Combining drinking water treatment and hand washing for diarrhoea prevention, a cluster randomised controlled trial

Stephen P. Luby[1], Mubina Agboatwalla[2], John Painter[1], Arshad Altaf[3], Ward Billhimer[4], Bruce Keswick[4] and Robert M. Hoekstra[1]

1 *Division of Bacterial and Mycotic Diseases, National Centers for Infectious Diseases, Centers for Disease Control & Prevention, Atlanta, Georgia, USA*
2 *Health Oriented Preventive Education, Karachi, Pakistan*
3 *Community Health Sciences, Aga Khan University, Karachi, Pakistan*
4 *The Procter and Gamble Company, Cincinnati, Ohio, USA*

Summary

OBJECTIVES   To evaluate the effectiveness of point of use water treatment with flocculent-disinfectant on reducing diarrhoea and the additional benefit of promoting hand washing with soap.

METHODS   The study was conducted in squatter settlements of Karachi, Pakistan, where diarrhoea is a leading cause of childhood death. Interventions were randomly assigned to 47 neighbourhoods. Households in 10 neighbourhoods received diluted bleach and a water vessel; nine neighbourhoods received soap and were encouraged to wash hands; nine neighbourhoods received flocculent-disinfectant water treatment and a water vessel; 10 neighbourhoods received disinfectant-disinfectant water treatment and soap and were encouraged to wash hands; and nine neighbourhoods were followed as controls. Field workers visited households at least once a week from April to December 2003 to promote use of the interventions and to collect data on diarrhoea.

RESULTS   Study participants in control neighbourhoods had diarrhoea on 5.2% of days. Compared to controls, participants living in intervention neighbourhoods had a lower prevalence of diarrhoea: 55% (95% CI 17%, 80%) lower in bleach and water vessel neighbourhoods, 51% (95% CI 12%, 76%) lower in hand washing promotion with soap neighbourhoods, 64% lower (95% CI 29%, 90%) in disinfectant-disinfectant neighbourhoods, and 55% (95% CI 18%, 80%) lower in disinfectant-disinfectant plus hand washing with soap neighbourhoods.

CONCLUSIONS   With an intense community-based intervention and supplies provided free of cost, each of the home-based interventions significantly reduced diarrhoea. There was no benefit by combining hand washing promotion with water treatment.

keywords diarrhoea, water, soaps, disinfection, sodium hypochlorite, randomised controlled trial

Introduction

Diarrhoea is a leading cause of childhood death globally (WHO 1999). When introduced separately, both point-of-use drinking water treatment and hand washing with soap decrease the frequency of childhood diarrhoea (Mintz *et al.* 2001; Curtis & Cairncross 2003). Recent meta-analyses estimate a mean 47% reduction in diarrhoea with hand washing with soap and a mean 35% reduction with point of use water treatment (Curtis & Cairncross 2003; Fewtrell *et al.* 2005). If either of these interventions was actively promoted by a public health organisation, the marginal cost of promoting the second one would be reduced. However, we are unaware of any studies evaluating the

combined effectiveness of hand washing promotion with point-of-use water treatment.

In Pakistan, diarrhoea is a leading cause of death, especially in the squatter settlements of its large cities (Marsh *et al.* 1995; Khan *et al.* 1993). Previous intervention studies in squatter settlements in Pakistan have demonstrated that both point-of-use drinking water treatment with sodium hypochlorite and hand washing with soap reduced diarrhoea (Luby *et al.* 2004a, b). We introduced a new flocculent-disinfectant for home water treatment as part of a neighbourhood-based intervention. We evaluated its effect in reducing diarrhoea and the added effect of including hand washing promotion with soap.

Methods

Setting

This study was conducted in adjoining multi-ethnic squatter settlements in central Karachi—Bhittaiabad, Bilal Colony, Mujahid Colony, Manzoor Colony and Zia Colony. The field work was done by Health Oriented Preventive Education (HOPE), a local non-governmental organisation that operates health clinics and undertakes community-based health and development initiatives in the area.

Design

The study was a cluster randomised controlled trial. Randomisation and intervention assignment was made at the neighbourhood level, because important components of the efforts to encourage adoption and regular use of the intervention occurred at this level. These included formal meetings and presentations by study personnel to community leaders and community members, lane meetings with community residents, as well as the normal discussions that neighbours had with each other about the interventions when no study personnel were present.

Study groups

Field workers identified communities that typically received at least one hour of running water twice weekly, and had not received soap or water treatment in a previous study with HOPE. Within these communities the study team identified barriers, for example a commercial street or industrial zone that separated groups of households into 49 identifiable clusters of between 54 and 245 households. Within the clusters field workers approached each household. If the female or male head of household confirmed that they had at least one child under the age of 5 years living in the household and if they provided informed consent, the field workers administered a baseline questionnaire. Ultimately, they identified 49 clusters with between 16 and 37 eligible, consented households per cluster.

The 49 clusters were listed in the order that they had been identified. Using a spreadsheet, the five study groups (bleach water treatment, hand washing promotion with soap, flocculent-disinfectant water treatment, flocculent-disinfectant plus hand washing promotion with soap and control) were assigned a computer generated random number. The five study groups were ordered according to their random number, and this order was consecutively and repetitively applied to the list of the 49 clusters. Each study group continued to have clusters assigned until just over

260 households were assigned to the group. Any additional clusters that would have been assigned to that group by consecutive assignment, but would have been more than necessary to encompass 260 households, were left unassigned. Ultimately 47 clusters and 1340 households were assigned to the five study groups (Figure 1).

Field workers

Field workers, recruited from the study or nearby communities, were extensively trained in interviewing techniques, in data recording, in general approaches to community motivation and in specific techniques for promoting hand washing and drinking water treatment. The same field workers promoted regular use of the interventions and collected outcome data during their household visits.

Interventions

Field workers arranged neighbourhood meetings. They used slide shows, videotapes and pamphlets to illustrate health problems resulting from hand and water contamination and to provide specific instructions on how to use the intervention assigned to that neighbourhood. Field workers, who spoke the first language of the study subjects, visited each participating household at least twice weekly. They encouraged use of the interventions, answered questions, and provided families with the consumable supplies necessary for ongoing use of the intervention.

Each participating household received a 20-litre insulated plastic water vessel with a wide mouth (15 cm), lid and tap. Field workers diluted three parts of locally manufactured bleach (4.4 mg% sodium hypochlorite) with 17 parts distilled water, and packaged the dilute hypochlorite into 10-ml reusable plastic bottles. One plastic bottle of dilute bleach added to 20 l of locally available water, typically produced a free chlorine residual between 0.5 and 2.0 mg/l. Households were instructed to empty one bottle of the dilute hypochlorite into the filled 20 l water vessel and to wait 30 min before drinking. Field workers encouraged families to drink only treated water, but neither encouraged nor discouraged hand washing.

The intervention soap was 90 g white bars of Safeguard®* bar soap (Procter and Gamble, Cincinnati, USA). The soap was generically packaged without a brand name or symbol. Field workers encouraged participants to wet

---

* Inclusion of trade names is for identification only and does not imply endorsement by CDC or the Department of Health and Human Services.
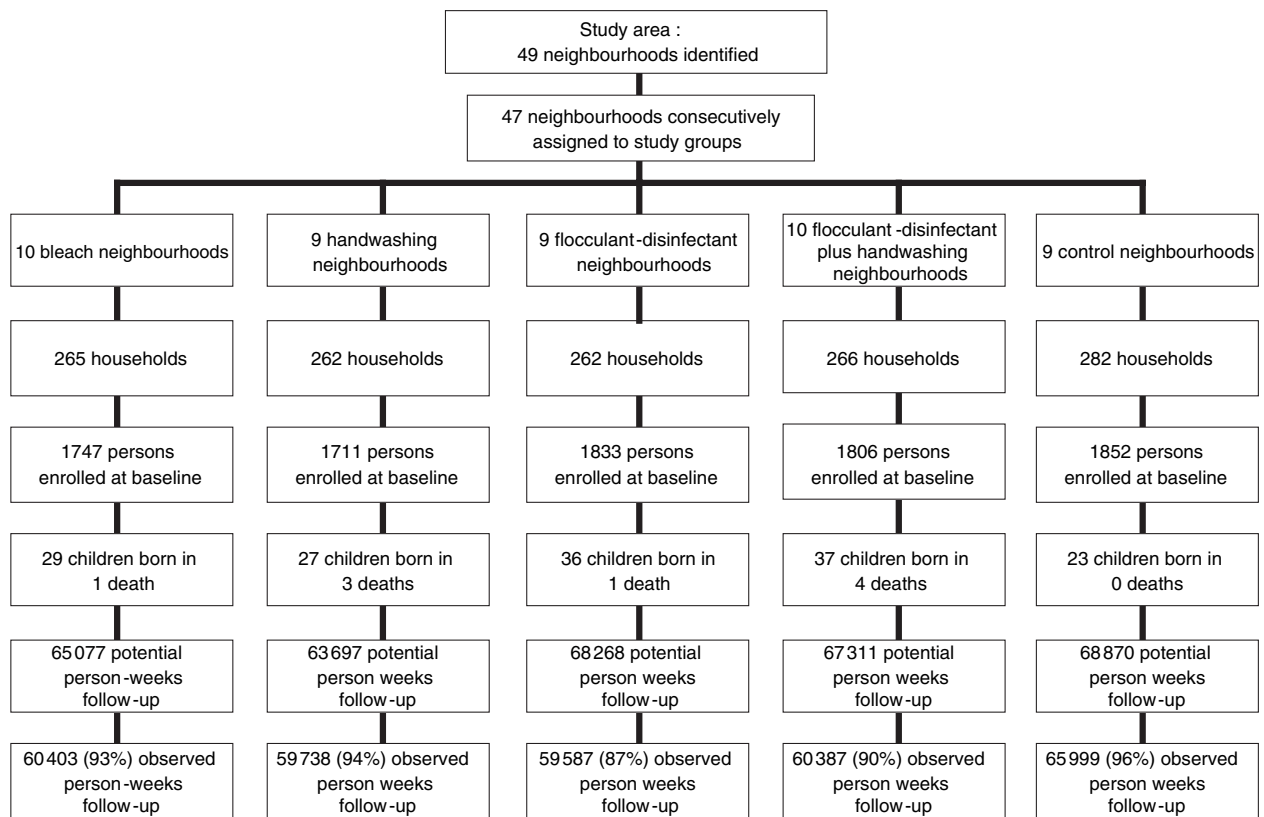
S. P. Luby *et al.* **Drinking water treatment and hand washing**


```
┌─────────────────────────────────┐
│          Study area :           │
│  49 neighbourhoods identified   │
└─────────────────────────────────┘
┌─────────────────────────────────┐
│  47 neighbourhoods consecutively │
│     assigned to study groups    │
└─────────────────────────────────┘
```

10 bleach neighbourhoods	9 handwashing neighbourhoods	9 flocculent-disinfectant neighbourhoods	10 flocculent-disinfectant plus handwashing neighbourhoods	9 control neighbourhoods
265 households	262 households	262 households	266 households	282 households
1747 persons enrolled at baseline	1711 persons enrolled at baseline	1833 persons enrolled at baseline	1806 persons enrolled at baseline	1852 persons enrolled at baseline
29 children born in 1 death	27 children born in 3 deaths	36 children born in 1 death	37 children born in 4 deaths	23 children born in 0 deaths
65 077 potential person-weeks follow-up	63 697 potential person weeks follow-up	68 268 potential person weeks follow-up	67 311 potential person weeks follow-up	68 870 potential person weeks follow-up
60 403 (93%) observed person-weeks follow-up	59 738 (94%) observed person weeks follow-up	59 587 (87%) observed person weeks follow-up	60 387 (90%) observed person weeks follow-up	65 999 (96%) observed person weeks follow-up

Figure 1 Intervention assignment and completed follow-up.

their hands, lather them completely with soap, and rub them together for 45 s. Hands were typically dried on the participants' clothing. Field workers encouraged all persons in intervention households old enough to understand (generally those over 30 months of age) to wash their hands after defecation, after cleaning an infant who had defecated, before preparing food, before eating and before feeding infants. Field workers encouraged adopting regular hand washing habits, but for this group neither encouraged nor discouraged drinking water treatment.

Field workers instructed study subjects to add a single sachet of the flocculent-disinfectant to 10 l of water in a bucket, to stir it vigorously for 5 min, and then let it stand until the floc settled to the bottom. Then study subjects were instructed to decant the flocculent-disinfectant treated water through a piece of flannel cloth into their water storage vessel, and discard the remaining residue in the toilet. They washed the filter cloth with detergent, and hung it to dry before re-use. The treated water was ready to drink 30 min after the flocculent-disinfectant was introduced. Field workers encouraged families to drink only treated water, but for this group they neither encouraged

nor discouraged hand washing. Field workers provided the supplies and instructions for both hand washing promotion and water treatment with flocculent-disinfectant.

Field workers provided control households with a regular supply of children's books, notebooks, pens and pencils to help with their children's education, but no products that would be expected to affect diarrhoea. Field workers neither encouraged nor discouraged hand washing or drinking water treatment in control households. Field workers visited control households and intervention households with equal frequency to collect health outcome data, but the visits were shorter in control households because no health education or encouragement for behaviour change was provided.

Measurements

Field workers conducted a pre-intervention baseline survey of household characteristics. They identified the mother or caregiver and each child in the household. Children's dates of birth were confirmed with birth certificates, immunization records, or event calendars. Field workers visited

participating households at least weekly, for 37 weeks (April 2003–December 2003), and asked the mother or other caregiver if the children had diarrhoea (three or more loose stools within 24 h) in the preceding week, and, if so, for how many days. The mother was also asked about her own symptoms of diarrhoea. Typically, field workers visited each household twice during the week to ensure that episodes of diarrhoea from both early and late in the week were recalled. Supervisors revisited 40% of homes each week and reviewed the history of diarrhoea among family members. The history recorded by the supervisor was compared to the history recorded by the field worker, and if there was a discrepancy, the fieldworker and supervisor revisited the house to clarify the difference.

Statistics

The primary hypotheses of the study included that each of the interventions would reduce diarrhoea compared to the control group and that the combination of water treatment with flocculent-disinfectant and hand washing promotion with soap would result in less diarrhoea than either intervention separately. The primary study outcome was the percent of person-weeks that study subjects had at least one day of diarrhoea. For a more precise analysis we also calculated the percent of person-days with diarrhoea that is we summed the number of days each study subject had diarrhoea and divided it by the total number of days of observation. We measured diarrhoea using longitudinal prevalence, rather than incidence, because longitudinal prevalence is more closely associated with growth faltering and child mortality than is diarrhoea incidence (Morris *et al.* 1996).

We calculated a sample size of 256 households per intervention group assuming diarrhoea would occur in 3% of person weeks in the control group, a 35% lower prevalence (1.95%) with the single intervention of either hand washing promotion or water treatment, an additional 30% lower prevalence (1.365%) with combined hand washing promotion and water treatment, 3.8 children per household, 10% dropout, 95% follow-up, 80% power, 95% confidence, one-sided testing, and a quadrupling of sample size to offset the effect of clustering by neighbourhood and repeated measures.

Because we assigned study groups at the neighbourhood level, we analysed the comparison of outcomes at the neighbourhood level. Specifically, within each neighbourhood, among person-weeks within the subgroup of interest, we identified the total number of person-weeks (or days) with diarrhoea and divided it by the total number of person-weeks (or days) at risk for persons in that neighbourhood within the subgroup of interest. For evaluation

of severe diarrhoea we identified children under age 5 years at the end of the study who were observed for at least 11 weeks and calculated the proportion who had diarrhoea during >10% of observed days. We calculated prevalence by intervention assignment by taking the mean of the appropriate neighbourhood prevalences weighted by the number of observations. We calculated prevalence ratios by dividing the weighted means from intervention neighbourhoods by the weighted means from control neighbourhoods (Donner & Klar 2000). We calculated standard confidence intervals for a ratio of normal means (Cox & Hinkley 1974). This approach calculated confidence intervals that reflected the different distribution of proportions at the neighbourhood level. We report the percent difference in outcome between intervention and control, that is, the prevalence ratio minus one. Similarly, we report the 95% confidence around this percent difference by subtracting 1 from the upper and lower confidence limit of the prevalence ratio.

The disease experience of each child, household, and neighbourhood was tracked and analysed with the group they were originally assigned to, that is the analysis was intention to treat. To calculate the intracluster correlation coefficient we first constructed an analysis of variance model. We used the longitudinal prevalence of diarrhoea among each participant throughout the study as the dependent variable, and intervention group and neighbourhood as independent variables. We then compared the variance between neighbourhoods to the variance within neighbourhoods to calculate the intracluster correlation coefficient and the design effect (Donner & Klar 2000).

Ethics

Community leaders and heads of households provided informed consent. Ill children were assessed by field workers and referred to the appropriate level of health care. The first line of treatment for diarrhoea was oral rehydration solution. Ill children referred by field workers were offered clinical services free of charge at HOPE health care facilities located in these communities. This included hospital admission and associated costs in case of emergencies. The study protocol was approved by the Ethics Review Committee of the Aga Khan University, the HOPE Human Research Review Board and an Institutional Review Board of the Centres for Disease Control and Prevention.

Results

Among 6962 households in the study neighbourhoods, 1337 households (19%) met the inclusion criteria and

enrolled in the study. The number of clusters, households, persons and births was similar across the intervention groups (Figure 1). Overall, data were collected from 92% of the potential person-weeks of follow-up, though it differed across groups, ranging from 87% among persons living in households that received flocculent-disinfectant to 96% in control households.

At baseline, the households in the different study groups were similar in size, socio-economic status, drinking water source, hand washing and sanitary facilities, and purchases of soap and water (Table 1). During the course of the study, children were routinely breastfed in all of the groups, although there was some difference by intervention group in exclusive breast-feeding among children under age 6 months.

Persons living in neighbourhoods that received any of the interventions had markedly less diarrhoea compared to persons living in control neighbourhoods (Table 2). The reduction in daily longitudinal prevalence of diarrhoea ranged from 51% among households receiving soap and hand washing promotion to 64% among households receiving flocculent-disinfectant. There was no apparent additional benefit to flocculent-disinfectant water treatment plus hand washing promotion with soap, compared to either of these interventions individually.

The longitudinal prevalence of diarrhoea varied markedly over the course of the study. In July 2003, 190 mm of rain fell in Karachi, 2.6 times the 50-year mean July rainfall of 72 mm (U.S. Department of Commerce 2003). In the first 3 months of observation, persons living in neighbourhoods that received flocculent-disinfectant had a lower prevalence of diarrhoea compared to households that received soap and hand washing promotion or soap and hand washing promotion plus flocculent-disinfectant (Figure 2). During the heavy rains in July, the prevalence of diarrhoea in intervention neighbourhoods was the same as in control neighbourhoods. Diarrhoea prevalence peaked in the control group following the heavy July rains. During the last 5 months of observation the diarrhoea prevalence across the intervention groups tracked fairly closely together, and was markedly lower than control neighbourhoods.

Younger children had a higher longitudinal prevalence of diarrhoea, with infants having the highest prevalence (Table 3). The largest reductions in diarrhoea prevalence with interventions occurred among children 5–15 years. Diarrhoea prevalence was consistently lower among infants and children ≥1–2 years who lived in intervention neighbourhoods compared to control neighbourhoods, however the magnitude of the reductions were less than the overall reduction, and many of the individual age and intervention specific reductions were not statistically significant (Table 3).

Persons living in intervention neighbourhoods were significantly less likely to visit a practitioner for diarrhoea treatment (Table 4). Hospitalisation for diarrhoea was a rare outcome that did not occur at significantly different rates in intervention versus control neighbourhoods (Table 4). Intervention neighbourhoods had a substantially lower proportion of children under age 5 years with >10% of observed days with diarrhoea than persons in control neighbourhoods, though the 95% confidence limit in the bleach water treatment group did not quite exclude zero (Table 4).

The percentage of study participants followed up each week declined during the course of the study (Figure 3). This decline was most marked among persons living in neighbourhoods assigned to flocculent-disinfectant and least common among households in the control and hand washing promotion neighbourhoods. Excluding children born during the study, 82% of study subjects completed 34 (92%) or more weeks of follow-up. During the weeks they were observed, study subjects with fewer than 34 weeks of follow-up reported a similar mean longitudinal prevalence of diarrhoea compared to the mean longitudinal prevalence of study subjects in their same study group who completed 34 or more weeks of follow-up (Table 5).

There was some reported difference in exclusive breast-feeding across intervention groups, especially among children under the age of 6 months (Table 1). However, children under the age of 6 months represent less than 1% of the total person-weeks observed, and the effects of the interventions were clearly independent of exclusive breast-feeding for the majority of the population who was beyond the age of breastfeeding (Table 3).

Households in the flocculent-disinfectant water treatment group averaged using 21.6 sachets per week or 4.4 l of treated water per person per day. Households in the flocculent-disinfectant plus hand-washing group averaged 20.4 sachets or 4.3 l of treated water per person per day. The consumption of sachets during July when there were heavy rains (21.5 sachets per household per week) was consistent with consumption throughout the summer. Households receiving bleach consumed sufficient bleach to treat an average of 3.0 l of treated water per person per day. Soap households averaged consuming 2.5 bars of soap per week, for a mean 3.5 g of soap per person per day.

Households often added ice purchased in the market to their drinking water. Between July and October households receiving the bleach water treatment added ice 5.3 times per week, households receiving the flocculent disinfected added ice an average of 5.2 times per week and households receiving the flocculent disinfected plus soap added ice an average of 4.9 times per week.

Table 1 Characteristics of households by intervention group, Karachi Flocculent Health Study, Karachi, Pakistan, 2003

	Bleach water treatment (n = 252)	Soap and hand washing promotion (n = 262)	Flocculent-Disinfectant water treatment (n = 261)	Flocculent-Disinfectant plus Soap (n = 266)	Control (n = 282)
Baseline					
Mean					
Persons per household	9.4	9.2	10.1	9.3	8.8
Children <5 years of age per household	1.7	1.7	1.8	1.8	1.8
Children <2 years of age per household	0.57	0.52	0.61	0.64	0.60
Rooms in house	2.1	2.1	2.0	1.9	2.1
US$ spent on water in a normal week	0.60	0.52	0.52	0.60	0.50
Bars of hand soap purchased in preceding 2 weeks	1.1	1.2	1.2	1.2	1.2
% of					
Mother of the youngest child is literate	35	32	30	30	37
Mother of the youngest child finished secondary school	10	10	9	10	10
Monthly household income <54 US$	51	51	51	56	56
Father's occupation					
Salaried employee	56	50	56	55	50
Works for daily wages	38	40	39	38	42
Other	7	9	5	8	8
Owns					
Refrigerator	26	29	25	21	23
Television	58	59	62	59	60
Radio	19	27	26	23	21
Primary drinking water source					
Municipal supply within the house	30	28	37	28	33
Municipal supply at a community tap	29	42	36	38	37
Tanker truck	18	15	12	14	12
Water bearer	13	11	10	10	13
Tube well	10	4	5	10	5
Re-supply household drinking water less frequently than once a day	37	39	39	32	37
Toilet without flush tank in the home	98	95	96	98	96
Place to wash hands with soap seen by study workers	24	22	23	21	24
Feces visible where children have access	8	9	12	12	11
Kitchen judged by field worker to be dirty or very dirty	43	49	45	44	44
During intervention					
% of person-weeks children <1 year were breastfed (n = 9527)	99	100	98	99	99
% of person-weeks children <1 year were exclusively breastfed (n = 9454)	12	22	16	17	13
% of person-weeks children <6 months were exclusively breastfed (n = 3012)	33	55	42	46	30

Table 2 Primary diarrhoea outcomes by intervention group, Karachi 2003

Intervention group (person-weeks at risk)	Diarrhoea daily longitudinal prevalence (306 069)		Diarrhoea weekly longitudinal prevalence (306 069)	
	Mean† prevalence‡	Difference from control (95% CI)§	Mean‡ prevalence¶	Difference from control (95% CI)
Bleach water treatment	2.36	−55% (−17%, −80%)	4.07	−53% (−22%, −75%)
Soap and hand washing promotion	2.57	−51% (−12%, −76%)	4.73	−45% (−12%, −68%)
Flocculent-disinfectant water treatment	1.87	−64% (−29%, −90%)	3.51	−59% (−29%, −82%)
Flocculent-disinfectant plus soap	2.36	−55% (−18%, −80%)	4.34	−50% (−18%, −72%)
Control	5.19	–	8.62	–

† Mean was calculated by taking the mean of the neighborhood prevalences weighted by the number of observations.
‡ Days with diarrhoea/Days of observation.
§ Confidence interval.
¶ Person-weeks with diarrhoea/Person-weeks of observation.
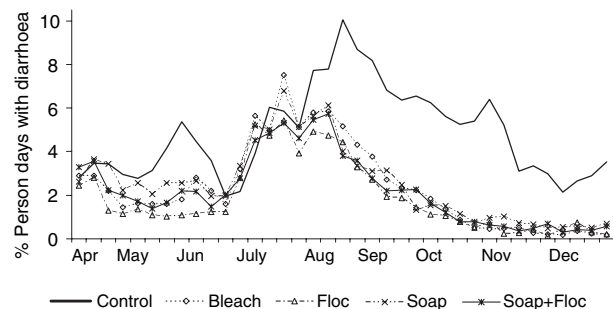
Figure 2 Longitudinal prevalence of diarrhoea by week and intervention group, Karachi 2003.

For the primary study outcome, the longitudinal prevalence of diarrhoea, the intracluster correlation coefficient was 0.105. The design effect was 21.1.

Discussion

Point-of-use water treatment with either bleach or flocculent-disinfectant as well as hand washing promotion with soap resulted in marked reductions in the overall prevalence of diarrhoea. The magnitude of the reduction in diarrhoea seen with hand washing promotion with soap and with dilute sodium hypochlorite was consistent with previous evaluations (Mintz *et al.* 2001; Curtis & Cairncross 2003; Luby *et al.* 2004a,b; Fewtrell *et al.* 2005). The 64% reduction in diarrhoea seen with flocculent-disinfectant was larger than the reductions noted in three previous trials in rural non-refugee settings including a 24%–29% reduction in an initial study in rural Guatemala (Reller *et al.* 2003), a 40% reduction in a follow-up study in rural Guatemala (Chiller *et al.* 2006) and a 16%

reduction in rural Western Kenya (Crump *et al.* 2005). The most salient difference among these studies was that in Karachi, product consumption was substantially higher with a mean of over 20 sachets used per household per week compared to six in the first Guatemala study, 10 in the second Guatemala study and 10 in the Kenya study (Reller *et al.* 2003; Crump *et al.* in press; Chiller *et al.* in press).

The combination of household water treatment plus hand washing promotion with soap failed to reduce diarrhoea more than either intervention separately. Although this is the first simultaneous comparison of combined hand washing and water treatment compared against either intervention alone that we are aware of, in Fewtrell's meta analysis (2005) interventions that combined water, hygiene and sanitation interventions were no more effective in reducing diarrhoea than programs interventions that focused on a single intervention. One possible explanation is that 65%–75% of diarrhoea among persons living in this sewage contaminated environment is caused by pathogens that require a large dose to cause disease. A substantial reduction in the number of organisms ingested, either through hand washing or water treatment, may markedly reduce diarrhoea, but once ingested dose is below a certain threshold, further modest reduction in the dose of ingested organisms may not markedly reduce disease risk. Other possible explanations include that a substantial part of the reported reduction in diarrhoeal disease was a result of courtesy bias. Intervention households were given supplies free of cost, and may have wanted to meet the expectation of the study workers. Courtesy bias would not be expected to be additive with more interventions. A third possible explanation is that improving one hygiene behaviour in the home may lead to improvement in other hygiene related behaviours. Study

S. P. Luby *et al.* **Drinking water treatment and hand washing**

Table 3 Longitudinal prevalence of diarrhoea by age group and intervention group, Karachi, 2003

Age groups (observed person-weeks) (persons)	<1 year (11 930) 575		≥1–2 years (12 867) 663		≥2–5 years (55 475) 1824		≥5–15 years (158 107) 4719		>15 years (67 690) 2002	
	Diarrhoea prevalence (%)	Difference from control (95% CI)†	Diarrhoea prevalence (%)	Difference from control (95% CI)	Diarrhoea prevalence (%)	Difference from control (95% CI)	Diarrhoea prevalence (%)	Difference from control (95% CI)	Diarrhoea prevalence (%)	Difference from control (95% CI)
Bleach water treatment	8.30	−20% (14%, −48%)	6.02	−32% (0%,−57%)	4.15	−46% (−14%, −69%)	1.66	−67% (−20%, −98%)	0.79	−55% (32%, −97%)
Soap and hand washing promotion	7.86	−24% (6%, −48%)	6.36	−28% (6%, −55%)	4.63	−40% (−5%, −64%)	1.91	−62% (−11%, −95%)	0.79	−55% (31%, −98%)
Flocculent-disinfectant water treatment	6.20	−40% (−15%, −60%)	5.96	−32% (2%, −60%)	3.01	−61% (−32%, −83%)	1.36	−73% (−26%, −100%)	0.60	−66% (13%, −100%)
Flocculent-disinfectant plus Soap	6.48	−38% (−15%, −55%)	5.80	−34% (−6%, −56%)	3.94	−49% (−17%, −71%)	1.85	−63% (−13%, −95%)	0.78	−56% (30%, −97%)
Control	10.38		8.82		7.67		5.06		1.75	

†Confidence interval.

Table 4 Severe diarrhoea outcomes by intervention group, Karachi 2003

Intervention group (Child–weeks at risk)	Saw a practitioner for diarrhoea (306 069)		Hospitalised for diarrhoea (305 966)		Proportion of children <5 years with longitudinal prevalence of diarrhoea >10% (2273 children‡)	
	Proportion* of person-weeks (%)	Percent difference versus control (95% CI)†	Proportion of person-weeks (%)	Percent difference versus control (95% CI)	Proportion§	Percent difference versus control (95% CI)
Bleach water treatment	3.8	−54% (−22%, −77%)	0.015	−39% (106%, −100%)	19.3	−44% (2%, −75%)
Soap and hand washing promotion	4.3	−48% (−15%, −71%)	0.020	−17% (157%, −86%)	15.6	−55% (−14%, −83%)
Flocculent-disinfectant water treatment	3.2	−61% (−31%, −84%)	0.018	−24% (134%, −84%)	10.4	−70% (−35%, −96%)
Flocculent-disinfectant plus soap	3.8	−55% (−23%, −77%)	0.038.	56% (347%, −32%)	13.0	−62% (−25%, −89%)
Control	8.3	–	0.024	–	34.4	–

* The proportion was calculated for each neighbourhood, and the mean of the proportions, weighted by the person-weeks contributing within each neighbourhood reported in the table.
† Confidence interval.
‡ Children who contributed fewer than 11 person weeks of observation were excluded from this analysis.
§ The proportion was calculated for each neighbourhood, and the mean of the proportions, weighted by the number of person contributing data within each neighbourhood reported in the table.
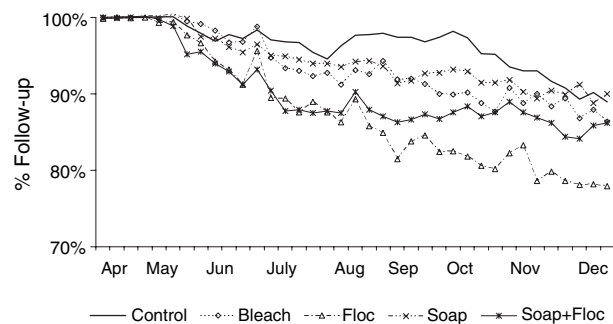
Figure 3 Percent of study subjects (excludes children born into study families) followed up by week and group.

Table 5 Characteristics of study subjects with above and below average follow-up*

	Follow up >33 person-weeks ($n = 7313$)	Follow up ≤33 person-weeks ($n = 1636$)
Mean age (years)	12.3	11.9
Mean diarrhoea longitudinal prevalence	2.9%	2.5%
Mean diarrhoea longitudinal prevalence by age at study initiation		
<1 year	8.2%	6.2%
≥1–2 years	6.7%	5.8%
≥2–5 years	4.7%	3.8%
≥5–15 years	2.3%	2.0%
≥15 years	1.0%	0.7%
Mean diarrhoea longitudinal prevalence by study group		
Bleach water treatment	2.4%	2.6%
Soap and hand washing promotion	2.6%	2.2%
Flocculent-disinfectant water treatment	1.9%	1.9%
Flocculent-disinfectant plus soap	2.2%	2.1%
Control	4.8%	4.6%

* Excludes children born into the study.

workers provided supplies and messages only for the assigned intervention, but in descriptive studies hygiene behaviours are typically closely associated (Bartlett *et al.* 1992). Self-efficacy in one area could lead to self-efficacy in another. Fourth, it is possible that the combination of water treatment and hand washing promotion would have an additive effect, but introducing two interventions simultaneously did not allow their optimal combined use. Behaviour change is best achieved with single simple messages (Loevinsohn 1990), an approach that combining two interventions in one season did not permit. However, product consumption was similar in the combined and separate intervention arms.

Prior studies in squatter settlements in Karachi have noted a delay between distribution of household interventions and effect on diarrhoea outcome (Luby *et al.* 2004a,b). We hypothesize that with time there is technical mastery and increasingly habitual use of household interventions to prevent diarrhoea. During the present study after 6 weeks of intervention, the disease experience of the intervention neighbourhoods had diverged from the control neighbourhoods. However, none of the interventions appeared to be effective in preventing diarrhoea during the heavy rain and acute flooding in July. There was no fall off in product consumption during these weeks. This suggests that during the heavy rains and flooding there was so much fecal contamination of the environment that neither water treatment nor hand washing with soap reduced the ingested dose of pathogens sufficiently to prevent diarrhoea. After the flooding abated, the difference between intervention and control neighbourhoods re-emerged and was stable into the lower prevalence winter season as has been noted in a prior hand washing intervention study (Luby *et al.* 2004b).

Although intervention supplies were provided at no cost, fewer households were available for follow-up for each of the intervention groups compared to control. The largest drop off in use was among households using the most time-intensive intervention, the flocculent-disinfectant. For any of these household-based interventions to have a substantial public health impact they need to be valued enough so that a large proportion of the at-risk population chooses to become regular users.

There are important limitations to the study. First, study personnel and participants were not blinded to the intervention. It is possible that study participants in the intervention groups, grateful for the supplies, minimized reported episodes of diarrhoea in the household, or field workers recorded fewer episodes because of a desire to meet the expectation of study sponsors. However, field workers were formally trained, and the importance of accurate recording of reported symptoms was stressed. Unannounced supervisory visits did not identify systematic errors.

A second limitation is that the differential follow-up among groups suggests that persons who used the interventions more conscientiously may have been over-sampled compared to less regular users. However, the prevalence of diarrhoea did not differ among persons who were followed for fewer weeks, so their loss to follow-up is unlikely to have had a marked effect on the results.

In this setting where diarrhoea is a leading cause of death and the environment is heavily contaminated with sewage, household-level interventions to improve drinking water quality and hand washing promotion with soap resulted in

a marked reduction in diarrhoea. Outside of a randomised controlled trial, in which participants were provided supplies at no cost and regularly encouraged to use them, water treatment and hand washing would probably be less consistent. Some families and individuals may be more inclined to adopt one or the other intervention. Thus, as part of a public health program, promoting both hand washing and point-of-use water treatment with safe storage may expand the proportion of the population that adopts a protective behaviour and thereby produce additive benefit. However, these data suggest that an additive benefit of hand washing and water treatment should not be assumed, that the cost of multiple messages both for public health programs to deliver and for low income families to adopt may not be justified. The next step in determining the role that these approaches have in preventing diarrhoea globally is to implement them at larger scale and evaluate their practicality, uptake and effectiveness.

Acknowledgements

References

Bartlett AV, Hurtado E, Schroeder DG & Mendez H (1992) Association of indicators of hygiene behaviour with persistent diarrhoea of young children. *Acta Paediatrica Supplementum* **381**, 66–71.

Chiller TM, Mendoza CE, Lopez MB *et al.* (2006) Reducing diarrhoea in Guatemalan children: a randomized controlled trial of a flocculent-disinfectant for drinking water. *Bulletin of the World Health Organization* **84**(1), 28–35.

Cox DR & Hinkley DV (1974) *Theoretical Statistics*. Chapman and Hall, London.

Crump JA, Otieno PO, Slutsker L *et al.* (2005) Household based treatment of drinking water with flocculant-disinfectant for

preventing diarrhoea in areas with turbid source water in rural western Kenya: cluster randomised controlled trial. *BMJ*, **331**, 478–483.

Curtis V & Cairncross S (2003) Effect of washing hands with soap on diarrhoea risk in the community: a systematic review. *Lancet Infectious Diseases* **3**(5), 275–281.

Donner A & Klar N (2000) *Design and Analysis of Cluster Randomization Trials in Health Research*. Oxford University Press, New York.

Fewtrell L, Kaufmann RB, Kay D, Enanoria W, Haller L & Colford JM (2005) Water, sanitation, and hygiene interventions to reduce diarrhoea in less developed countries: a systematic review and meta-analysis. *Lancet Infectious Diseases* **5**, 42–52.

Khan Sr, Jalil F, Zaman S, Lindblad BS & Karlberg J. (1993) Early child health in Lahore, Pakistan: X. Mortality. *Acta Paediatrica Supplementum* **390**, 109–117.

Loevinsohn BP (1990) Health education interventions in developing countries: a methodological review of published articles. *International Journal of Epidemiology* **19**(4), 788–794.

Luby SP, Agboatwalla M, Hoekstra RM, Rahbar MH, Billhimer W & Keswick BH (2004a) Delayed effectiveness of home-based interventions in reducing childhood diarrhoea, Karachi, Pakistan. *American Journal of Tropical Medicine & Hygiene* **71**(4), 420–427.

Luby SP, Agboatwalla M, Painter J, Altaf A, Billhimer WL & Hoekstra RM (2004b) Effect of intensive hand washing promotion on childhood diarrhoea in high-risk communities in Pakistan: a randomized controlled trial. *Journal of the American Medical Association* **291**(21), 2547–2554.

Marsh D, Husein K, Lobo M, Shah MA & Luby S (1995) Verbal autopsy in Karachi slums: comparing single and multiple cause of child deaths. *Health Policy and Planning* **10**, 395–403.

Mintz E, Bartram J, Lochery P & Wegelin M (2001) Not just a drop in the bucket: expanding access to point-of-use water treatment systems. *American Journal of Public Health* **91**(10), 1565–1570.

Morris SS, Cousens SN, Kirkwood BR, Arthur P & Ross DA (1996) Is prevalence of diarrhoea a better predictor of subsequent mortality and weight gain than diarrhoea incidence? *American Journal of Epidemiology* **144**(6), 582–588.

Reller ME, Mendoza CE, Lopez MB *et al.* (2003) A randomized controlled trial of household-based flocculent-disinfectant drinking water treatment for diarrhoea prevention in rural Guatemala. *American Journal of Tropical Medicine and Hygiene* **69**(4), 411–419.

U.S. Department of Commerce, National Oceanic and Atmospheric Administration (NOAA) and the U.S. Department of Agriculture (2003) *Weekly Weather and Crop Bulletin* **90**(31), 27.

World Health Organization (1999) *The World Health Report 1999*. World Health Organization, Geneva.

Corresponding Author Dr Steve Luby, Programme Infectious Diseases and Vaccine Sciences, ICDDRB: Centre for Health and Population Research, GPO Box 128, Mohakhali, Dhaka 1212 Bangladesh. E-mail: sluby@icddrb.org

Combinaison du traitement de l'eau de boisson et du lavage des mains pour la prévention de la diarrhée: une étude randomisée contrôlée en grappe

OBJECTIFS   Evaluer l'efficacité du traitement de l'eau au point d'utilisation avec un désinfectant floculant sur la réduction des diarrhées et le bénéfice additionnel de la promotion du lavage des mains.

MÉTHODES   l'étude a été conduite dans les installations d'habitations de fortune de Karachi au Pakistan où la diarrhée est la cause principale de mortalité infantile. Les interventions ont été assignées de façon randomisée à 47 quartiers. Dans 10 quartiers, les familles ont reçu de l'eau de javel diluée et des conteneurs pour l'eau. Dans 9 quartiers, elles ont reçu du savon et ont été motivées pour le lavage des mains. Dans 9 quartiers, elles ont reçu le désinfectant floculant pour le traitement de l'eau et des conteneurs pour l'eau. Dans 10 quartiers, elles ont reçu le désinfectant floculant et du savon et ont été motivées pour le lavage des mains. 9 quartiers ont été suivis comme contrôles. Les agents de terrain ont visité chaque famille au moins une fois par semaine, d'avril à décembre 2003 pour promouvoir l'utilisation des interventions et pour collecter des données sur la diarrhée.

RÉSULTATS   Les participants dans les quartiers contrôles avaient la diarrhée sur 5,2% des jours. Comparés au contrôles, les participants des quartiers recevant l'intervention avaient une prévalence de diarrhée plus faible repartie comme suit: 55% (IC95%: 17–80) plus faible dans les quartiers ayant reçu l'eau de javel et des centenaires, 51% (IC95%: 12–76) plus faible dans les quartiers ayant reçu la promotion du lavage des mains, 64% (IC95%: 29–90) dans les quartiers ayant reçu le désinfectant floculant et 55% (IC95%: 18–80) plus faible dans les quartiers ayant reçu le désinfectant floculant en plus de savon pour le lavage des mains.

CONCLUSION   Avec une forte intervention basée sur la communauté et des moyens procurés sans charge, chacune des interventions a entraîné une réduction significative de la diarrhée. Il n'y avait pas de bénéfice supplément en combinant la promotion du lavage des mains et le traitement de l'eau.

mots clés diarrhée, eau, savon, désinfectant, hypochlorite de sodium, étude contrôlée randomisée

Combinando el tratamiento del agua potable y el lavado de manos para la prevención de la diarrea, un ensayo aleatorizado, controlado por clusters.

OBJETIVOS   Evaluar la efectividad del tratar el agua con desinfectante floculado en la reducción de la diarrea, así como los beneficios adicionales en la promoción del lavado de manos con jabón.

MÉTODOS   El estudio fue conducido en asentamientos ilegales de Karachi, Pakistán, en los que la diarrea es la principal causa de mortalidad infantil. Las intervenciones fueron asignadas aleatoriamente en 47 barrios. Las casas de 10 barrios recibieron lejía diluida y un recipiente para agua; en 9 barrios se entregó jabón y se les animó a que se lavasen las manos; en otros 9 barrios se entregó desinfectante floculado para tratamiento del agua y un recipiente para agua; 10 barrios recibieron desinfectante floculado para tratamiento del agua y jabón, y se les animó a que se lavaran las manos; y 9 barrios fueron seguidos como controles. Los trabajadores de campo visitaron las casas al menos una vez por semana, entre Abril y Diciembre del 2003, para promover el uso de la intervención y para recolectar datos sobre diarreas.

RESULTADOS   Los participantes de los barrios controles tuvieron diarrea en un 5.2% de los días. Comparado con los controles, los participantes que vivían en uno de los barrios en los que se intervino tuvieron una menor prevalencia de diarrea: 55% (95% IC 17, 80) menos en los barrios en los que se entregó lejía y un recipiente para el agua, 51% (95% IC 12, 76) menos en los barrios en los que se promovió el lavado de manos con jabón, 64% menos (95% IC 29, 90) en los barrios con desinfectante floculado, y 55% (95% IC 18, 80) menos en los barrios con desinfectante floculado más promoción del lavado de manos con jabón.

CONCLUSIONES   Con una intervención comunitaria intensiva y suministros gratuitos, cada una de las Intervenciones redujo la diarrea de forma significativa. No se halló beneficio en combinar la promoción del lavado de manos con el tratamiento del agua.

palabras clave diarrea, agua, jabón, desinfección, hipoclorito de sodio, ensayo aleatorizado y controlado