

# Papers

## 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

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### Abstract

**Objective** To compare the effect on prevalence of diarrhoea and mortality of household based treatment of drinking water with flocculant-disinfectant, sodium hypochlorite, and standard practices in areas with turbid water source in Africa.

**Design** Cluster randomised controlled trial over 20 weeks.

**Setting** Family compounds, each containing several houses, in rural western Kenya.

**Participants** 6650 people in 605 family compounds.

**Intervention** Water treatment: flocculant-disinfectant, sodium hypochlorite, and usual practice (control).

**Main outcome measures** Prevalence of diarrhoea and all cause mortality. *Escherichia coli* concentration, free residual chlorine concentration, and turbidity in household drinking water as surrogates for effectiveness of water treatment.

**Results** In children < 2 years old, compared with those in the control compounds, the absolute difference in prevalence of diarrhoea was -25% in the flocculant-disinfectant arm (95% confidence interval -40 to -5) and -17% in the sodium hypochlorite arm (-34 to 4). In all age groups compared with control, the absolute difference in prevalence was -19% in the flocculant-disinfectant arm (-34 to -2) and -26% in the sodium hypochlorite arm (-39 to -9). There were significantly fewer deaths in the intervention compounds than in the control compounds (relative risk of death 0.58,  $P=0.036$ ). Fourteen per cent of water samples from control compounds had *E coli* concentrations < 1 CFU/100 ml compared with 82% in flocculant-disinfectant and 78% in sodium hypochlorite compounds. The mean turbidity of drinking water was 8 nephelometric turbidity units (NTU) in flocculant-disinfectant households, compared with 55 NTU in the two other compounds ( $P<0.001$ ).

**Conclusions** In areas of turbid water, flocculant-disinfectant was associated with a significant reduction in diarrhoea among children < 2 years. This health benefit, combined with a significant reduction in turbidity, suggests that the flocculant-disinfectant is well suited to areas with highly contaminated and turbid water.

### Introduction

Around 1.1 billion people in low income countries lack access to improved water sources,<sup>1</sup> and diarrhoeal diseases cause an

estimated 2.2 million deaths a year.<sup>2</sup> The importance of household based treatment of water at point of use in reducing diarrhoeal disease has been increasingly recognised.<sup>3-5</sup>

Several studies in developing countries have shown that household based disinfection of drinking water with sodium hypochlorite or with a new flocculant-disinfectant reduces the incidence of diarrhoea by 20-48%.<sup>6-9</sup> A key challenge has been encouraging people to use disinfectants that may adversely affect the taste of drinking water and may not improve its appearance. Furthermore, sodium hypochlorite—a widely used household based disinfectant—is less effective in highly turbid water<sup>10</sup> and for pathogens resistant to chlorine.<sup>11</sup>

In response to the limitations, a new flocculant-disinfectant technology, that incorporates techniques used for municipal water purification, has been developed for treating water in the home.<sup>8 12 13</sup> We hypothesised that this treatment could be useful in areas with turbid source water as the improvement in water clarity would encourage use. The lower chlorine demand associated with reduced turbidity and the removal of some chlorine-resistant organisms may provide a health advantage over sodium hypochlorite.

We conducted a 20 week study to evaluate the efficacy of the flocculant-disinfectant in preventing diarrhoea in rural western Kenya, an area where source waters were both heavily faecally contaminated and highly turbid (100-1000 nephelometric turbidity units (NTU)).<sup>10</sup> Although no health-based guideline value for turbidity has been proposed, the World Health Organization suggests that drinking water turbidity below 5 NTU is usually acceptable to consumers and that median turbidity should be below 0.1 NTU for adequate disinfection. The primary hypothesis was that children < 2 years living in family compounds—circumscribed plots containing several houses of family members—that received flocculant-disinfectant would have fewer episodes of diarrhoea than children in compounds using sodium hypochlorite. We also compared the effect on prevalence of diarrhoea of both interventions compared with usual water handling practices to assess the effect of water treatment on diarrhoea among household residents of all ages and to assess the relative acceptability of the two interventions for treating highly turbid water.

## Methods

### Setting

The study was conducted in 49 villages near Lake Victoria in Siaya and Bondo Districts, western Kenya. The demographic characteristics of people living in the area have been described elsewhere.<sup>14–16</sup> An established clinic based surveillance system monitors the aetiology of diarrhoea among the population.<sup>17–19</sup> Infant mortality is about 130 per 1000 inhabitants.<sup>20</sup> Surface water used for drinking is typically obtained from ponds, rivers, and springs; it is regularly contaminated with both human and animal faeces. Water is typically carried in 20 l plastic drums and is stored in wide mouthed clay vessels holding 20–30 l.<sup>21</sup>

### Interventions

**Flocculant-disinfectant**—The flocculant-disinfectant is a new technology formulated in single use sachets to work quickly on small volumes of water. It aggregates and facilitates the removal of suspended organic matter, bacteria, viruses, parasites, and heavy metals in treated water.<sup>12–15</sup> One packet contains enough calcium hypochlorite to leave a residual chlorine concentration of 3.5 mg/l in 10 l of demineralised water.

**Sodium hypochlorite**—The sodium hypochlorite treatment was modelled on that of the Safe Water System ([www.cdc.gov/safewater](http://www.cdc.gov/safewater)) and used 1% sodium hypochlorite solution (marketed as Klorin or WaterGuard in Kenya) manufactured commercially by Jet Chemicals (Nairobi, Kenya).

**Control**—In the control group, participants continued their usual water collection, treatment, and storage practices. This included turbidity mitigation by settling and decanting, cloth filtration, and treatment with alum to achieve modest reductions in turbidity. Disinfection by boiling or chemical measures was uncommon.

### Enrolment and randomisation

We identified 600 family compounds with at least one child aged < 2 years; 300 used pond water and 300 used river water. Family compounds were randomly assigned to one of the three study arms at each of the two sites.

### Weekly visits

Field workers visited participating compounds weekly and used a standardised questionnaire to record the presence or absence of diarrhoea and any deaths during the seven days since the last visit for each person.<sup>22</sup> Diarrhoea in children was usually defined by the mother.<sup>23</sup>

Field workers provided oral rehydration salts and instructions for their use to all participating families. Field workers urged mothers to seek care at a community health facility for any family member with severe diarrhoea; healthcare costs for these individuals were reimbursed.

### Knowledge and acceptance of intervention

Field workers administered standardised questionnaires to assess the mothers' knowledge of and attitudes towards the interventions during the fifth and 15th week of the study.

### Water quality

During the baseline survey and during unannounced visits every four weeks field workers collected samples of stored drinking water to measure free chlorine concentration and turbidity and samples of source water to measure turbidity. During the baseline survey and the 10th week of the study, field workers collected samples of stored drinking water and from source water to measure the concentration of *Escherichia coli*.

### Compliance with intervention

Participants given flocculant-disinfectant retained the empty sachets after use. Each week field workers collected and counted empty sachets and replaced them. For participants using sodium hypochlorite, field workers collected and replaced bottles as needed each week. At the end of the study, partially used bottles were collected and weighed to determine the total use of sodium hypochlorite.

### Laboratory measurements

Samples of stored household water were collected in sterile plastic Whirlpack bags (Nasco, Fort Atkinson, WI) on unannounced visits, and residual free chlorine concentration was measured by using the N,N-diethyl-*p*-phenylenediamine (DPD) colorimetric method with a digital Hach Portable DR/890 Colorimeter (Hach Company, Loveland, CO) within 24 hours of collection. During routine weekly visits, residual free total chlorine concentration was measured in the field with the same method with Hach Color Disk test kits. Turbidity was measured with a Hach 2100P Portable Turbidimeter (Hach Company, Loveland, CO). Household water samples for bacteriology were collected with sterile technique in 150 ml sterile plastic vessels containing sodium thiosulfate (IDEXX Laboratories Incorporated, Westbrook, ME) to neutralise any free chlorine in the water samples. Samples were transported on icepacks to the CDC/KEMRI water bacteriology laboratory for processing within eight hours of collection. Samples were processed with the Colilert Quantitray 2000 system (IDEXX Laboratories Incorporated, Westbrook, ME).

### Statistical analysis

We calculated that 200 family compounds, each containing at least one child < 2 years, per intervention group followed for 20 weeks would allow us to detect a  $\geq 20\%$  difference in prevalence of diarrhoea between the children < 2 years in the flocculant-disinfectant and sodium hypochlorite arms. We assumed a 20% weekly prevalence of diarrhoea among children in the sodium hypochlorite group (based on unpublished prevalence data from Homa Bay, western Kenya), 90% follow-up, 10% drop out, 95% confidence, and a halving of statistical power due to intracluster correlation and repeated measures.

Data were analysed with SAS System for Windows, release 9.00 (SAS Institute, Carey, NC). To evaluate the effects of interventions on prevalence of diarrhoea, we aggregated and compared results at the level of randomisation (the compound level) and over time to account for clustering and repeated measures. We fitted a generalised linear model to the data, with log link binomial distribution and adjustment for overdispersion, to compare the proportional reduction in overall prevalence of diarrhoea.

## Results

### Participant flow

Of 1860 family compounds screened for the presence of a child < 2 years and use of turbid water for drinking between 12 March and 8 April 2003, 605 met these criteria and the families agreed to participate. Of the 605 family compounds, 201 were assigned to flocculant-disinfectant, 203 to sodium hypochlorite, and 201 to standard water handling. Of 133 000 potential person weeks of observation for diarrhoea, 24 525 (18.4%) were missing because of short or long term outward migration or death (fig 1). We did not exclude any family compound from the analysis.

Ultimately, the study team completed 108 475 person weeks of observation for 6650 people in 605 participating family com-

**Table 1** Baseline characteristics of randomised family compounds, western Kenya, 2003

Baseline characteristics	Flocculant-disinfectant	Sodium hypochlorite	Control	Total or mean
No of family compounds	201	203	201	605
Mean No of people/compound	10.6	11.1	11.3	11.0
Female	1160 (55)	1227 (55)	1227 (54)	3614 (55)
Household head English literacy	127 (64)	127 (62)	125 (63)	381 (63)
Defecate on the ground outside	67 (33)	78 (38)	58 (29)	203 (33)
Primary water source:				
Pond	101 (51)	101 (49)	99 (50)	301 (50)
River	96 (48)	99 (48)	98 (49)	295 (49)
Spring	3 (2)	4 (2)	3 (2)	10 (2)
Borehole	0 (0)	1 (0)	0 (0)	1 (0)
Water storage vessel:				
Clay pot	122 (61)	131 (61)	123 (62)	378 (62)
Plastic container	76 (38)	74 (36)	77 (39)	227 (37)
Metal	0 (0)	0 (0)	1 (1)	1 (0)
Vessel mouth $\geq 10$ cm	150 (75)	157 (77)	155 (78)	462 (77)
Remove drinking water by cup or ladle	162 (81)	168 (83)	167 (84)	499 (82)
Median concentration of <i>E coli</i> /100 ml of drinking water	52	116	130	98
Mean turbidity (nephelometric turbidity units)	106	115	152	125

pounds, including 9999 person weeks of observation for 715 children < 2 years.

#### Baseline characteristics and group comparability

At baseline, the intervention and control groups had similar family compound sizes, level of English speaking household head, sanitation, and water handling practices (table 1).

#### Weekly prevalence of diarrhoea

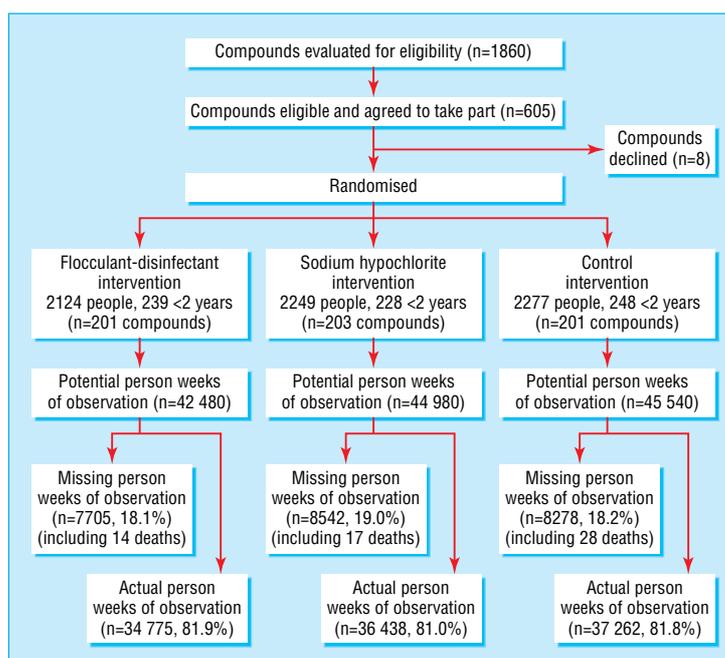
The crude weekly prevalence of diarrhoea in control compounds varied markedly during the study period, ranging from 1.69 weeks with diarrhoea per 100 person weeks in July 2003 to 4.61 weeks with diarrhoea per 100 person weeks in May 2003 at the onset of the long seasonal rains (fig 2).

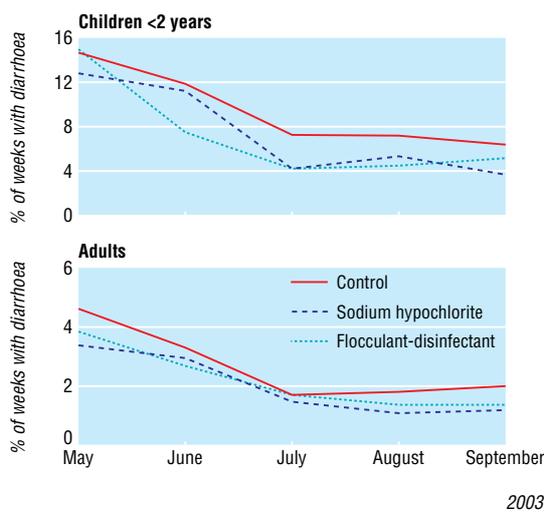
Among children < 2 years, compared with those in control compounds, the adjusted absolute difference in prevalence of diarrhoea was -25% in the flocculant-disinfectant compounds

and -17% in the sodium hypochlorite compounds. Children < 2 years in control compounds had 9.64 weeks with diarrhoea per 100 person weeks, much lower than the 20 weeks with diarrhoea per 100 person weeks we used to estimate the sample size. Children in the two intervention compounds had similar prevalence of diarrhoea (table 2).

For all age groups compared with control, the adjusted absolute difference in prevalence was -19% in the flocculant-disinfectant compounds and -26% in the sodium hypochlorite compounds (table 2).

There were 28/2277 deaths in the control group, 14/2124 in the flocculant-disinfectant group (relative risk of death 0.53,  $P=0.052$  compared with control), and 17/2249 in the sodium hypochlorite group (0.61,  $P=0.108$ ). The pooled data showed that there were significantly fewer deaths in the intervention compounds than the control compounds (0.58,  $P=0.036$ ) (fig 1).

**Fig 1** Recruitment and flow of participants



**Fig 2** Crude prevalence of diarrhoea in children aged <2 and in all age groups by intervention

Fifteen (54%) of the 28 who died in the control compounds were children <5 years compared with five (36%) in the flocculant-disinfectant compounds and four (26%) in the sodium hypochlorite compounds. Verbal autopsy was not performed.

**Acceptability of intervention**

Participants expressed satisfaction with the interventions. By the fifth week, all 191 respondents from the flocculant-disinfectant compounds reported that their water looked better after treatment compared with 149 (77%) of 193 in the sodium hypochlorite compounds (relative risk 1.3, 95% confidence interval 1.2 to 1.4). Ratings of taste and smell did not differ significantly between the two groups. All respondents from flocculant-disinfectant compounds and 99% from sodium hypochlorite compounds preferred treated water to untreated water.

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**Use of intervention**

During scheduled visits 86% of drinking water samples from flocculant-disinfectant compounds and 85% from sodium hypochlorite compounds had free chlorine concentrations >0.1 mg/l. In samples collected during unannounced visits, 44% of flocculant disinfectant households and 61% of sodium hypochlorite households had free chlorine concentrations >0.1 mg/l. The median free residual chlorine concentrations in treated waters, however, was only 0.4 mg/l in both intervention arms, which may indicate substantial binding of free chlorine to residual organic and inorganic material in drinking water or prolonged storage of treated water in open containers (table 3).

Samples of drinking water from intervention households were more likely to meet the WHO guidelines for bacteriological quality than samples from control households. Furthermore, drinking water from flocculant-disinfectant households had much lower turbidity than samples from control or sodium hypochlorite households (P < 0.001, by Student's t test) (table 3).

**Discussion**

In this setting where diarrhoea is a leading cause of childhood death and drinking water is highly turbid and contaminated with faeces, we found that children <2 years from family compounds that treated their drinking water with flocculant-disinfectant had significantly less diarrhoea than compounds that used standard practices (control). Among people of all ages, those in compounds where water was treated with flocculant-disinfectant or sodium hypochlorite had significantly less diarrhoea than control compounds. There was no significant difference in prevalence of diarrhoea between the two interventions in either age group.

**Table 2** Prevalence of diarrhoea by water treatment intervention group among various age groups, western Kenya

Age group(intervention)	Person level observations		Compound level observations*		Compound level observations*			
	Person weeks of observation	Weeks with diarrhoea	Compounds under observation	Weeks with diarrhoea/100 weeks	Absolute difference in diarrhoea prevalence v control (%)		Absolute difference in diarrhoea prevalence v sodium hypochlorite (%)	
					Crude	Adjusted (95% CI)†	Crude	Adjusted (95% CI)†
<b>Age &lt;2 years</b>								
Flocculant-disinfectant	3381	251	171	7.65	-21	-25 (-40 to -5)	-2	-9 (-29 to 16)
Sodium hypochlorite	3151	258	169	7.81	-19	-17 (-34 to 4)	Ref	Ref
Control	3467	342	176	9.64	Ref	Ref	—	—
<b>All ages</b>								
Flocculant-disinfectant	34 775	699	201	2.22	-17	-19 (-34 to -2)	8	9 (-12 to 34)
Sodium hypochlorite	36 438	675	203	2.06	-23	-26 (-39 to -9)	Ref	Ref
Control	37 262	929	201	2.67	Ref	Ref	—	—

Ref=reference category.

\*Data aggregated and compared at the level of randomisation (compound level).

†Compared by generalised linear model with log link binomial distribution and adjustment for overdispersion.

**Table 3** Characteristics of household drinking water by intervention group, western Kenya, May to September 2003

Intervention	No* (%) of samples with effective free chlorine concentration‡	Median free chlorine (mg/l) in samples with >0.1 mg/l free chlorine	Mean (range) turbidity* (NTU‡)	No§ (%) of samples meeting WHO guidelines¶
Flocculant-disinfectant	439 (44)	0.4	8 (0-1010)	162 (82)
Sodium hypochlorite	616 (61)	0.4	55 (0-1000)	156 (78)
Control	53 (5)	0.2	55 (1-1588)	27 (14)

\*Samples collected for measurement of chlorine and turbidity five times during unannounced visits.

‡Free chlorine >0.1 mg/l on unannounced visits.

§NTU=nephelometric turbidity units.

¶Samples collected once for bacteriological testing.

¶Guidelines for bacteriological quality of drinking water: <1 E coli/100 ml.

This is the first study of household based water treatment to show a significant reduction in mortality. This reduction was detected despite a modest reduction in prevalence of diarrhoea. The trend towards younger age at death in the control arm suggests an effect on mortality among infants and children in the intervention arms. Because our study was not designed to evaluate an effect on mortality and we found a significant reduction in mortality only when we pooled intervention arms, further research is needed to better understand the relation between household based water treatments and reduction in mortality.

The lack of observed difference in prevalence of diarrhoea between the two intervention arms may have been due to a lack of statistical power. Weekly prevalence of diarrhoea in the sodium hypochlorite arm reached only one third of that modelled in our estimation of sample size. The lack of observed differences between study arms may also have been due to limited intervention effects. Initially, water may not have been turbid enough for us to show the differential effects of the flocculant-disinfectant on water quality compared with sodium hypochlorite.<sup>10</sup> Also, flocculant-disinfectant delivers 3.5 mg/l free chlorine compared with 5.0-10.0 mg/l delivered by sodium hypochlorite. Our decision not to promote safe storage of treated water to prevent recontamination may have blunted the effect on health observed in both intervention arms. Though compliance with the intervention was moderate to high, the effect on health may have been greater if use had been higher or if it had been possible to minimise the drinking of untreated water outside the home. Free chlorine concentrations in treated water measured during unannounced visits were low, perhaps because of prolonged storage or binding of free chlorine associated with residual turbidity or the storage vessel. These factors can reduce the effect of initial water treatment and also increase the risk of recontamination during storage.

The flocculant-disinfectant was highly acceptable to consumers, and acceptability was closely linked to its ability to reduce turbidity. If the flocculant-disinfectant were available in the market place, the visible effect on turbidity may lead more families to adopt household based water treatment. Low use of household based water treatments in communities has been a key challenge, so properties that encourage purchase and use could improve the effectiveness of an intervention.<sup>3 21 24</sup> Sodium hypochlorite makes water safer to drink but also alters the taste and does not reduce turbidity. The flocculant-disinfectant offers improvements in the aesthetic qualities of water while also providing a health benefit.

## Conclusion

Worldwide, many people drink contaminated water. No single solution is likely to be suitable to all demographic settings. Our study shows that among people who have highly turbid water, flocculant-disinfectant can provide water that looks cleaner and reduces the risk of diarrhoea, particularly among infants and children.

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## What is already known on this topic

Household based water treatments such as sodium hypochlorite reduce the risk of diarrhoeal disease in developing countries

Sodium hypochlorite is less effective in highly turbid water, does not mitigate turbidity, and adversely affects taste

## What this study adds

Compared with standard water handling practices, household based flocculant-disinfectant treatment of water reduced the prevalence of diarrhoea by 25% among children <2 years in areas with turbid source water

Turbidity of drinking water was significantly lower with flocculant-disinfectant than with sodium hypochlorite and standard water handling practices and was more acceptable to families

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Contributors: SPL and JAC were responsible for study concept and design. JAC, POO, DHR, and LS gathered the data, JAC, SPL, RMH, and DHR carried out the analysis, and JAC, SPL, POO, LS, RMH, and DHR interpreted the data. JAC, SPL, POO, LS, BHK, DHR, RMH revised the manuscript. JAC, SPL, and BHK obtained funding. JAC, SPL, DHR, LS, and JMV provided administrative, technical, or material support. JAC and SPL supervised the study. JAC drafted the manuscript and is guarantor.

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Competing interests: BHK is employed by Procter & Gamble. He critically reviewed the study protocol, made some technical suggestions, arranged for the delivery to Kenya of flocculant-disinfectant sachets, and assisted with the delivery of other supplies. Procter & Gamble employees were not involved in data collection or analysis. They commented on the interpretation of the analysis after oral presentation of the results and in response to drafts of the manuscript. The Centers for Disease Control and Prevention retained the right to publish results without approval from Procter & Gamble.

Ethical approval: An institutional review board at CDC and the scientific steering committee and ethical review committee of KEMRI reviewed and approved the study protocol.

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