A RANDOMIZED CONTROLLED TRIAL OF HOUSEHOLD-BASED FLOCCULANT-DISINFECTANT DRINKING WATER TREATMENT FOR DIARRHEA PREVENTION IN RURAL GUATEMALA

MEGAN E. RELLER, CARLOS E. MENDOZA, M. BEATRIZ LOPEZ, MARICRUZ ALVAREZ, ROBERT M. HOEKSTRA, CHRISTY A. OLSON, KATHLEEN G. BAIER, BRUCE H. KESWICK, AND STEPHEN P. LUBY

Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia; Universidad del Valle de Guatemala, Medical Entomology Research and Training Unit, Guatemala City, Guatemala; Procter & Gamble Company, Cincinnati, Ohio

Abstract. We conducted a study to determine if use of a new flocculant-disinfectant home water treatment reduced diarrhea. We randomly assigned 492 rural Guatemalan households to five different water treatment groups: flocculant-disinfectant, flocculant-disinfectant plus a customized vessel, bleach, bleach plus a vessel, and control. During one year of observation, residents of control households had 4.31 episodes of diarrhea per 100 person-weeks, whereas the incidence of diarrhea was 24% lower among residents of households receiving flocculant-disinfectant, 29% lower among those receiving flocculant-disinfectant plus vessel, 25% lower among those receiving bleach, and 12% lower among households receiving bleach plus vessel. In unannounced evaluations of home drinking water, free chlorine was detected in samples from 27% of flocculant-disinfectant households, 35% of flocculant-disinfectant plus vessel households, 35% of bleach households, and 43% of bleach plus vessel households. In a setting where diarrhea was a leading cause of death, intermittent use of home water treatment with flocculant-disinfectant decreased the incidence of diarrhea.

INTRODUCTION

Approximately 1.1 billion persons living in low-income countries lack access to improved water sources,[1] and many more lack safe drinking water. In low-income countries, where safe drinking water is scarce, diarrhea causes an estimated 2.2 million deaths per year.[2]

Ideally, water purified centrally is kept separate from sewage until its delivery to both urban and rural residents. However, most of the communities where diarrhea is a leading cause of death lack the capital and the administrative capacity to build and maintain the infrastructure this long-term solution requires. As an interim response, the Centers for Disease Control and Prevention (CDC) and the Pan American Health Organization developed a household-based system to treat water at its point-of-use. There are three components to this approach: dilute sodium hypochlorite (household bleach) as a disinfectant, a narrow-mouthed water storage vessel of standard volume, and a program of behavioral change to encourage people to use the system.[3] In field trials, this approach has reduced diarrhea by 44% in Bolivia,[4] 85% in Uzbekistan,[5] and 48% in Zambia.[6] However, it can be difficult to persuade people to add bleach to their drinking water. Bleach is less effective if water is turbid or contaminated with chlorine-resistant pathogens. Adding bleach does not make the water look any cleaner, and it may worsen the taste and smell, especially when there is substantial organic contamination. When external funding has supported sophisticated efforts to change behavior, more households have treated their drinking water. However, sufficient subsidies to support widespread behavioral change and maintenance of that change are not available globally to reach the billion plus persons whose drinking water is contaminated with sewage.

In response to these limitations and the persistent unmet need for water treatment, the Procter & Gamble Company (Cincinnati, OH) developed a new flocculant-disinfectant technology for treating water in the home that incorporates techniques used in municipal water purification. The product is a powder that is added to water; uses precipitation, coagulation, and flocculation to remove heavy metals, organic matter, and microorganisms; and leaves a free chlorine residual. After decanting, the treated water is microbiologically and chemically cleaner[7] and looks clearer. The immediate improvement in clarity may encourage more people to treat their water. A three-week pilot study in November 2000 demonstrated the microbiologic efficacy and short-term acceptability of this technology in rural Guatemalan households.[8]

Therefore, we conducted a one-year study to evaluate the effectiveness of the flocculant-disinfectant in preventing diarrhea. Our primary hypothesis was that children ≤ 1 year of age who lived in households that received flocculant-disinfectant would have fewer episodes of diarrhea than children in households with traditional water handling and storage. We also planned to assess the effect of water treatment on diarrhea among household residents of all ages and to evaluate the importance of using a specially designed storage vessel.

MATERIALS AND METHODS

Setting. Diarrhea is the second leading cause of death in Guatemala.[9] The study was conducted in 12 indigenous Kachiquel Mayan villages in the Department of San Juan Sacatepéquez, a region in the highlands 30 km north of Guatemala City. Village residents typically live in small dwellings with dirt floors; five or more persons sleep in the same room. Few households have latrines or other sanitary facilities, so most residents defecate outside on the ground. In this region, the infant mortality rate is 47.7 per 1,000 inhabitants[9] and 51% of the children in their first year of school meet the criteria for moderate or severe stunting of the World Health Organization (WHO).[10] Surface water used for drinking is typically obtained from shallow wells, rivers, and springs; it is regularly contaminated with both human and animal feces. Piped water, when available, is rarely chlorinated. Water is typically carried and stored in plastic large-mouthed vessels holding 10–15 liters (Figure 1A).

A team at the Medical Entomology Research Training Unit (MERTU), a CDC field station located at the Universidad del Valle de Guatemala in Guatemala City, implemented the
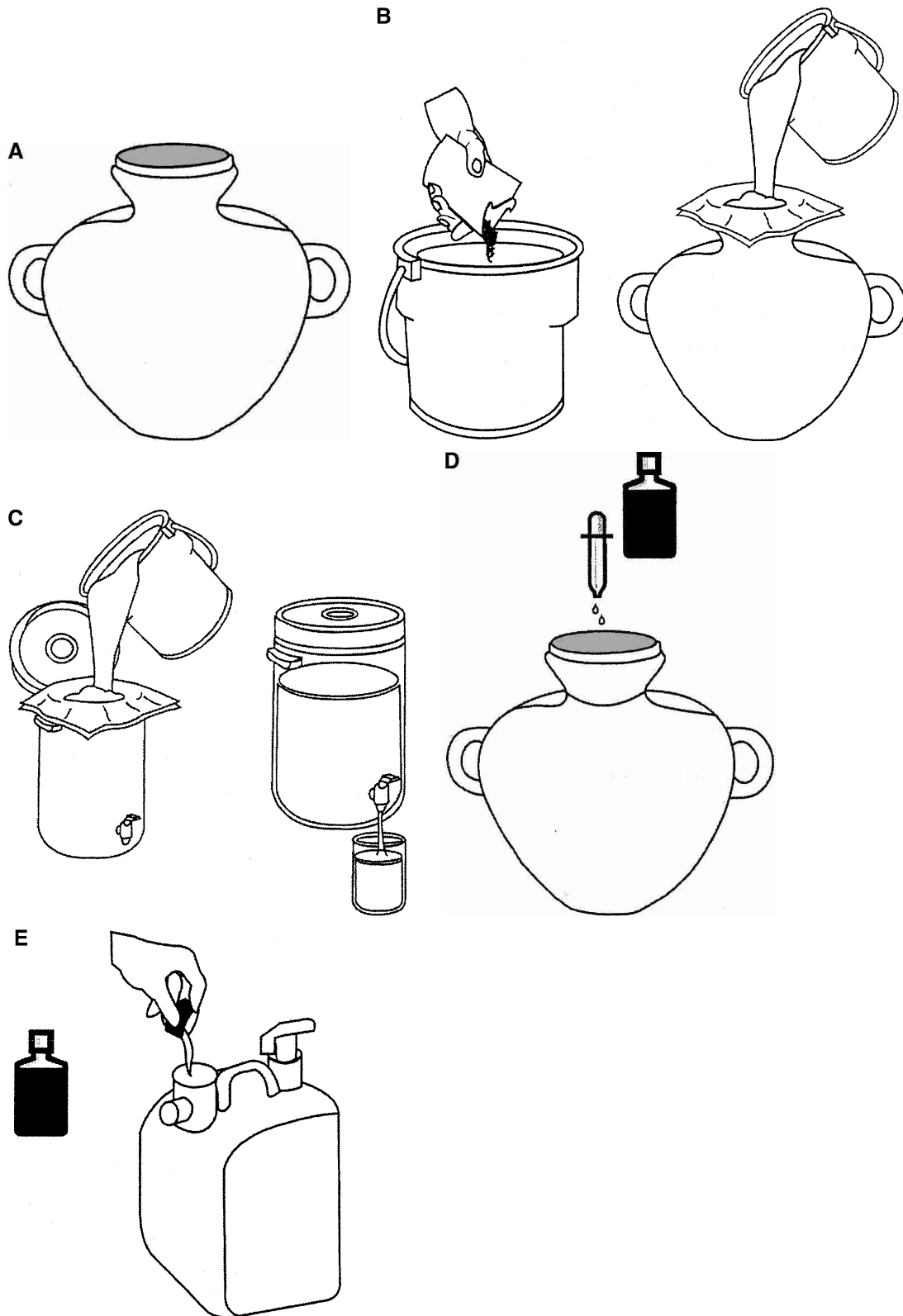
FIGURE 1. Five water treatments groups used in the study. **A**, Standard habits and practices; **B**, flocculant-disinfectant alone (used with traditional vessels); **C**, flocculant-disinfectant with special vessel; **D**, bleach with traditional vessel; **E**, bleach with special vessel.

field activities. Nine Ladino (of Spanish descent) and three Kachiquel Mayan field workers, all with a high-school education and trained in interviewing, visited households to administer questionnaires and collect water samples. Three lo-

cal physicians provided on-site supervision and medical consultation for severe diarrhea when needed.

Interventions. *Flocculant-disinfectant alone.* The flocculant-disinfectant is a new technology developed by the

Procter & Gamble Company. Its ingredients include ferric sulfate, bentonite, sodium carbonate, chitosan, polyacrylamide, potassium permanganate, and calcium hypochlorite. Each of the ingredients are commonly used in municipal water treatment plants. The ingredients have been specially formulated in single-use sachets to work quickly on small volumes of water. The water treatment process combines precipitation, coagulation, and flocculation with disinfection. It aggregates and facilitates the removal of suspended organic matter, bacteria, viruses, parasites, and heavy metals in treated water. One single-use packet contained sufficient calcium hypochlorite to leave a residual chlorine concentration of 3.5 mg/liter when added to 10 liters of demineralized water. When added to contaminated surface water, the mean chlorine residual was 1.5 mg/liter.[8]

Study subjects were taught to add a sachet of the flocculant-disinfectant to 10 liters of water, to stir vigorously for 30 seconds, and then to let the slurry stand for five minutes; they then repeated the stirring and settling process twice. Finally, they decanted the flocculant-disinfectant treated water through a piece of flannel cloth into their traditional storage vessel, and discarded the remaining residue in the preparation vessel out of the reach of animals and children. Since most families do not have access to latrines, the refuse site was most often the side of a hill or several meters away from the living area. They washed the filter cloth with detergent, and sometimes bleach, and hung it to dry before re-use. The clear, treated water was ready to drink 30 minutes after the flocculant-disinfectant was introduced.

Field workers typically gave households 14 sachets of flocculant-disinfectant weekly, but larger families were given more. The field workers provided each family two cloths initially. Families could exchange cloths for new ones whenever they wished. Families in this group used their own equipment to prepare and store the water. Most used a bucket to prepare water and a plastic jug with a wide mouth and narrow neck to store it (Figure 1B).

Flocculant-disinfectant plus vessel. Participants used the same process to treat water as the flocculant-disinfectant alone arm. However, participants received a large plastic spoon for stirring, a large-mouthed bucket for mixing, and a vessel with a secure lid and a spigot for storing treated water (Figure 1C).

Bleach alone. This arm was modeled on the recommendations of the Guatemalan Ministry of Health. Field workers supplied these households with a 125-mL brown plastic bottle filled with an undiluted, locally manufactured commercial bleach verified to have 50,000 parts per million (ppm) of sodium hypochlorite. These households also received a smaller bottle with dropper integrated into the lid to help them dose bleach accurately. Field workers instructed participants to use the medicine dropper to add two drops of bleach per liter of water into their water vessel, stir the water to distribute the bleach evenly, and wait 30 minutes to allow adequate time for microbial killing. In trials with demineralized water, water thus treated had on average 3.6 ppm of sodium hypochlorite (range = 3.0–4.2 ppm). Each month field workers exchanged the partially used stock bottles of bleach for a new one. Participants in this arm provided their own storage vessel, and made their own estimates of its size. Most used a 10–15-liter plastic vessel (Figure 1D).

Bleach plus vessel. This arm was modeled on the CDC's

safe water system.[11] Field workers provided participants with a 250-mL brown plastic bottle of dilute bleach and a 20-liter narrow-mouthed storage vessel. The dilute bleach was prepared by diluting locally manufactured commercial bleach 0.44:1 with distilled water to yield a solution with 14,400 ppm of sodium hypochlorite. Participants were instructed to fill the storage vessel to the 20-liter line, add a capful (5 mL) of dilute bleach, shake vigorously to distribute the bleach evenly, and wait 30 minutes to allow adequate time for microbial killing. In the laboratory, demineralized water thus treated had 3.6 ppm of sodium hypochlorite (range = 3.0–4.2 ppm). The storage vessel provided was plastic, and had a lid, a spigot, and a narrow mouth to prevent removal of water by dipping (Catalog number 180-100A; Tolco, Inc., Toledo, OH) (Figure 1E).

Control. In the control group, participants continued their usual water collection, treatment, and storage practices (Figure 1A). As an incentive for participation, each week they received small items that would not be expected to affect diarrhea, for example, kitchen utensils or an article of infant clothing.

Enrollment. We first identified 12 villages whose source water was contaminated with *Escherichia coli*. Field workers then identified households located within the 12-village study area that either had a child ≤ 11 months of age or a mother in her last trimester of pregnancy. We excluded households that had participated in the three-week pilot study of the intervention. For each of the 12 villages, we used a spreadsheet with a random number generator to assign each eligible household to one of the five water treatment groups. Thus, treatment groups were randomized and assigned by household and were balanced within each village. Field workers approached residents of eligible households, and if they consented to participate, completed a baseline survey.

Education/motivation. In each village field workers discussed the importance of water treatment, demonstrated the water preparation process, and distributed water treatment supplies to small groups of mothers assigned to the same intervention in August and September 2001. In an attempt to more closely mimic a market model, field workers were instructed only to collect data and not to provide explicit encouragement to use any of the water treatment methods on follow-up visits. In December, when an interim analysis suggested that a minority of participants were using the interventions, the field workers coupled education and encouragement to promote use with their weekly surveillance visits. Motivational and educational messages about water treatment were limited to the intervention groups, but proper use of oral rehydration and referral of ill children to the health care system were encouraged for all. Other methods of diarrhea prevention including handwashing and safe food preparation were not discussed with study participants.

Weekly visits. Field workers visited participating households weekly and used a standardized questionnaire to record the presence or absence of diarrhea since the last visit for each family member. Diarrhea was defined by the respondent, usually the mother. Information about breastfeeding and consumption of food and water during the preceding week was recorded for the youngest infants (less than two years of age).

Field workers provided packets of oral rehydration solution and instructions for their use to all participating families, in-

cluding controls. Field workers urged mothers to seek care at a community health post for any family member with persistent diarrheal symptoms. If field workers judged that a family member needed urgent medical attention, they arranged for rapid assessment by one of the three field physicians or for transport to the hospital.

Intervention-specific knowledge and acceptance. Field workers administered standardized questionnaires to assess mothers' knowledge of and attitude towards the interventions one week, one month, three months, and six months after the interventions were distributed.

Water quality. Field workers collected samples of stored drinking water from households and from household water sources to measure *E. coli* and total coliform counts, chlorine concentration, and turbidity at baseline and 2, 6, and 10 months into the study. Approximately monthly field workers collected stored drinking water samples from households on unannounced visits to assess free and total chlorine concentration and turbidity.

Product consumption. Participants given flocculant-disinfectant retained the empty sachets after use. Each week field workers collected and counted both the empty and unused sachets and provided new supplies. Participants using bleach were given new bottles monthly or sooner if requested. Partially used bottles from the previous month were collected and weighed to determine consumption.

Laboratory measurements. *Chlorine.* Field workers collected stored household water samples in sterile plastic Whirl-pack™ (Nasco, Fort Atkinson, WI) bags on unannounced monthly visits. Residual free and total bleach were measured using the N,N-diethyl-*p*-phenylenediamine colorimetric method within four hours of collection (Hach Company, Loveland, CO).

Turbidity. Laboratory technicians measured the turbidity of water with an instrument that measures optical density and provides a direct readout in nephelometric turbidity units (portable turbidimeter model H193703; Hanna Instruments, Woonsocket, RI).

Water bacteriology. Field workers collected household water samples in sterile 100-mL plastic bottles containing 1% sodium thiosulfate solution to neutralize any free chlorine in the water samples. Samples were transported on ice packs (at 6°C) to the laboratory at MERTU for culture within 4–6 hours of collection. Samples were processed with the Colilert Quantitray 2000 kit (IDEXX Laboratories, Inc., Westbrook, ME). A most probable number table was used for quantification of total coliforms and *E. coli*. All household water samples were tested undiluted and diluted 1:100. Water samples from sources were collected in 500-mL sterile wide-mouth polypropylene bottles. They were transported and processed under similar conditions. Source water samples were tested undiluted and diluted 1:10, 1:100, and 1:1,000.

Statistical analysis. We calculated that 100 households per intervention group followed for one year would provide sufficient power to detect a ≥30% difference in diarrhea incidence between intervention and control children ≤1 year of age, assuming an incidence of diarrhea in the control group of 11.3 episodes per 100 person-weeks among children ≤one year of age (based on a pilot study in these same communities during 2000–2001), 95% weekly follow-up, 10% dropout, 95% confidence, and 20% loss in statistical efficiency from repeated measures.

If an episode of diarrhea was reported during the week, then the week was classified as a week with diarrhea. Weeks with diarrhea were classified as new episodes of diarrhea only if the study subject reported no diarrhea in the preceding week. We calculated diarrhea incidence as the number of person-weeks of observation that included a new episode of diarrhea divided by the total number of person-weeks at risk.

The field team continued weekly surveillance of diarrhea in all households that permitted it, even if they discontinued water treatment. All participants were analyzed in the group to which they were randomized, i.e., by intention-to-treat.

We used the Student's *t*-test to evaluate if differences in normally distributed means between groups were likely due to chance. For turbidity, we first calculated the mean reading for each household, and then compared the households by group with the Student's *t*-test.

To evaluate if the effects of the interventions on diarrhea were independent of other determinants, we constructed a multivariate model with generalized estimating equations. We developed the model using exposures that were strongly associated with diarrhea in bivariate analysis. We grouped exposure information into epidemiologically relevant categories. We eliminated exposures that were not significantly associated with diarrhea, that did not significantly improve the fit of the model, or that had no substantial effect on the parameters of the main effects in the model. For analysis of children ≤ 1 year of age, we assumed an exchange correlation structure of the repeated measures of the same child on different weeks. For analysis of all household residents, we imposed a nested correlation structure where the correlation of repeated observations of an individual was treated as a subset of the correlation structure of the household. We used SAS software for data analysis (SAS System for Windows, Version 8; SAS Institute, Inc., Cary, NC).

Ethics. The field team explained the purpose of the study to each prospective female or male head of household in Spanish or Kachiquel. Field workers emphasized that participation was voluntary and that subjects could withdraw at any time; they obtained written informed consent from those heads of household who were literate and verbal consent from those who were not. An Institutional Review Board at CDC and the Ethics Committee Review Board at the Universidad del Valle de Guatemala reviewed and approved the study protocol.

RESULTS

Of 568 eligible households randomly assigned to one of the five groups, 492 consented to participate; 102 were assigned to flocculant-disinfectant, 97 to flocculant-disinfectant plus vessel, 97 to bleach, 100 to bleach plus vessel, and 96 to standard water-handling. At baseline, the intervention and control groups had similar household sizes (means = 5.7–6.1 persons), maternal literacy (21–32%), sanitation (49–57% defecate on ground outside), and handling practices of water (Table 1).

Eighty-nine (87%) of those assigned to flocculant-disinfectant alone, 74 (76%) to flocculant-disinfectant plus vessel, 83 (86%) to bleach alone, 87 (87%) to bleach plus vessel, and 91 (95%) to standard water-handling practice completed 50 weeks of observation. Thirty-one (46%) of the 68 households that did not complete follow-up moved out of

TABLE 1
Baseline characteristics of randomized households in San Juan Sacatepéquez, Guatemala, July 2001

Baseline characteristics	Flocculant/disinfectant alone, n = 102 (%)	Flocculant/disinfectant with vessel, n = 97 (%)	Bleach alone, n = 97 (%)	Bleach with vessel, n = 100 (%)	Control, n = 96 (%)	Total, n = 492 (%)
Mean number of persons per household	5.9	6.1	5.7	5.9	6.1	5.9
Maternal literacy	23 (23)	20 (21)	26 (27)	22 (22)	30 (32)	122 (25)
Primary water source						
Tap	35 (34)	37 (38)	38 (39)	34 (34)	32 (33)	176 (36)
River or spring	39 (38)	35 (36)	40 (41)	47 (47)	44 (46)	205 (42)
Well	29 (28)	25 (26)	20 (21)	18 (18)	20 (21)	112 (23)
Store water in uncovered vessel	34 (35)	32 (34)	33 (36)	42 (42)	37 (42)	178 (38)
Remove drinking water by dipping a cup	72 (71)	77 (79)	70 (72)	78 (78)	75 (78)	374 (76)
Median concentration of *Escherichia coli* per 100 ml of drinking water	77	68	53	73	52	63
Proportion (%) of households drinking water with detectable free chlorine > 0.1 mg/L	0	0	1	0	1	0.4

the community. The two other common reasons for dropping out were not liking the taste or smell of the water (two households in the bleach arms and five in the flocculant-disinfectant arms) and that participation took too much time (four households in the flocculant-disinfectant arms and one in the bleach plus vessel group).

Ultimately, the study team completed 134,583 person-weeks of observation for 2,982 persons in the 492 participating households, including 9,331 person-weeks of observations of 522 children ≤ 12 months of age. Diarrhea was reported during 9,828 (7.3%) person-weeks. During the 120,054 person-weeks that study participants were at risk for a new episode of diarrhea, there were 4,258 such episodes (3.5 episodes of diarrhea per 100 person-weeks.)

Persons living in households that received the flocculant-disinfectant had fewer episodes of diarrhea than persons living in control households, 24% fewer in flocculant-disinfectant alone households and 29% fewer in flocculant-disinfectant plus vessel households (Table 2). Among recipients of bleach, those given bleach alone had 25% fewer diarrheal episodes than controls, whereas those given bleach plus vessel had 12% fewer episodes than controls. Among children ≤ 12 months of age, the differences in diarrhea incidence with interventions were less marked (Table 3).

The overall difference in diarrhea incidence between households receiving the flocculant-disinfectant plus vessel versus households receiving the flocculant disinfectant alone (3.07 versus 3.28 episodes per 100 person-weeks) resulted from differences among infants. The incidence of diarrhea among participants more than 12 months of age was similar in households receiving the flocculant-disinfectant plus vessel compared with households receiving the flocculant disinfectant alone (2.67 versus 2.63 episodes per 100 person-weeks.) However, among children ≤ 12 months of age, those in flocculant-disinfectant plus vessel households had 30% fewer episodes of diarrhea compared with flocculant-disinfectant alone households (10.4 versus 14.8 episodes per 100 person-weeks).

Children ≤ 12 months of age received breast milk during 97% of the evaluated person-weeks, but also received supplementary liquids in 92% and supplementary solids in 65%. The risk of diarrhea in the subsequent week was increased among children ≤ 12 months of age given either supplementary liquids (relative risk [RR] = 2.1) or solids (RR = 1.2).

The incidence of diarrhea varied markedly from week to week, ranging from 1.8 episodes of diarrhea per 100 person-weeks during the third week in August 2002 to 6.5 episodes during the third week in June 2002, shortly after the onset of the seasonal rains. In the first four months of the study, the monthly incidence of diarrhea was occasionally lower in the control group than in one or more of the intervention groups. After December 2001, all household intervention groups had consistently lower rates of diarrhea than control households (Figure 2). Literate mothers reported somewhat higher rates of diarrhea in their children (RR = 1.3). There were only modest difference in diarrhea rates among different measures of socioeconomic status, except among the 7% of families wealthy enough to own a refrigerator (RR = 0.6).

In a general estimated equations model that adjusted for age, time period, sex, maternal literacy, and radio and refrigerator ownership, persons in households that received floccu-

TABLE 2
Crude diarrhea incidence and adjusted odds ratios by water treatment intervention group among all study participants in San Juan Sacatepéquez, Guatemala*

Intervention	Person-weeks of observation	No. (%) of new episodes of diarrhea (episodes/100 person-weeks)	Relative difference in diarrhea incidence versus control (%)	Adjusted odds ratio†	95% CI	P†
Flocculant-disinfectant alone	25,251	829 (3.28)	−24	0.79	0.62, 0.99	0.04
Flocculant-disinfectant with vessel	23,289	715 (3.07)	−29	0.74	0.58, 0.94	0.02
Bleach alone	23,353	760 (3.25)	−25	0.74	0.59, 0.92	0.01
Bleach with vessel	23,486	905 (3.80)	−12	0.97	0.76, 1.26	0.84
Control	24,315	1,049 (4.31)	Ref	Ref	Ref	Ref

* CI = confidence interval; Ref = reference value.
† Of episode of diarrhea versus control adjusted through a general estimated equation model for age, time period, sex, and socioeconomic status.

Table 3

Crude diarrhea incidence and adjusted odds ratios by water treatment intervention group among children ≤12 months of age in San Juan Sacatepéquez, Guatemala*

Intervention	Person-weeks of observation	No. (%) of new episodes of diarrhea (episodes/100 person-weeks)	Relative difference in diarrhea incidence versus control (%)	Adjusted odds ratio†	95% CI	P†
Flocculant-disinfectant alone	1,369	202 (14.8)	17	1.05	0.78, 1.41	0.76
Flocculant-disinfectant with vessel	1,211	126 (10.4)	−21	0.69	0.50, 0.95	0.02
Bleach alone	1,362	156 (11.5)	−13	0.77	0.56, 2.08	0.13
Bleach with vessel	1,395	178 (12.8)	−3	0.92	0.66, 1.30	0.65
Control	1,355	179 (13.2)	Ref	Ref	Ref	Ref

* CI = confidence interval; Ref = reference value.
† Of episode of diarrhea versus control adjusted through a general estimated equation model for time period, supplementary liquids, and supplementary solids.

lant-disinfectant, with or without a vessel, and persons in households that received bleach alone had significantly fewer episodes of diarrhea than controls (Table 2). The magnitude of the reduction was similar to the crude differences. There was no significant difference in diarrhea incidence among households receiving bleach plus vessel versus control households. Breastfeeding and supplementary food and water exposures were not included in the model because these data were only collected for study subjects less than two years of age.

In a general estimated equations model limited to children ≤ 12 months of age and adjusted for time period and exposure to supplementary liquids and solids in the preceding week, children from households that received the flocculant-disinfectant plus vessel were the only intervention group that

FIGURE 2.   Diarrhea incidence by month and intervention group versus control in San Juan Sacatepéquez, Guatemala.

had significantly fewer episodes of diarrhea than controls (adjusted odds ratio = 0.69, 95% confidence interval = 0.50, 0.95) (Table 3).

Children less than five years of age who lived in households with water treatment had fewer episodes of severe (more than five loose stools per day) diarrhea than controls, but they did not have fewer episodes of prolonged (longer than 14 days) diarrhea (Table 4).

Participants learned how to use their interventions quickly and expressed satisfaction with them. After the first week of use, more than 90% answered all knowledge questions about the treatment process appropriately. On further follow-up, 88% of bleach alone, 88% of flocculant-disinfectant plus vessel, 87% of flocculant-disinfectant alone, and 86% of bleach plus vessel participants rated their treated water as good or very good. Participants receiving the flocculant-disinfectant alone or flocculant-disinfectant plus vessel reported that their water was clearer (93% and 89%, respectively) more frequently than participants who received bleach alone or bleach plus vessel participants (85% and 82%, respectively). Taste and smell ratings did not differ between flocculant-disinfectant and bleach arms. Those given bleach alone and bleach plus vessel were more likely than those given flocculant-disinfectant and flocculant-disinfectant plus vessel to say that the time and effort invested in water preparation was worth it (100% and 94%, respectively, versus 77% and 89%, respectively).

Despite these expressions of satisfaction, participants treated their drinking water inconsistently. On monthly unannounced visits, drinking water had > 0.1 mg/L of free chlorine in 2% of control households, 27% of flocculant-disinfectant alone households, 34% of flocculant-disinfectant plus vessel households, 36% of bleach alone households, and 44% of bleach plus vessel households (Table 5).

Water samples with detectable chlorine (> 0.1 mg/L) on unannounced visits from households using the flocculant-disinfectant had lower median and a narrower range of concentrations of free chlorine compared with samples from households using bleach (Figure 3). A larger proportion of water samples collected from households using bleach had free chlorine concentrations that exceeded 1.5 mg/L (49%) than did samples from households using flocculant-disinfectant (21%).

Drinking water samples from intervention households were more likely to meet the WHO guidelines for bacteriologic quality than samples from control households (Table 5). Drinking water from households receiving the flocculant-
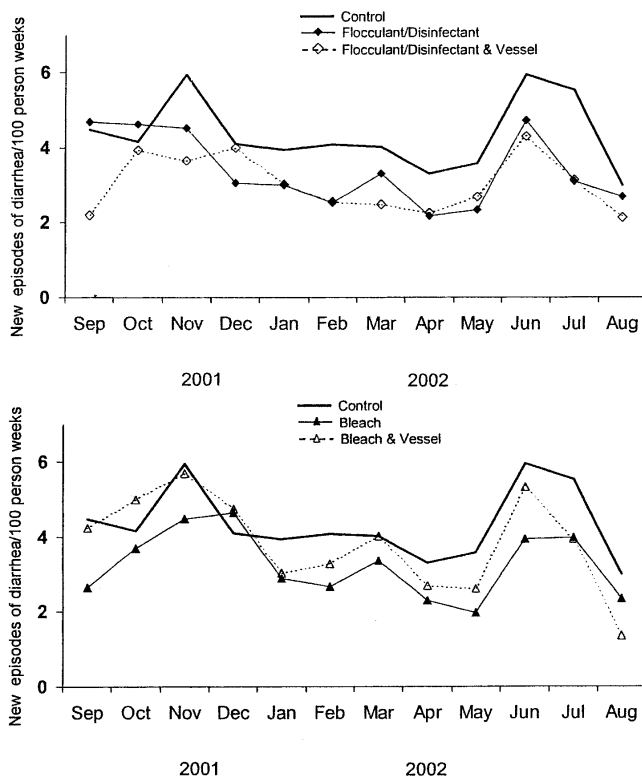
TABLE 4
Incidence of severe and prolonged diarrhea among children < 5 years old by group*

Intervention (person-weeks of observation)	No. (%) of new episodes of severe diarrhea† (episodes/100 person weeks)	Relative difference in severe diarrhea incidence versus control (%)	No. (%) of new episodes of prolonged diarrhea‡ (episodes/100 person weeks)	Relative difference in prolonged diarrhea incidence versus control (%)
Flocculant-disinfectant alone	229 (3.13)	−16	67 (0.91)	1
Flocculant-disinfectant with vessel	227 (3.37)	−9	56 (0.82)	−9
Bleach alone	204 (2.97)	−20	72 (1.04)	16
Bleach with vessel	220 (3.24)	−13	75 (1.09)	21
Control	265 (3.71)	Ref	65 (0.90)	Ref

* Ref = reference value.
† Severe diarrhea = > 5 loose stools per day.
‡ Prolonged diarrhea = diarrhea episode lasting > 14 days.

disinfectant had moderately, but statistically significantly, lower turbidity than samples from control or bleach households ($P = 0.02$, by Student's t-test) (Table 5).

Households receiving the flocculant-disinfectant alone averaged using 6.0 sachets per week, the equivalent of 8.6 liters of drinking water per day or 61% of their estimated daily drinking water at baseline. Flocculant-disinfectant plus vessel households used 5.8 sachets per week, the equivalent of 8.3 liters of drinking water per day or 57% of their estimated daily drinking water. Among households that completed the study, those that used more than the median 6.2 sachets of flocculant-disinfectant per week had free chlorine > 0.1 mg/L on 40% of unannounced follow-up visits compared with 31% among households using fewer than 6.2 sachets per week ($P = 0.01$).

Households receiving bleach alone used a mean 112 mL of bleach per month, a quantity sufficient to treat 38 liters of drinking water per day or 252% or their estimated daily drinking water. Bleach plus vessel households consumed a mean 202 mL of dilute bleach per month, a quantity sufficient to treat 27 liters of drinking water per day or 185% of their estimated daily drinking water. Among households that completed the study, those that used more than the median consumption of bleach were no more likely to have free chlorine > 0.1 mg/L on follow-up visits than households using less than the median.

DISCUSSION

A new point-of-use technology for water treatment that combined precipitation, coagulation, flocculation, and chlorination reduced the incidence of diarrhea between 24% and 29% in a setting where diarrhea was a leading cause of childhood death, more than half of families lacked any sanitary facilities, and available water was consistently contaminated with fecal organisms. Only two other point-of-use drinking water treatment methods, solar disinfection and chlorination with bleach, have reduced diarrhea in controlled studies under similar conditions. In studies in Kenya, water treated with solar disinfection resulted in a 10–16% reduction in diarrheal episodes.[12,13] In studies in Saudi Arabia,[14] Bolivia,[4] and Zambia[6] in which bleach was added to stored drinking water, diarrheal episodes were reduced 44–48%.

The magnitude of reduction in the incidence of diarrhea among persons receiving bleach in the present study, 12% in the bleach plus vessel group and 25% in the bleach alone group, was lower than the 44–48% reduction seen in these previous studies. This lower effectiveness likely reflects lower rates of use. In the present study, only 34% of households receiving bleach alone and 43% of households receiving the bleach plus vessel had water with detectable free chlorine in the vessel on unannounced follow-up visits. This contrasts with 63% of Bolivian and 83% of Zambian households that had water with detectable free chlorine and 81% of Saudi households that had no coliforms in stored drinking water on follow-up visits.[4,6,14] Overall, these data suggest that when families treat their water intermittently, there is a reduction in diarrhea but less than would occur with regular treatment.

The levels of use and magnitudes of reduction in incidence of diarrhea were similar in households receiving the flocculant-disinfectant and those receiving bleach alone. The study was not designed to compare the efficacy of flocculant-disinfectant versus bleach. The bleach arms were included as positive controls and provided a second assessment of the

TABLE 5
Household drinking water characteristics by intervention group in San Juan Sacatepéquez, Guatemala, September 2001–July 2002

Intervention	No.* (%) of drinking water samples with effective free chlorine level†	Median free chlorine (mg/L) among samples with > 0.1 mg/L free chlorine	Mean turbidity (NTU‡)	No.§ (%) of samples meeting WHO guidelines for bacteriologic quality of drinking water¶
Flocculant-disinfectant alone	245 (27)	0.6	3	90 (40)
Flocculant-disinfectant with vessel	297 (34)	0.8	2.7	114 (57)
Bleach alone	315 (36)	1.9	4.2	110 (51)
Bleach with vessel	397 (44)	1.2	4.1	137 (61)
Control	20 (2)	0.3	5.1	18 (7)

* Drinking water samples were collected 10 times during unannounced visits.
† Free chlorine > 0.1 parts per million on unannounced visits.
‡ NTU = nephelometric turbidity units.
§ Post-intervention samples for microbiology were collected 3 times.
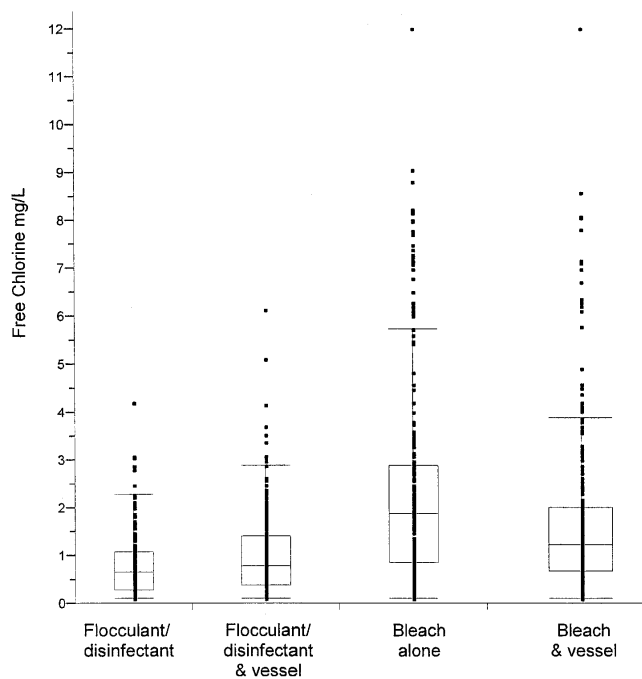¶ < 1 *Escherichia coli* per 100 mL. WHO = World Health Organization.

FIGURE 3.   Distribution of free chlorine levels by group among water samples with detectable chlorine collected on unannounced visits. Shown are the median, 10th, 25th, 75th, and 90th percentiles marked by the box plots.

marginal value of a special vessel for water storage. Theoretically, flocculant-disinfectant would be more effective in treating water contaminated with the chlorine-resistant parasites such as *Cryptosporidium parvum* and *Cyclospora cayetanensis*. However, studies of Guatemalan children have shown *Cryptosporidium* and *C. cayetanensis* are responsible for fewer than 11% of diarrheal episodes;[15,16] moreover, the extent to which contaminated drinking water contributes to their transmission is unknown.

The water treatments were less effective than predicted among the youngest children, those ≤ 12 months of age who are at greatest risk for death from diarrheal disease. None of the tested interventions produced the predicted 30% reduction in diarrheal episodes; only the 21% reduction in the flocculant-disinfectant plus vessel group was statistically significant. The muted effects of water treatment on episodes of prolonged diarrhea among children less than five years of age provides further evidence of limited effectiveness in the highest risk population. An important reason for the less than expected effectiveness was inconsistent use. In 92% of observed weeks, children ≤ 1 year of age drank liquids other than breast milk, and thus were potentially exposed to waterborne pathogens. Also, younger children with less developed immune and gastrointestinal systems would be at higher risk of disease from a lower dose of pathogens. Because of increased vulnerability and regular exposure to supplemental liquids, inconsistent use of water treatment may be ineffective in preventing infections in this age group.

The limited effect of the vessel in the flocculant-disinfectant arm further supports the idea that infants may specifically benefit from decreased contamination of drinking water. Use of flocculant-disinfectant was similar among households receiving the special vessel designed to prevent recontamination and those that used flocculant-disinfectant

with locally available vessels (5.8 versus 6.0 sachets per week). However, households receiving the special vessel were more likely to have water that met the WHO guidelines for bacteriologic quality (57% versus 40%) and reported 30% fewer episodes of diarrhea among children ≤ 1 year of age (10.4 versus 14.8 episodes per 100 person-weeks) than those assigned to flocculant-disinfectant and locally available vessels.

The incidence of diarrhea among households receiving the bleach plus vessel was not significantly lower than in the control group. This finding contrasts with multiple other intervention studies with bleach and a safe storage vessel.[4–6] Use may have been particularly low in the bleach plus vessel group. Households in the bleach plus vessel group were the most likely to have detectable chlorine in their stored water on unannounced follow-up visits, but water prepared and stored in the vessel would be expected to remain chlorinated for several days. These families continued to use local water vessels. Consequently, even if chlorinated water were prepared in the special vessel, it would require a change of habit to drink from the new vessel rather than their usual vessel. Indeed, the lack of association between bleach consumption and measured levels of free chlorine on unannounced visits strongly suggests that households receiving bleach were not strictly following instructions.

Several factors likely contributed to the inconsistent use of water treatment. First, the initial presentation of the interventions without ongoing advocacy to adopt a new habit provided insufficient motivation in a conservative culture where water has been collected from springs and wells and consumed untreated for centuries. Second, randomizing the interventions on the household level meant that neighbors, who were often members of the same extended families, had different water treatments. The consequences were inconsistent messages within the community, confusion, and many requests by participants to be assigned to a different group. Third, chlorine concentrations were quite high, higher than they needed to be for effective disinfection and high enough to adversely affect taste. Each of the water treatments produced a free chlorine residual of 3.5 mg/L when added to deionized water in the laboratory and were expected to produce a free chlorine residual between 0.5 and 1.5 mg/L when added to the highly contaminated village water. Indeed, only 21% of the water samples with detectable chlorine from households using the single dose sachet of flocculant-disinfectant had a chlorine residual greater than 1.5 mg/L. In contrast, 49% of the water samples with detectable free chlorine collected from bleach households, who were instructed to count the number of drops or measure one capful from multi-dose bottles, had free chlorine levels that exceeded 1.5 mg/L.

There are important limitations to this study. First, neither households nor field workers were blinded to the interventions. Thus, it is possible that field workers may have asked questions somewhat differently or mothers may have reported differently depending upon whether they were in an intervention or control household. However, field workers were trained to collect information in a standard manner from all participants. Training stressed that the study team wanted to learn what was occurring even if it did not fit our preconceptions. Regular supervisory revisits did not identify any systematic misclassification of diarrhea.

A second limitation is that since participants did not have to pay for their water treatment, the observed health effects

may not be realized in a setting with fewer incentives. However, the study demonstrated that even with sub-optimal use, households using flocculant-disinfectant or chlorine bleach alone had fewer episodes of diarrhea.

Ultimately, the full effect of home water treatment on health depends on how well individual families adopt new behaviors. This study demonstrates that there is a specific challenge to preventing diarrhea among the youngest children with home water treatment. Efforts to improve consistency of water treatment and safe storage in the home is particularly important for this group. Affordable methods that successfully motivate families to regularly treat their drinking water at point-of-use are needed to reduce global deaths from diarrhea. A market-based approach that effectively promotes use of the flocculant-disinfectant in settings where diarrhea is a substantial public health problem could contribute importantly to a reduction in diarrheal disease.

Authors' addresses: Megan E. Reller, Division of Infectious Diseases, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115, Telephone: 617-732-5500, Fax: 617-732-6829. Carlos E. Mendoza, M. Beatriz Lopez, Maricruz Alvarez, Centro de Investigaciones y Adiestramiento en Entomología Médica, Universidad del Valle de Guatemala, 18 Av. 11-95, Zona 15 VH, Guatemala City, Guatemala, Telephone: 50-2-364-0492, Fax: 50-2-364-0354. Robert M. Hoesktra, Biostatistics and Information Management Branch, Centers for Disease Control and Prevention, Mailstop C-09, Atlanta, GA 30333, Telephone: 404-639-4712. Christy A. Olson, Compass Quality Research, 7 Waterbury Court, Little Rock, AR 72223, Telephone: 501-367-0003, Fax: 501-868-6200, Kathleen G. Baier, 3660 Hanley Road, Cincinnati, OH 45247, Telephone: 513-385-2059. Bruce H. Keswick, Personal Health Care R&D, The Procter & Gamble Company, 8700 Mason Montgomery Road, Mason, OH 45040, Telephone: 513-622-4333, Fax: 513-622-4226. Stephen P. Luby, Foodborne and Diarrheal Diseases, Centers for Disease Control and Prevention, Mailstop A-38, 1600 Clifton Road, Atlanta, GA 30333, Telephone: 404-639-4348, Fax: 404-639-2205, E-mail: sluby@cdc.gov.

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