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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Editorial by Tumwine

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 flocculant-disinfectant is well suited to areas with highly contaminated and turbid water.

Introduction

Studies in developing countries have shown that household based disinfection of drinking water reduces the incidence of diarrhoea by 20-48%.[1–4] Disinfectants, however, may adversely affect the taste of drinking water and may not improve its appearance. Sodium hypochlorite—a widely used household based disinfectant—is less effective in highly turbid water[5] and for pathogens resistant to chlorine.[6]

A new flocculant-disinfectant technology has been developed for treating water in the home.[3 7 8] This treatment could be useful in areas with turbid source water as the improvement in water clarity would encourage use, reduce chlorine demand, and remove some chlorine-resistant organisms.

We conducted a 20 week study to evaluate the efficacy of the flocculant-disinfectant in preventing diarrhoea in rural western Kenya, an area with heavily faecally contaminated and highly turbid source water. The primary hypothesis was that children <2 years living in family compounds 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 in all ages compared with usual water handling practices (see bmj.com) and assessed the relative acceptability of the two interventions.

Methods

Setting

The study was conducted in 49 villages near Lake Victoria in Siaya and Bondo Districts, western Kenya. Infant mortality is about 130 per 1000 inhabitants.[9] Drinking water is usually 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 stored in wide mouthed clay vessels holding 20-30 l.[10]

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Interventions

The flocculant-disinfectant comes in single use sachets for use with small volumes of water. It aggregates and facilitates the removal of suspended organic matter, bacteria, viruses, parasites, and heavy metals in treated water.[7 8] One packet contains enough calcium hypochlorite to leave a residual chlorine concentration of 3.5 mg/l in 10 l of demineralised water. The sodium hypochlorite treatment used 1% sodium hypochlorite solution. In the control group, participants continued their usual water collection, treatment, and storage practices (see bmj.com).

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.

Data collection

Field workers visited participating compounds weekly and recorded the presence or absence of diarrhoea and any deaths during the seven days since the last visit for each person.[11] They also assessed the mothers' knowledge of and attitudes towards the interventions during the fifth and 15th week of the study. 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, the concentration of *Escherichia coli* was measured in samples of stored drinking water.

To assess compliance each week field workers collected and counted empty sachets of flocculant-disinfectant and empty sodium hypochlorite bottles and replaced them. At the end of the study, partially used bottles were collected and weighed to determine the total use of sodium hypochlorite.

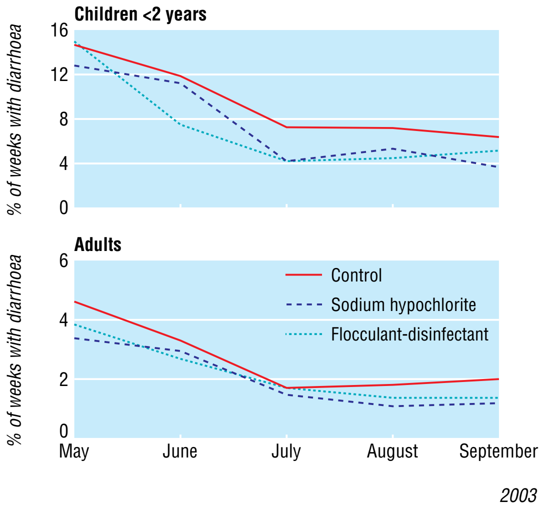
Residual free chlorine concentration was measured in samples of stored household water collected in sterile plastic bags. During routine weekly visits, residual free total chlorine concentration and turbidity was measured in the field. Household water samples were also tested for bacteriology. See bmj.com for further details of methods.

Statistical analysis

We calculated that we would need 200 family compounds, each containing at least one child <2 years, per intervention group to detect relevant difference in the prevalence of diarrhoea between the children <2 years in the two intervention groups. 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

Of 1860 family compounds, 605 had a child aged <2 years, used turbid drinking water, and agreed to participate. Of these, 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. We did not exclude any family compound from the analysis. The study team completed 108 475 person weeks of observation for 6650 people, including 9999 person weeks of observation for 715 children <2 years. At baseline, all groups were similar in terms of family compound sizes, education level of the household head, sanitation, and water handling practices.



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

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Weekly prevalence of diarrhoea

The crude weekly prevalence of diarrhoea among control compounds varied during the study period 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 (figure).

The adjusted absolute difference in prevalence of diarrhoea among children <2 years 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. Children in the two intervention compounds had similar prevalence of diarrhoea (table). The adjusted absolute difference in prevalence of diarrhoea was −19% in the flocculant-disinfectant compounds and −26% in the sodium hypochlorite compounds (table).

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). 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.

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

Age group (intervention)	Person level observations: Person weeks of observation	Person level observations: Weeks with diarrhoea	Compound level observations*: Compounds under observation	Weeks with diarrhoea/ 100 weeks	Absolute difference in diarrhoea prevalence *v* control (%): Crude	Adjusted (95% CI)†	Absolute difference in diarrhoea prevalence *v* sodium hypochlorite (%): Crude	Adjusted (95% CI)†
Age <2 years								
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	—	—
All ages								
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.

Acceptability of intervention

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.

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.

Samples of drinking water from intervention households were more likely to meet 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 (8 *v* 555 nephelometric turbidity units, P<0.001, by Student's *t* test).

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.

This is the first study of household based water treatment to show a significant reduction in mortality, 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.

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.[5] 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.

The flocculant-disinfectant was highly acceptable to consumers, and this was closely linked to its ability to reduce turbidity. If the flocculant-disinfectant was available in the market place, the visible effect on turbidity may lead more families to use household based water treatment. Low use has been a key challenge, so properties that encourage purchase and use could improve effectiveness.[10 12 13] 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.

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-disinfection 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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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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Skin biopsy rates and incidence of melanoma: population based ecological study

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Abstract

Objectives To describe changes in skin biopsy rates and to determine their relation to changes in the incidence of melanoma.
Design Population based ecological study.
Setting Nine geographical areas of the United States.
Participants Participants of the Surveillance Epidemiology and End Results (SEER) programme aged 65 and older.
Main outcome measures For the period 1986 to 2001, annual skin biopsy rates for each surveillance area from Medicare claims and incidence rates for melanoma for the same population.
Results Between 1986 and 2001 the average biopsy rate across the nine participating areas increased 2.5-fold among people aged 65 and older (2847 to 7222 per 100 000 population). Over the same period the average incidence of melanoma increased 2.4-fold (45 to 108 per 100 000 population). Assuming that the occurrence of true disease was constant, the extra number of melanoma cases that were diagnosed after carrying out 1000 additional biopsies was 12.6 (95% confidence interval 11.2 to 14.0). After controlling for a potential increase in the true occurrence of disease, 1000 additional biopsies were still associated with 6.9 (3.1 to 10.8) extra melanoma cases diagnosed. Stage specific analyses suggested that 1000 biopsies were associated with 4.4 (2.1 to 6.8) extra cases of in situ melanoma diagnosed and 2.3 (0.0 to 4.6) extra cases of local melanoma, but not with the incidence of advanced melanoma. Mortality from melanoma changed little during the period.
Conclusion The incidence of melanoma is associated with biopsy rates. That the extra cases diagnosed were confined to early stage cancer while mortality remained stable suggests overdiagnosis—the increased incidence being largely the result of increased diagnostic scrutiny and not an increase in the incidence of disease.

Detailed model outputs are on bmj.com

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