited households were lost to follow-up due to households leaving the study site. In Pakistan, approximately 10% of recruited households were lost to follow-up, due to having either left the study site or stated lack of interest in the products for water treatment. Of the latter, half returned to the study site after seeing the continued use in the rest of the community; we included data from these households in the analysis. Other descriptive data from both trial sites are provided in Table 1.

In Zambia, the primary water sources for over 90% of households were public standpipes serving the community. Water delivered to standpipes was reportedly treated by municipal authorities; we periodically tested sources before and during this study and found no evidence of chlorine residual (detection limit: 0.2 mg l^{-1}). Shallow dug wells accounted for the main secondary water source, and were used regularly by households, mostly for washing, cleaning, and cooking, though also for supplementary drinking water.
When asked about previous use of household water treatment, 1% of respondents reported ever using filtration, 14% reported occasional boiling, and 58% occasionally used liquid chlorine solution, which had been previously distributed in the community during cholera outbreaks.

In Pakistan, the primary water source for all households – the Indus River – was accessed via a rudimentary piped supply delivering water to either on-plot taps (68% of households) or community standpipes (32% of households). The only treatment step was mechanical filtration of large particles via screening at the river intake and further settling in the storage tank. As in Zambia, we tested sources before and during this study and found no evidence of chlorine residual. In reporting previous use of household water treatment, 36% of participating households reported boiling their water at least some of the time, 27% reporting using alum when turbidity was high, and 82% reported using simple cloth filtration to strain particulates from water before use.

Table 1. Selected key descriptive characteristics of households enrolled at both trial sites.

Variable	**Zambia**	**Pakistan**
Households enrolled	214	247
Households lost to follow-up (%)	17 (8%)	25 (10%)
Median household size (range)	6 (2 – 17)	5 (1 – 13)
Individuals enrolled	1211	1218
Female (%)	51%	51%
Children under 5 at trial start (%)	17%	20%
Median age (range)	17 (<1 – 88)	20 (<1 – 90)
Adults fully literate (%)	60%	5%
Self-reported household daily expenditure ($USD)		
≤2	18%	19%
>2 – 5	41%	31%
>5 – 8	25%	31%
> 8	17%	19%
Household primary drinking water source		
Public standpipe	92%	32%
On-plot piped water	7%	68%
Shallow well	1%	-
Household sanitation		
None/open defecation	10%	3%
Own pit latrine	14%	48%
Shared pit latrine	76%	49%

We present intervention use across three measures of adherence: (i) used sachet counts and calculated volume of treated water per person per day, (ii) detection of chlorine residual in household drinking water, and (iii) self-reported daily use. Results are summarized in Table 2 for both products and both trial sites collapsed by crossover period. Figures 2 and 3 present adherence measures at each surveillance point for both trial sites. As general trends, we noted decreases in adherence in the second month of exposure, after households switched products at the crossover point, overall statistically comparable usage between the two products, and some variability in adherence across the four visits in each crossover period. Results specific to each adherence measure are described further below.

Sachet usage and calculated volume of treated water. Sachet usage, indicated by counts of used and unused sachets retained by households, has been used previously to measure use of batch flocculant-disinfectant POU methods.[13, 44, 45] By this measure, adherence was higher in Pakistan than it was in Zambia across all time points (Table 2). Weekly household sachet usage in Pakistan dropped from a median of 9 in the first crossover period to near 5 sachets household^{-1} week^{-1} in the second. In Zambia, median usage per visit dropped from 6 sachets household^{-1} week^{-1} in the first crossover period to 4 sachets in the second period.

To translate sachet count data into a readily interpretable measure indicating the potential for treated water to meet households' basic drinking water needs, we used retained sachet counts to calculate the daily per capita volume of treated water available to household residents. We calculated this by counting the number of used sachets since the previous surveillance point, multiplying by 10 liters of treated water per sachet, and dividing by the number of days and number of individuals in the household. Examining this measure, differences in calculated per capita production of treated water over time were greatest between crossover periods, though there was also a slight but statistically significant difference across the four visits in the second crossover period in Pakistan ($p=0.001$, Table S1, Supporting Information), and across the first four visits of the first crossover period in Zambia ($p=0.029$, Table S1, Supporting Information). Volume treated did not differ based on which product was used, in either Pakistan ($p=0.36$, Table S1, Supporting Information) and Zambia ($p=0.91$, Table S1, Supporting Information).

We estimated production of treated water to be approximately 2.5 l person^{-1} day^{-1} in the first crossover period in Pakistan (Table 2), dropping significantly ($p<0.001$, Table S1, Supporting Information) by approximately 44% to 1.4 l person^{-1} day^{-1} in the second crossover period. Overall, estimated use was lower in Zambia: 1.4 l person^{-1} day^{-1} in the first crossover period, dropping by 21% to 1.1 l person^{-1} day^{-1} (Table 2) in the second crossover period ($p<0.001$). Figures 2 and 3 illustrate the decrease in treated water consumption over the crossover period and the changes by surveillance point during each crossover period.

We compared our calculated quantity of treated water per capita to the Sphere-recommended minimum guideline value for daily water consumption in emergencies : 2.5 l person^{-1} day^{-1}.[46] In Pakistan, 52% of households consumed at least 2.5 l person^{-1} day^{-1} in the first crossover period, dropping to 31% in the second period (Table 2). In Zambia, 30% of households consumed at least 2.5 l person^{-1} day^{-1} in the first crossover period, dropping to 20% in the second crossover period. We used generalized ordered logistic regression to assess whether crossover period, product, or consumption of untreated water was associated with achieving ≥ 50% of the Sphere-recommended minimum volume for drinking water across sites; results are presented in Table 3. Accounting for clustering of adherence outcomes by repeated household measures, household size, and order of product allocation, we estimated reduced odds of meeting this threshold in the second crossover period for each product and trial site, compared with the first crossover period: aOR = 0.56 (95% CI 0.49 – 0.69) in Zambia and aOR = 0.31 (95% CI 0.25 – 0.40) in Pakistan. Although one product (PoW) was associated with borderline-significant increased odds of meeting this threshold in the Pakistan trial, we observed no clear differences in products for this measure. Self-reported untreated water consumption was associated with decreased odds of treatment sufficient to reach the Sphere minimum: aOR = 0.79 (95% CI 0.64 – 0.97) in Zambia and aOR = 0.71 (95% CI 0.57 – 0.89) in Pakistan.

Table 2. Adherence measures by product, crossover period, and trial site.

	Zambia			Pakistan		
Crossover period 1	**Pureit**	**Purifier of Water**	**Both products**	**Pureit**	**Purifier of Water**	**Both products**
Median number sachets used daily per capita	0.80	0.86	0.83	1.3	1.3	1.3
Calculated per capita daily volume water treated: median, l $person^{-1}$ day^{-1} (range)	1.4 (0-28)	1.6 (0-27)	1.4 (0-28)	2.5 (0-21)	2.5 (0-24)	2.5 (0-24)
Drinking water total chlorine ≥ 0.2 mg l^{-1}, % total household visits	30%	27%	29%	72%	67%	70%
Reported untreated water consumption, % total household visits	49%	49%	49%	23%	28%	25%
Calculated daily per capita water treated ≥ 2.5 l $person^{-1}$ day^{-1}, % total household visits	28%	31%	30%	52%	52%	52%
Crossover period 2	**Pureit**	**Purifier of Water**	**Both products**	**Pureit**	**Purifier of Water**	**Both products**
Median number sachets used daily per capita	0.63	0.60	0.60	0.67	0.80	0.73
Calculated per capita daily volume water treated: median, l $person^{-1}$ day^{-1} (range)	1.1 (0-15)	1.0 (0-10)	1.1 (0-15)	1.4 (0-25)	1.6 (0-33)	1.4 (0-33)
Drinking water total chlorine ≥ 0.2 mg l^{-1}, % total household visits	31%	25%	28%	47%	50%	49%
Reported untreated water consumption, % total household visits	60%	63%	61%	40%	31%	36%
Calculated daily per capita water treated ≥ 2.5 l $person^{-1}$ day^{-1}, % total household visits	21%	20%	20%	31%	32%	31%

Table 3. Adjusted odds ratios (aORs) describing associations between selected variables and adherence, using the threshold of ≥ 50% of the Sphere-recommended minimum volume for drinking water as calculated from used sachet counts.

Variable	**Zambia**		**Pakistan**	
	aOR* (95% CI)	P-value	aOR (95% CI)	P-value
Crossover period				
Period 1	1		1	
Period 2	0.56 (0.49 – 0.69)	<0.001	0.31 (0.25 – 0.40)	<0.001
Product				
Pureit	1		1	
Purifier of Water	0.97 (0.79 – 1.2)	0.73	1.3 (1.0 – 1.6)	0.064
Reported untreated water consumption				
No	1		1	
Yes	0.79 (0.64 – 0.97)	0.026	0.71 (0.57 – 0.89)	0.0003

*Logistic regression models adjusted for time between surveillance points, household size, order of product allocation, clustering of repeat measures, as well as crossover period, product, and reported untreated water consumption as appropriate.

Figure 2. Median calculated per capita production of treated drinking water, from used sachet counts, collapsed across both products. The Sphere-recommended minimum is 2.5 l $person^{-1}$ day^{-1} for meeting drinking water needs only.[46]

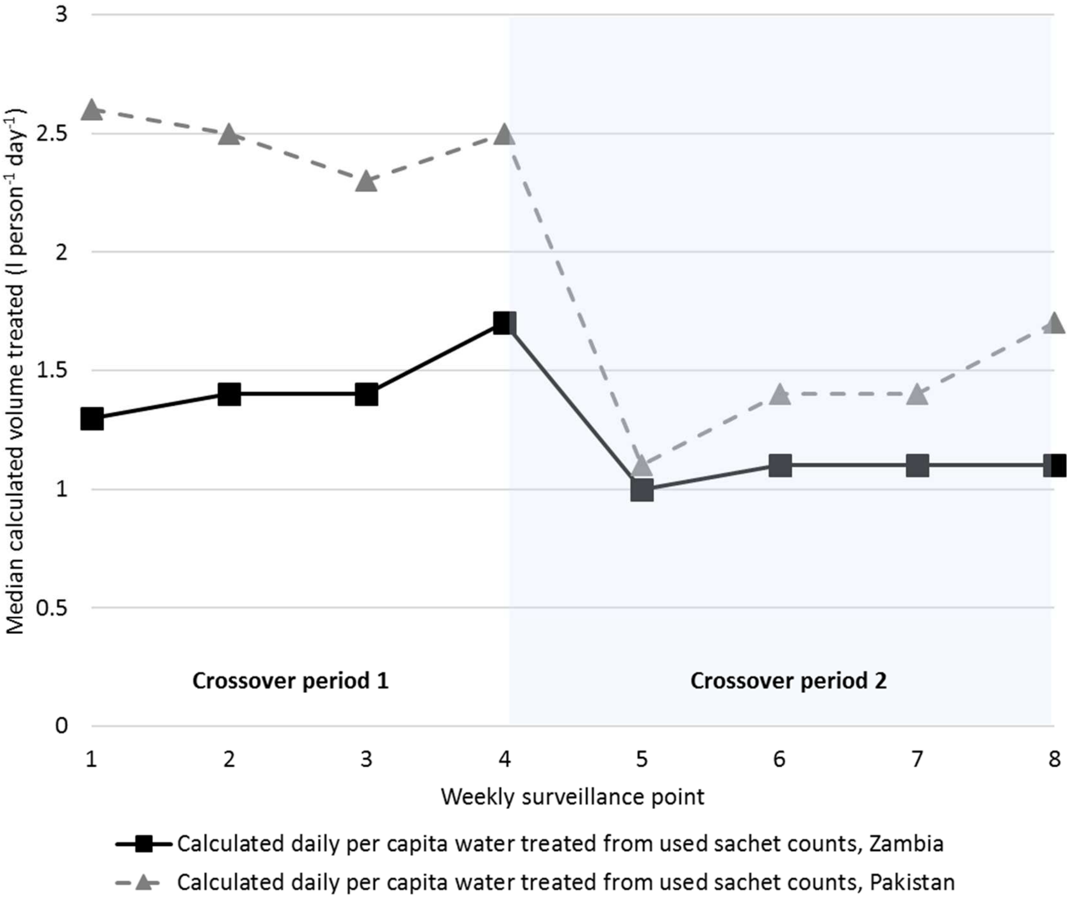
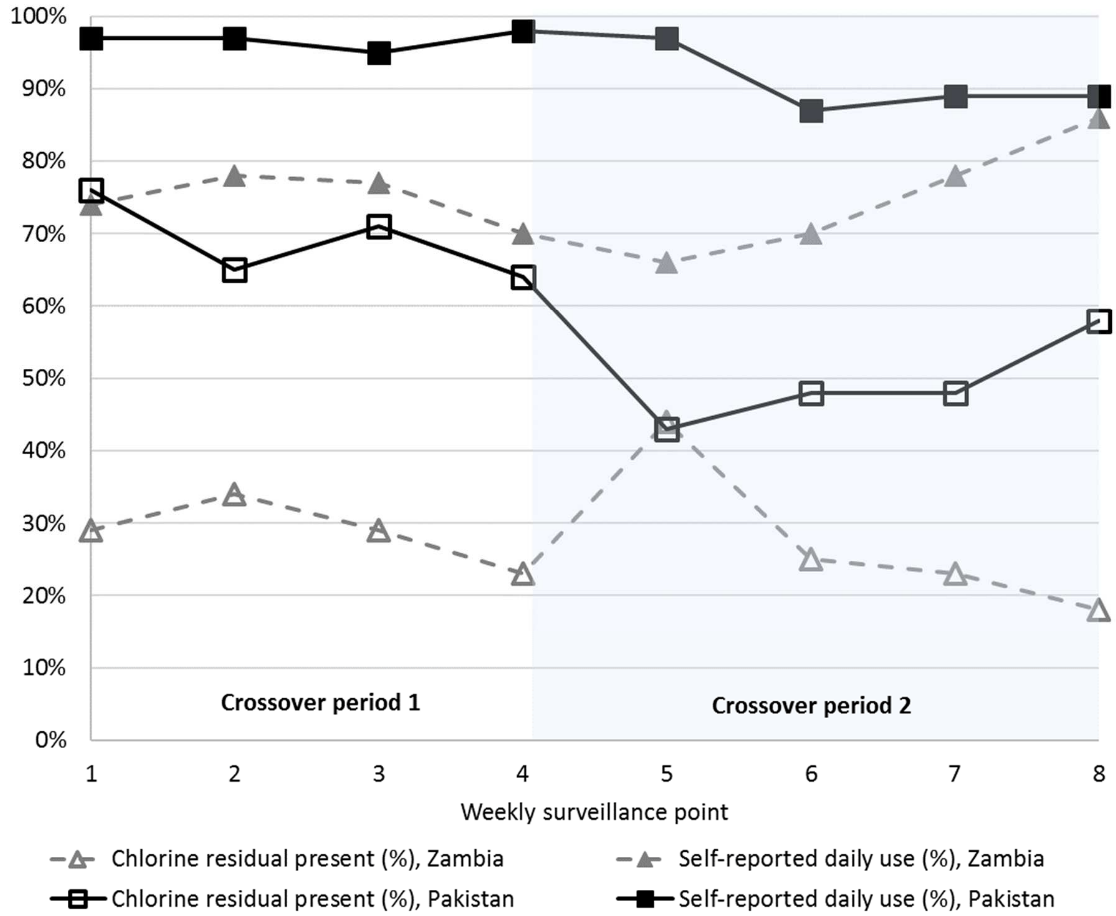


Figure 3. Median self-reported daily use and presence of chlorine residual (total chlorine ≥ 0.2 mg l^{-1}) in household drinking water, collapsed across both products.



Chlorine residual as indicator of use. Direct detection of chlorine residual in household drinking water is an unambiguous, objectively measurable indicator of past treatment[11] using either product we assessed. In Zambia, detectable chlorine (total chlorine ≥ 0.2 mg l^{-1}) was observed in between 18% and 44% of households across surveillance points, without apparent large difference between the two crossover periods (Figure 3). Approximately 4% of households reported having treated drinking water on hand at the time of unannounced visits across all eight surveillance points (Table S3, Supporting Information). Less than 60% of samples indicated to have been treated by respondents in the 24 hours preceding the household visit were observed to have detectable chlorine. In Pakistan, detectable chlorine was observed in between 64% and 76% of households' drinking water during the first crossover period, dropping to between 43% and 58% in the second crossover period (Figure 3); 19% of households had samples of reportedly treated water across all eight surveillance points (Table S3). When water was indicated by the survey respondent to have been treated in the 24 hours preceding the household visit, detectable chlorine was found in 90% of samples.

Self-reported intervention use was not associated with presence of detectable chlorine at either trial site: aOR = 0.86 (95% CI 0.59 – 1.2) in Zambia and aOR = 1.1 (95% CI 0.27 – 4.2) in Pakistan (Table 4). Counts of ≥ 1 used sachet per day were associated with increased odds of detection of chlorine in Zambia but not Pakistan. Self-report of untreated water consumption was not associated with lower probability of chlorine detection in household drinking water at either trial site.

Self-reported use and consumption of untreated water. In contrast to more objective measures of adherence, self-reported use of both products was relatively high at both trial sites (Table 2, Figure 3). We asked household respondents to estimate their adherence over the week preceding each follow-up point, to compare with observed adherence measures. In Zambia, the median percentage of respondents indicating daily use of the intervention varied between 66% and 86%; in Pakistan, median values were between 87% and 98% throughout the trial (Figure 3). Self-report of drinking untreated water was also common, however. Households in Zambia reported consuming untreated water alongside treated water throughout the study, increasing from approximately 49% in the first crossover period to 61% in the second period (Table 2). Self-report of untreated water consumption was associated with lower adherence (Table

3). Approximately 25% of households reported consuming untreated water in the first crossover period in Pakistan, increasing to 36% in the second period (Table 2).

Table 4. Adjusted odds ratios describing associations between selected variables and presence of detectable total chlorine (≥ 0.2 mg l^{-1}) in household drinking water, both products.

Variable	Zambia		Pakistan	
	aOR* (95% CI)	P-value	aOR (95% CI)	P-value
Self-reported daily usage				
No	1		1	
Yes	0.86 (0.59 – 1.2)	0.43	1.1 (0.27 – 4.2)	0.93
Sachet count				
<1 per household per day	1		1	
≥1 per household per day	1.6 (1.2 – 2.2)	0.004	1.0 (0.66 – 1.5)	0.97
Reported untreated water consumption				
No	1		1	
Yes	0.76 (0.58 – 1.0)	0.053	1.3 (0.78 – 2.1)	0.32

*Logistic regression models adjusted for time between surveillance points, household size, order of product allocation, clustering of repeat measures, as well as crossover period, product, and reported untreated water consumption as appropriate.

DISCUSSION

Our objective was to assess adherence to two similar POU treatment options during short-term implementation via crossover trials using the same design in two different contexts. We found no evidence of a significant difference in adherence between products, suggesting that differences between products (e.g., taste, smell, user burden) were not meaningful in determining adherence. We found variable adherence at both sites, with use decreasing over the surveillance period for both products via all measures, with the exception of self-reported daily use in Zambia, which increased overall during the trial. Calculated volume of water treated per capita per day (from used sachet counts) decreased markedly following crossover at both trial sites, with a greater reduction in Pakistan. We hypothesize that this reduction could be a period effect[47], resulting from habituation to the product during the first crossover period and subsequent resistance to uptake of the new product following crossover. Exploring this and other explanatory hypotheses will require further statistical analysis of potential quantitative and qualitative determinants to adherence in the context of these trials.

Besides decreasing over the trial duration, overall adherence was relatively low. The highest average per capita treatment estimates (Pakistan in the first crossover period) met the minimum Sphere-recommended guidelines of 2.5 l person^{-1} day^{-1}, suggesting that these water treatment methods may provide sufficient treated water to meet basic daily drinking water requirements under some conditions. Overall estimated production of treated water by this measure decreased by more than 40% in the second crossover period in Pakistan, however. Per capita consumption was well below 2 l person^{-1} day^{-1} in Zambia during both crossover periods, suggesting that the level of observed use would be insufficient for meeting minimum needs. The Sphere guideline value is a conservative estimate for drinking water only (not including other consumptive uses such as cooking), below the World Health Organization-recommended 7.5 l person^{-1} day^{-1} to provide for hydration and food preparation in non-emergency contexts.[48, 49] Moreover, respondents at both trial sites reported consuming untreated water throughout the trial. There is an emerging consensus that to deliver health impact, safe drinking-water must represent a high proportion of total water consumption, given that overall waterborne disease risks can be dominated by brief periods of exposure when treatment is inconsistent and untreated water is of moderate to high risk.[7-9] Given that consistent treatment is central to realizing the health benefits of POU interventions,[7] our findings indicate that the protective effect of these interventions would have been limited if waterborne pathogen risks had been present in these contexts.

Our findings of variable and generally low adherence are consistent with several studies reporting on POU adoption and use,[4, 19, 44, 50] including reductions in adherence over time[18, 19] and the concomitant consumption of untreated water.[51, 52] Our findings also support the hypothesis that decreases in health impact of longer duration health impact trials may be due to decreased adherence over time.[11, 16, 53] Our study questions the assertion that short term, high-follow-up contexts are likely to be especially amenable to POU interventions[21]: we did not observe this in either trial. Further, our findings are consistent with the few available studies of POU uptake in humanitarian response[4, 5, 54, 55] that suggest considerable barriers remain to realizing benefits of POU over short-term deployment, though we stress that our trial settings should not be interpreted as closely resembling the humanitarian context. Our trials examined adherence to products that were distributed at no cost to the user. Cost recovery might well have resulted in different levels and patterns of adherence in this non-emergency intervention context.

Our study allowed us to examine the advantages and disadvantages of several measures of adherence. Self-reported adherence exceeded more objective measures at both trial sites, adding to a growing evidence base suggesting possible bias in self-reported measures of use for POU interventions.[4,39,42–44] The assumption that households with access to a water treatment intervention actually use it consistently and correctly over time – as is assumed in intention-to-treat analysis, common in POU health impact trials – may not generally hold. It is advisable to build in multiple measures of adherence so that adherence can be estimated empirically, consistent with WHO guidance on monitoring and evaluation in POU trials.[45] Measurement of adherence is critical to evaluating interventions whose impacts are closely linked with user behaviors that influence exposure risks.

These trials had a number of important limitations. First, while we intentionally focused on communities with recent histories of waterborne disease risks, there were no outbreaks concurrent with trials. Perception of risk can motivate water treatment and may have other effects on behavior.[56, 57] Therefore, we cannot conclude that the results from this study indicate adherence in emergency response situations: when there is an obvious, immediate threat to health, such as during an outbreak, increased uptake and use could realistically be expected. Second, though we aimed to assess real-world short-term usage, courtesy bias may have been introduced as the study was overtly a research trial without masking trial intent to participants: the "implementers" in this case were also the enumerators conducting interviews on use. Users may have felt compelled to respond to perceived investigator biases, including reporting increased adherence. Although used sachet counts might be a more objective measure of use than self-report, the measure can be manipulated and is therefore not immune to bias: respondents could empty sachets intentionally, though we did not observe this. Because the timing of unannounced follow-up visits followed a pattern (approximately weekly) and were not always random in order on a given day, households could have treated water selectively on days when visits were expected, without our knowledge. Third, households were provided with all the necessary supplemental material to treat their water, which could have acted as further incentive to join or continue participation in the study insofar as additional sachets had value to users, or may have contributed further to courtesy bias. We observed no on-selling of sachets at either site, but it is possible that this occurred without our knowledge. Fourth, adherence measures – even the several we have included – are imperfect measures of "true" adherence, defined as the percentage of water consumed that has been effectively treated; in typical field settings, this is probably impossible to measure exactly. Fifth, this study was based on two specific flocculant-disinfectant sachets that may not be representative of other POU products, each with characteristics that may differ meaningfully from other POU methods or technologies. POU methods are subject to different perceived benefits and costs to users, with potential implications for short- and long-term adherence. For example, flocculant-disinfectants have been noted for their considerable time and effort requirements[10] while filters may require relatively less effort for regular usage in most settings.[16, 58] Finally, our ability to detect chlorine residuals was limited by the detection limit of the colorimetric test at 0.2 mg l^{-1}, resulting in potential underestimation of adherence by this measure.[59]

Despite weekly contact with households by the study team, we did not include intensive behavior change programming in these trials beyond basic training and ongoing support at surveillance points. Achieving high adherence to household water treatment may require significant investment of time and resources for successful implementation at scale, given the complexity of human behavior and the reality of water management practices in underserved settings.[60, 61] For some interventions in some settings, however, adherence may be low or may decline rapidly over time, suggesting low potential for reducing waterborne disease risk. Further work is required to appropriately match water quality interventions to specific settings where they have the greatest chance of impacting global public health.

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SUPPORTING INFORMATION

Supporting information includes instructions on use for both treatment methods, sample size calculations, further product description, and additional details on intervention methods. Supplementary tables provide details on additional statistical analyses.

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