An investigation of the effects of a hand washing intervention on health outcomes and school absence using a randomised trial in Indian urban communities

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Abstract

OBJECTIVES To evaluate how an intervention, which combined hand washing promotion aimed at 5-year-olds with provision of free soap, affected illnesses among the children and their families and children's school absenteeism.

METHODS We monitored illnesses, including diarrhoea and acute respiratory infections (ARIs), school absences and soap consumption for 41 weeks in 70 low-income communities in Mumbai, India (35 communities per arm).

RESULTS Outcomes from 847 intervention households (containing 847 5-year-olds and 4863 subjects in total) and 833 control households (containing 833 5-year-olds and 4812 subjects) were modelled using negative binomial regression. Intervention group 5-year-olds had fewer episodes of diarrhoea (−25%, 95% confidence intervals [CI] = −37%, −2%), ARIs (−15%, 95% CI = −30%, −8%), school absences due to illnesses (−27%, 95% CI = −41%, −18%) and eye infections (−46%, 95% CI = −58%, −31%). Further, there were fewer episodes of diarrhoea and ARIs in the intervention group for 'whole families' (−31%, 95% CI = −37%, −5%; and −14%, 95% CI = −23%, −6%, respectively), 6- to 15-year-olds (−30%, 95% CI = −39%, −7%; and −15%, 95% CI = −24%, −6%) and under 5 s (−32%, 95% CI = −41%, −4%; and −20%, 95% CI = −29%, −8%).

CONCLUSIONS Direct-contact hand washing interventions aimed at younger school-aged children can affect the health of the whole family. These may be scalable through public–private partnerships and classroom-based campaigns. Further work is required to understand the conditions under which health benefits are transferred and the mechanisms for transference.

keywords hand washing with soap, diarrhoea, acute respiratory infection, hygiene, school absence

Introduction

There is considerable evidence that hand washing with soap (HWWS) reduces the incidence of diarrhoeal disease (Curtis & Cairncross 2003; Aiello *et al.* 2008; Ejemot-Nwadiaro *et al.* 2012), respiratory infections (Rabie & Curtis 2006; Aiello *et al.* 2008; Cowling *et al.* 2009) and skin infections (Luby *et al.* 2005; Bloomfield *et al.* 2007). Additionally, associations have been seen between HWWS and reductions in worm infections (Bieri *et al.* 2013), eye infections (Montessori *et al.* 1998) and school absences (Bowen *et al.* 2007; O'Reilly *et al.* 2008).

The effects of hand washing interventions may extend beyond the individual exposed. HWWS among carers can reduce mortality among neonates (Manandhar *et al.* 2004; Rhee *et al.* 2008) and morbidity in young children unable to wash their own hands (Luby *et al.* 2004).

Our objective was to evaluate the effects of a hand washing intervention designed to optimise the possibility of observing broader effects on household members. 5-year-old children were the principal target because they are responsive to hand washing behaviour change messages (O'Reilly *et al.* 2008) and may be effective 'change agents' within the family (Alibhai & Ahmad 2001; Tobin & Van Koppen 2005; O'Reilly *et al.* 2008). Further, we involved the mother in the promotion in an attempt to encourage the child and to optimise transfer between family members.

The main hypotheses were that, for the 5-year-olds, the intervention would reduce episodes of diarrhoea, ARIs and school absences; while for the 'whole family', there would be reductions in diarrhoea and ARIs. We also investigated effects on other illnesses that may be affected by changes in HWWS.

Methods

This was a cluster randomised controlled study with one community in each of 35 matched pairs randomly allocated to intervention and one to control. For each community, we aimed to start 30 households containing one 'target' child in the first standard of a municipal school. Children were typically aged 5, although a minority were 6 or 7 years old.

Study setting

The study was located in low-income urban communities in west and south Mumbai. There was an average of six people in households which, typically, consisted of a single room without a water supply or sanitation. The vast majority had an income of less than US$60 a month (Table 2). Soap was widely available in local shops.

Sampling

Locally recruited fieldworkers were briefed to identify and characterise communities that were geographically distinct; a community being a set of households that were close together with a common leadership. 187 communities were characterised according to size (small, medium or large), location (west or south Mumbai), predominant language (Hindi, Marathi or Gujarati), most common work location (home or away from home) and kind of housing (temporary or permanent). Thirty five matched community pairs were created by, first, sorting communities into pools according to size. A total of 67 were small (<1000 households), 94 medium sized (1000–5000 households) and 26 large (>5000 households). A community was selected at random from a pool and matched with another from that pool according to location, language, work location and housing. Nine community pairs were small (26%), 21 medium sized (60%) and five large (14%). A coin toss was used to assign one community in each pair to intervention and one to control.

Households were recruited using a 'snowballing' method, whereby fieldworkers located the first household in a community on an ad hoc basis and further households through verbal references. In parallel, supervisor visits identified errors in the initial characterisations (on four occasions there were geographical overlaps between intervention and control communities, and once a community had been incorrectly characterised). These five communities were replaced by comparable communities drawn from the main pool, together with one further community where very low literacy levels would have prevented successful participation in the study.

Later the fieldworkers gained informed consent. Consent forms appropriate to condition were read to residents old enough to understand and were signed by all occupants aged 9 years or older. During consenting, fieldworkers expressed safety concerns when visiting two intervention communities and these were also replaced. No data were collected from these or any of the other replaced communities.

Intervention

This involved the provision of free soap and a social marketing programme (Sidibe *et al.* 2009) both carrying Lifebuoy branding. The 41 week programme was designed according to behaviour change principles (Claessen *et al.* 2008) and aimed to educate, motivate and reward children for HWWS after defecation, before each of three meals and during bathing. The help of the mother was enlisted through home visits, parents' evenings and establishment of a 'Good Mums' club.

During the first 17 weeks we introduced each of the individual hand washing occasions and created awareness of germs, how they are spread and their role in illness (but not specifically diarrhoea or ARIs). We also challenged the belief that if hands look clean they are free of germs and emphasised the importance of soap in removing germs.

From week 18 the behaviours were integrated into a single idea around five key hand washing occasions. Children were asked to hand wash at home on these occasions for 10 consecutive days supported by environmental cues to help them remember (e.g. wall hangers, danglers) and by small rewards handed out by their mother (e.g. stickers, coins, toy animals). Children were also encouraged to advocate HWWS within their families before shared evening meals.

As part of motivation, we established social norms for child and mother (Perkins 2003), used the fear of contamination and disgust (Curtis & Biran 2001), and created peer pressure (Sidibe 2003). Children and mothers were asked to pledge in front of peers; children committed to HWWS and mothers committed to help the child.

The programme was delivered by a dedicated team of 'promoters' primarily through a series of weekly 'classrooms' and 'home visits'. 'Classrooms' were held in community buildings after school, during which the 5-year-olds were taught through songs, poems and stories. During 'home visits', 'promoters' covered the same topics with mothers to those in the classroom, gave mothers assignments for the child and provided materials to use as reminders and/or rewards for hand washing. Mothers were also asked to provide hand washing tips for other mothers to use with their children.

Every 6 weeks, parents' meetings were used to boost morale, build a network of mothers and run the 'Best Mums' competition. 'Best Mums' received certificates for high levels of compliance, completing assignments and decorating children's folders. Soap was supplied to intervention households as wrapped 90-g Lifebuoy bars. Initially, households were given five bars, which were replenished on production of empty wrappers during data collection visits.

Registers were kept for the 'classrooms' and 'home visits'. Unless by prior arrangement, 3-week gaps in either register triggered supervisors to ask families to resume or be withdrawn from the study. We monitored whether soaps were being sold on the open market through marking soap wrappers with unique identifiers and performing twice-weekly checks in local shops.

The control group continued normal hand washing practices throughout the trial. Once a month, all target children received a gift to the value of 50 Rupees (approximately US$1).

Outcomes

The main period of data collection began on 22 October 2007 and ran concurrently with the intervention for 41 weeks until 2 August 2008. Households were visited twice a week, spaced three or 4 days apart. Only one visit was made during weeks 3, 10, 14, 21 and 27 (due to public holidays) and week 17 (due to civil unrest). Individual households were also allowed to take pre-arranged 'breaks' (e.g. due to family holidays).

Case record forms (CRFs) covering illnesses and school absences were completed solely through interviews, usually with primary caregivers. Illness questions covered the main health outcomes of diarrhoea and ARIs, as well as illnesses that might be affected by hand washing and could be recorded by data collectors without formal medical training (eye infections, vomiting, abscesses or boils, headaches and earaches).

Data collectors asked whether anyone in the household had suffered from each of the illnesses since the last visit. In case of positive responses, data collectors asked who had been ill and on which days. Interviewees were also asked whether the target child had been absent from school and, if so, the number of absent days and the reason ('child illness', 'illness of another family member', or 'other').

Operational definitions for all the illnesses were taken from Black's Medical Dictionary (MacPherson 1999). Diarrhoea was defined as 'Three or more loose or watery stools in a 24-h period.' and ARIs as 'Pneumonia, cough, fever, chest pain and shortness of breath, cold, inflammation of any or all of the airways, that is, nose, sinuses, throat, larynx, trachea and bronchi'.

Soap wrappers were collected and used as a soap consumption measure and as an indirect measure of hand washing behaviour. We planned to use 'soap acceleration sensors' (Ram *et al.* 2010) as a direct measure of behaviour with a subset of households. However, technical difficulties prevented us from doing this successfully. Compliance with data collection was encouraged through supervisors' visits. These were triggered when households missed 3-weeks data collection without prior arrangement. Households were removed from the study if they provided no data for five consecutive weeks.

The reliability of data recording was monitored by supervisors, who visited each household approximately every 2 months. Additional checks were made when data collectors reported low success rates in contacting families. Demographic data were collected during initial consenting and covered household composition, wealth indicators, and access to water and sanitation.

Data collectors were recruited locally and trained on identification of illnesses during a 1-day training session led by the study doctor. Data collectors were independent of the behaviour change intervention. Each was assigned, exclusively, either to households in the intervention group or to control households.

Sample size

We calculated the number of communities required to detect a between-group difference in diarrhoea incidence density for the 5-year-olds. We used Luby's data, collected from similar communities in Pakistan (Luby *et al.* 2004) to estimate a diarrhoea incidence of four episodes per 100 person weeks (SD = 1.4) in the control group. We calculated that we needed 64 communities (32 communities per group) to detect a difference of 25% in diarrhoea incidence at the 5% significance level (2-tailed) with a power of 80%. We recruited 35 communities per group because we anticipated a potential 10% attrition in communities during data collection.

Statistics

Main outcomes were episodes of diarrhoea, ARIs and school absences among target children, and episodes of diarrhoea and ARIs among their families. Secondary outcomes were episodes of eye infections, vomiting, abscesses or boils, headaches, and earaches.

We considered that subjects had only 'completed' the intervention if they remained on the study until the end. Therefore, the main analyses presented are 'per-protocol' based on 'completers'. 5-year-olds were treated as completers if they stayed on the study for all 41 weeks. Other family members' data were analysed when both they and their 5-year-olds completed 41 weeks. To check for biases in the data caused by dropouts, we also report 'intention-to-treat' analyses which included all collected data.

Illness and school absence incidences were calculated at a community level. Diarrhoea and ARIs are reported for 'whole families' (combined children and adults), and three independent child subgroups: target children (primary objective), non-target children aged 5 and under (born after 2001), non-target children aged 6–15 (children born between 1992 and 2001, inclusive). For school absences, we only collected data for target children.

With the exception of ARIs, subjects were considered 'at risk' if they had not reported suffering from an illness for three consecutive days. For ARIs, this 'clearance' period was set to 5 days. The maximum number of 'at-risk' days was 286 days for illnesses and 192 for school absences (the maximum number of days that a child could have attended school).

For each outcome, the total number of episodes was modelled using negative binomial regression, fitting the treatment and the pairing as covariates and the logarithm of the total number of at-risk days in study as an offset. Negative binomial regression is Poisson regression but with an additional term to allow for over-dispersion (Lawless 1987; McCullagh & Nelder 1989). The predicted relative risk reduction (RRR) was calculated using the equation '$RRR = 100 * \{(R_I/R_C)–1\}$', where R_I and R_C are the event rates in the intervention and control groups, respectively. In negative binomial regression analyses, the RRR is estimated from the model coefficient of the treatment group (b_{group}) by the formula $RRR = 100 * \{b_{group} – 1\}$.

The data were analysed by the Medical Statistics Group, Clinical Trial Research Unit, University of Sheffield, using the STATA/SE 10.0 statistical package.

Ethics

The protocol and subsequent amendments were approved by the Hindustan Unilever Research Ethics Committee.

Results

As Figure 1 shows, of 1026 target children that started each treatment, 179 (17%) in the intervention group and 191 (19%) in control were not entered into the 'per-protocol' analysis. The majority of non-completion was due to families either leaving the area or refusing to participate, 165/179 (92%) for intervention and 182/191 (95%) for control.

Table 1 shows the number of participants starting treatments and the number entered into the per-protocol analyses for the various subgroups. For a per-protocol analysis, there may be a concern that the dropouts were uneven across the groups. However, data from the baseline survey show that the two groups of completers were well matched, although there were some small differences in the access to sanitation (Table 2).

Overall, there were 73 086 (93.5%) successful data collection visits in the intervention group compared with 72 484 (92.5%) in control. For the completers, there were 2 591 936 observation days for all subjects and 445 726 for the target 5-year-olds. The mean number of observation days per subject was well matched between groups for all subjects (intervention = 268.0 days, control = 267.8 days) and for target 5-year-olds (intervention = 265.2 days, control = 265.4 days). There was a possible maximum of 303 408 days for school attendance, with both groups having a mean of 180.6 potential school days for each target child.

Diarrhoea and ARIs

Table 3 shows that in the intervention communities, there were significantly fewer episodes of diarrhoea and ARIs for 'whole families' and for all subgroups. Analyses on all subjects providing data yielded similar results (Table 4), with the exception that the difference in the diarrhoea incidence in the 5-year-olds was no longer significant.

School absence

Table 5 shows that target children in the intervention group had significantly fewer days absent due to their own or family illnesses. Analyses on all data collected yielded similar results. For absences due to child illness, PRRR = 28.4% (95% CI = 39.6%, 15.1%, $P < 0.001$); and for absences due to child or family illness, PRRR = 30.4 (95% CI = 41.7%, 16.9%, $P < 0.001$). 375 of 847 (44.3%) intervention children and 261 of 833 (31.3%) control children never missed school due to illnesses. After standardisation, this was calculated as a 41.3% risk reduction.

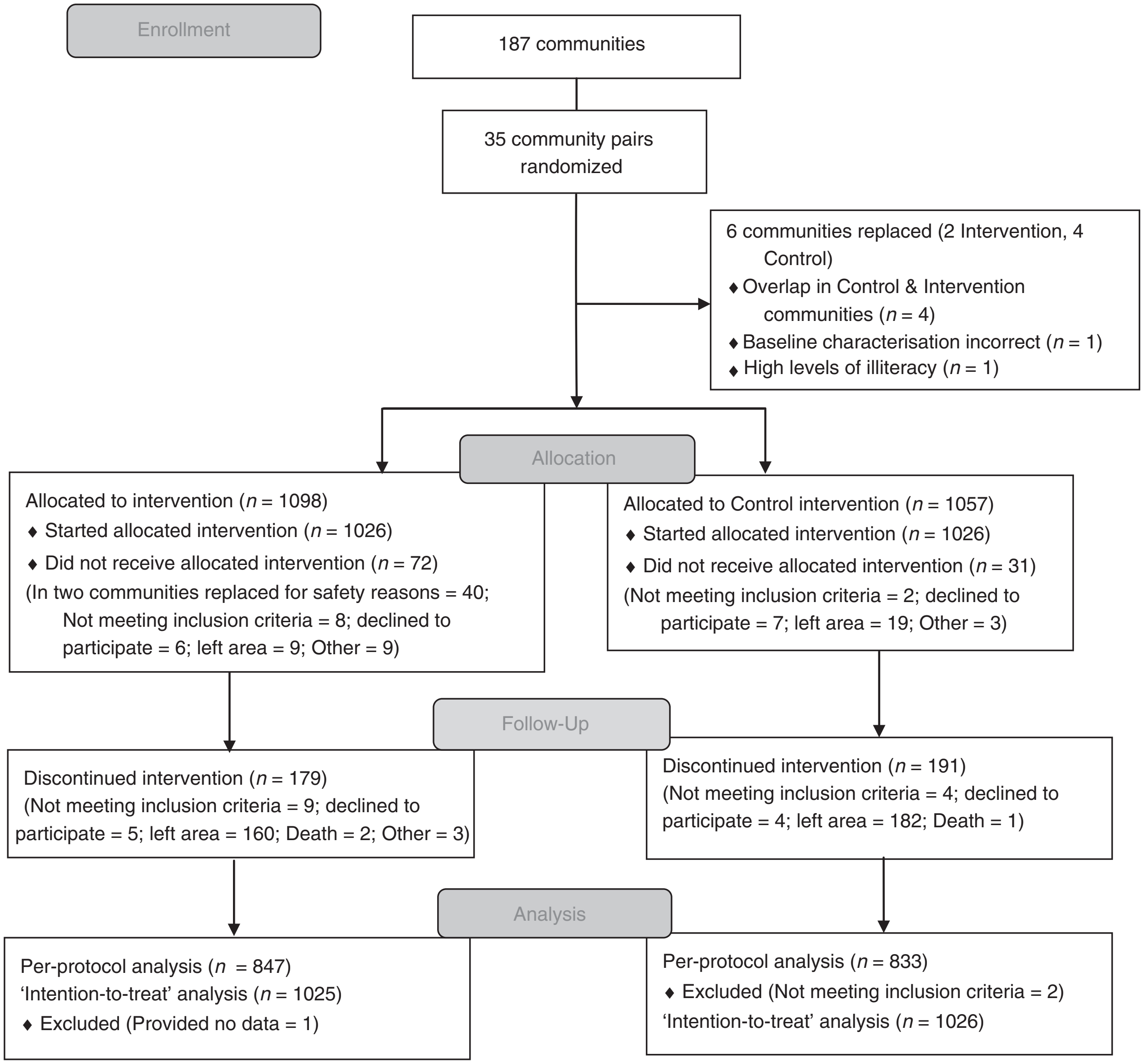

Figure 1 Participant flow.

Illnesses other than diarrhoea and ARIs

We restricted analyses on these illnesses to the 5-year-olds and 'whole families' due to concerns about a lack of power and a profusion of comparisons. Table 6 shows that 5-year-olds in the intervention communities had significantly fewer eye infection episodes. No other differences were significant.

Analyses on all subjects providing data were consistent with the per-protocol analyses with the exception of boils episodes for 'whole families', with significantly fewer episodes in controls (PRRR = 28.5%; 95% CI = 3.3%, 59.9%, $P = 0.024$). The eye infection effect was still present for the target 5-year-olds (PRRR = −40.7%, 95% CI = −53.3%, −24.7%, $P < 0.001$).

Soap consumption

830 of 833 control households completing the study returned at least one wrapper during the study, indicating that soap was used in over 99% of control households

over the course of data collection. We estimated the median soap consumption to be 45 g per household per week in control households compared with 235 g in intervention households.

Table 1 Number of subjects starting the study and number (and percentage) entered into the analyses

	Intervention		Control	
Age group	Started	Analysed (%)	Started	Analysed (%)
Target children	1026	847 (83)	1026	833 (81)
Children aged 5 and under (non-target)	1190	967 (81)	1279	1039 (81)
Children aged 6–15 (non-target)	1784	1499 (84)	1735	1459 (84)
Adults	1892	1550 (82)	1793	1481 (83)
All subjects	5892	4863 (83)	5833	4812 (82)

Table 2 Baseline survey data for the 'completers'

Characteristic	Intervention	Control
Household wealth indicators (%)		
Monthly household US income <$60 (<7000 rupees)	805 (95)	795 (95)
Home ownership	609 (72)	612 (73)
Mean rooms in home (SD)	1.1 (0.3)	1.12 (0.35)
Refrigerator ownership	33 (4)	49 (6)
Toilet access (%)		
In own home	60 (7)	29 (3)
Communal/In neighbours dwelling	785 (93)	775 (93)
No access	3 (<1)	31 (4)
Drinking water source (%)		
Bore well	2 (<1)	6 (<1)
Piped	202 (24)	292 (35)
Public standpipe	644 (76)	517 (62)
Water tank	0	2 (<1)
Other	0	18 (2)

Discussion

The results indicate that the intervention reduced episodes of diarrhoea and ARIs for target 5-year-olds and their families. There were also fewer absences from school due to illness for the 5-year-olds. Secondary analyses suggest that the intervention also reduced eye infections among the 5-year-olds.

The sizes of effects for diarrhoea and ARIs were broadly consistent with previous reviews. For diarrhoea, observed RRRs were 25.3% for the 5-year-olds and 30.7% for 'whole families'. Curtis and Cairncross (2003) suggested hand washing promotions can reduce the risk of diarrhoea by 47% (95% CI = 24%, 63%). However, our results are closer to Ejemot-Nwadiaro *et al.* (2012), who estimated risk reductions in low-income countries to be 32% (95% CI = 10%, 48%). Observed RRRs for ARIs were 14.9% for 5-year-olds and 13.9% for all subjects. These are close to Rabie and Curtis (2006) who estimated the ARI risk reduction to be 16% (95% CI = 11%, 21%).

The 27% reduction in absenteeism among intervention group 5-year-olds is lower than the 42% observed by Bowen *et al.* (2007). However, this study was larger than Bowen's, which did not reach statistical significance, and contributes more evidence of the effectiveness of hand washing with soap in reducing school absenteeism.

Finally, we saw a reduction in the incidence of eye infections. Montessori *et al.* (1998) previously made a link between infection control measures, such as hand washing, and reduction in the transmission of keratoconjunctivitis in an eye care clinic. However, we believe that this is the first direct evidence that a hand washing intervention alone can reduce incidence in a general population. While this is a secondary analysis, the effect is potentially important and may indicate that hand washing reduces transmission of infection from the fingers to the eyes.

Table 3 Per-protocol analyses for diarrhoea and acute respiratory infections (ARI) incidence

		Episodes per 100 person weeks					
Analysis group	Illness	Intervention	Control	Observed RRR (%)	Predicted RRR (%)	95% CI	*P*-value
Target children	Diarrhoea	1.70	2.28	25.3	21.3	36.6, 2.3	0.030
	ARI	16.13	18.83	14.9	19.6	29.6, 8.3	0.001
Children aged 5 and under (Non-target)	Diarrhoea	2.22	3.30	32.5	24.7	41.1, 3.8	0.023
	ARI	17.69	20.24	20.5	19.2	29.0, 8.1	0.001
Children aged 6–15 (Non-target)	Diarrhoea	1.13	1.62	30.0	24.3	38.7, 6.6	0.010
	ARI	12.21	13.68	11.8	15.5	24.4, 5.6	0.003
Whole families	Diarrhoea	1.14	1.64	30.7	23.1	37.5, 5.5	0.013
	ARI	9.90	11.15	13.9	13.9	23.1, 6.5	<0.001

Further research on the mechanisms at work is required as, from our data, we cannot be ascertain why the whole family seems to benefit from this intervention. Bowen *et al.* (2007) suggested that school age children may act as change agents with their friends and family. However, the mother may have also acted as the locus of behavioural change. Also, it is conceivable that the improved hygiene practices of the child and/or mother reduced their potency to act as vectors for transmissible illnesses. However, given the high level of soap consumption within intervention households, it seems unlikely that the behavioural change was confined to a single individual and more likely reflects increased soap use across a number of household members.

It was impossible to 'blind' either the participants or those responsible for data collection. We tried to reduce recording biases by appointing separate hygiene promotion and data collection teams. Further, data collectors were only assigned to one of the treatment groups.

We cannot rule out the possibility that respondents were, or became, aware of the link between HWWS and diarrhoea and ARIs. This may have led to over-reporting of these illnesses. However, such a specific bias does not explain the effects observed on eye infections for 5-year-olds, as participants would not have linked HWWS and eye infections. Over-reporting of eye infections would only result from a very general bias to over-report illnesses. If such a general bias existed, then we should have observed effects on all illnesses measured.

The second limitation is that we were unable to deploy a direct measure of behaviour. The relatively greater soap consumption in the intervention communities suggests that soap use, at least in part, mediated the observed effects. However, soap consumption is only a proxy for hand washing with soap and does not necessarily demonstrate that behavioural changes occurred at key moments.

Table 4 Analyses on all subjects providing data for diarrhoea and acute respiratory infections (ARI) incidence

Analysis group	Illness	Predicted RRR (%)	95% CI	*P*-value
Target children	Diarrhoea	21.3	36.6, 2.3	0.102
	ARI	19.9	29.8, 8.4	0.001
Children aged 5 and under (Non-target)	Diarrhoea	23.6	40.2, 2.5	0.03
	ARI	19.8	29.8, 8.3	0.001
Children aged 6–15 (Non-target)	Diarrhoea	21.1	35.3, 3.8	0.019
	ARI	15.7	24.9, 5.5	0.003
Whole families	Diarrhoea	22.5	36.5, 5.3	0.013
	ARI	15.0	23.1, 6.0	<0.002

Table 5 Per-protocol analyses for school absences

Reason	Number days absent per 100 at-risk days		Observed RRR (%)	Predicted RRR (%)	95% CI	*P*-value
	Intervention	Control				
Child illness	1.2	1.7	26.7	30.5	41.4, 17.6	<0.001
Child plus family illness	1.3	1.8	28.6	32.5	43.4 19.4	<0.001

Table 6 Per-protocol analyses for illnesses (except diarrhoea and ARIs)

Analysis group	Illness	Episodes per 100 person weeks		Predicted RRR (%)	95% CI	*P*-value
		Intervention	Control			
Target children	Boils	2.87	3.06	2.6	−19.7, 31.0	0.839
	Ear infections	0.99	1.35	−19.8	−38.9, 5.4	0.114
	Eye infections	0.38	0.70	−46.0	−57.6, −31.3	<0.001
	Headache	0.67	0.88	−16.9	−38.4, 12.2	0.227
	Vomiting	1.07	1.22	−4.1	23.7 20.6	0.719
Whole families	Boils	1.84	1.65	23.8	−1.1, 54.8	0.062
	Ear infections	0.65	0.79	−9.6	−27.8, 13.1	0.379
	Eye infections	0.62	0.80	−3.9	−28.2, 28.6	0.788
	Headache	2.98	2.58	16.3	−3.9, 40.8	0.120
	Vomiting	0.92	0.84	20.9	−1.7, 48.8	0.073

The third limitation was the replacement of communities after randomisation, which should be avoided if at all possible. This became necessary mainly through errors in the initial characterisations and arising safety concerns. However, no data were collected in any of these eight communities. An exclusion that should be avoided in future was the one community where mothers had very low literacy levels. Involvement of the mothers was an important part of our approach. However, future hygiene promotions should design materials to ensure that these potentially vulnerable families should be included in any intervention.

Policy and practice implications point towards the use of public–private partnerships (PPPs) to deliver school-based HWWS interventions. We designed our promotion using a commercial social marketing approach informed by academic behaviour change theories. Curtis *et al.* (2007) argue that effective marketing communication is a key competency that the private sector brings to PPPs. Further, targeting school-aged children highlights a role for governments in providing access to schools. Use of classrooms may further improve cost-effectiveness and reach children in a setting where peer influences can be used to affect behaviour.

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