

## Randomized Intervention Study of Solar Disinfection of Drinking Water in the Prevention of Dysentery in Kenyan Children Aged under 5 Years

Martella du Preez,<sup>†</sup> Ronan M. Conroy,<sup>‡</sup> Sophie Ligondo,<sup>§</sup> James Hennessy,<sup>§</sup> Michael Elmore-Meegan,<sup>§</sup> Allan Soita,<sup>§</sup> and Kevin G. McGuigan<sup>\*,||</sup>

<sup>†</sup>Natural Resources and the Environment, CSIR, P.O. Box 395, Pretoria, South Africa

<sup>‡</sup>Division of Population Health Sciences, Royal College of Surgeons in Ireland, 123 St Stephens Green, Dublin 2, Ireland

<sup>§</sup>ICROSS, P.O. Box 507, Kenya, Ngong Hills, Kenya

<sup>||</sup>Department of Physiology & Medical Physics, Royal College of Surgeons in Ireland, 123 St Stephens Green, Dublin 2, Ireland

**S** Supporting Information

**ABSTRACT:** We report the results of a randomized controlled intervention study (September 2007 to March 2009) investigating the effect of solar disinfection (SODIS) of drinking water on the incidence of dysentery, nondysentery diarrhea, and anthropometric measurements of height and weight among children of age 6 months to 5 years living in peri-urban and rural communities in Nakuru, Kenya. We compared 555 children in 404 households using SODIS with 534 children in 361 households with no intervention. Dysentery was recorded using a pictorial diary. Incidence rate ratios (IRR) for both number of days and episodes of dysentery and nondysentery diarrhea were significantly ( $P < 0.001$ ) reduced by use of solar disinfection: dysentery days IRR = 0.56 (95% CI 0.40 to 0.79); dysentery episodes IRR = 0.55 (95% CI 0.42 to 0.73); nondysentery days IRR = 0.70 (95% CI 0.59 to 0.84); nondysentery episodes IRR = 0.73 (95% CI 0.63 to 0.84). Anthropometry measurements of weight and height showed median height-for-age was significantly increased in those on SODIS, corresponding to an average of 0.8 cm over a 1-year period over the group as a whole (95% CI 0.7 to 1.6 cm,  $P = 0.031$ ). Median weight-for-age was higher in those on SODIS, corresponding to a 0.23 kg difference in weight over the same period; however, the confidence interval spanned zero and the effect fell short of statistical significance (95% CI  $-0.02$  to 0.47 kg,  $P = 0.068$ ). SODIS and control households did not differ in the microbial quality of their untreated household water over the follow-up period ( $P = 0.119$ ), but *E. coli* concentrations in SODIS bottles were significantly lower than those in storage containers over all follow-up visits ( $P < 0.001$ ). This is the first trial to show evidence of the effect of SODIS on childhood anthropometry, compared with children in the control group and should alleviate concerns expressed by some commentators that the lower rates of dysentery associated with SODIS are the product of biased reporting rather than reflective of genuinely decreased incidence.



### INTRODUCTION

Although a preventable and treatable disease, nearly 1.8 million children under 5 years of age die from diarrhea each year.<sup>1</sup> The World Health Organization estimates that in 94% of cases diarrhea is preventable by increasing the availability of clean water and improving sanitation and hygiene.<sup>1</sup> Diarrheal disease is strongly linked to fecal contamination. Contamination can occur at source or within the storage container during transport or storage.<sup>2</sup> Recontamination may also occur if the drinking utensils are not subject to a regular hygiene regimen.<sup>3,4</sup> The prohibitive cost of universally supplying piped water has made household water treatment (HWT) an attractive alternative worldwide. Reviews of the effectiveness of HWT methods<sup>5–7</sup> have confirmed that in-home interventions, such as filtration,<sup>8,9</sup> chlorination,<sup>10,11</sup> a combination of flocculation and chlorination,<sup>12,13</sup> and solar disinfection<sup>14–18</sup> can reduce the incidence of diarrhea substantially.

The fundamental principles of one of the simplest and cheapest HWT, solar disinfection (SODIS), were first discussed in 1877 by Downes and Blunt.<sup>19</sup> Acra and his colleagues from the American University of Beirut laid the foundations of current research on SODIS with their work on solar irradiation of water and oral rehydration solutions in 1980.<sup>14,20,21</sup> More recent laboratory studies have consistently shown that exposing water to sunlight results in significant reduction in bacterial contamination.<sup>22–26</sup> However, there are still relatively few controlled field trials to show that this reduction in bacterial levels translates into a reduction in risk of disease in people. Initial trials in

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Kenyan children reported that solar disinfection was associated with a significant reduction in the risk of diarrheal disease in children aged 5 and under<sup>16</sup> and in older children,<sup>15</sup> and a further study reported a significant reduction of risk of cholera in children.<sup>17</sup> A study by Rose and his colleagues in India in children under 5<sup>27</sup> showed a significant reduction in risk which occurred despite 86% of the children drinking water other than the solar disinfected water. Rai and co-workers showed a reduction of childhood diarrhea by approximately 76% in an urban population of 136 children under age 5 in North Eastern India.<sup>28</sup> A recent trial of solar disinfection in Bolivia by Mäusezahl and colleagues in a setting of very low compliance (32%) failed to show a statistically significant reduction in diarrheal disease, although a reduction in diarrhea was observed for both the test and control communities.<sup>29</sup> A study of SODIS in a South African peri-urban environment by du Preez and co-workers in 2009<sup>30</sup> also reported low compliance levels. Dysentery incidence rates were, however, lower in those drinking solar disinfected water (incidence rate ratio 0.64, 95% CI 0.39–1.0,  $P = 0.071$ ) but not statistically significantly so. Compared with the control, only participants with higher motivation (defined as adhering to the study protocol at least 75% of the time) achieved a significant reduction in dysentery (incidence rate ratio 0.36, 95% CI 0.16–0.81,  $P = 0.014$ ). There was no significant reduction in risk at lower levels of motivation. These two studies underline the importance of participant motivation in translating the bactericidal effects of SODIS into health gains.

The published research has also some deficiencies. All published trials to date have been carried out on children; there are no trials of the effect of solar disinfection in populations of adults at high risk of water-borne diseases, such as the elderly or those with compromised immune function. Previous Kenyan trials were all carried out in populations drinking heavily contaminated water with high levels of disease risk.<sup>31</sup> Furthermore, since the control group participants in these three studies stored their SODIS water indoors in lidded SODIS bottles and refrained from consuming drinking water normally stored in-house, the effect of this improved storage may have caused an underestimation of the true benefit of solar disinfection. Importantly, the previous trial methodology did not allow for the differentiation between dysentery, which has serious health consequences, and nondysentery diarrhea. This is an important weakness, as Wright and his colleagues reported that dysentery in children in rural South Africa and Zimbabwe is associated with faecal contamination of source water, while nondysentery diarrhea was uncorrelated with water quality.<sup>32,33</sup>

The present trial was one of a series of trials which were carried out in South Africa, Zimbabwe, Kenya, and Cambodia as part of the EU funded SODISWATER project.<sup>34</sup> It aimed to address some of the deficiencies of earlier research by distinguishing between dysentery and nondysentery diarrhea in a setting of moderate, rather than severe fecal contamination of drinking water. In the SODISWATER randomized intervention study of 12 month duration among a large population ( $n = 927$ ) of children under age 5 years in rural Cambodia, McGuigan and co-workers<sup>35</sup> have reported high compliance (>90%) and reduced incidence of dysentery, with an incidence rate ratio (IRR) of 0.50 (95% CI 0.27 to 0.93,  $p = 0.029$ ). SODIS also had a protective effect against nondysentery diarrhea, with an IRR of 0.37 (95% CI 0.29 to 0.48,  $p < 0.001$ ).

## METHODS

**Participant Selection.** Participants were recruited in August and September 2007 from six areas in the Nakuru District of Kenya. Three of these areas (Bondeni, Lanet, and Kaptembwa) are urban slum townships in the city of Nakuru, while three (Mogotio, Salgaa, and Wanyororo) are poor rural areas. The urban locations were supplied almost exclusively by standpipes provided by the Nakuru Water Sanitation Services Company. The Company uses conventional water treatment methods to treat ground- and surface water (personal communication, ICROSS, 2010). In the rural locations, water sources were more variable. Only Salgaa was partly supplied by standpipes (54 of 97 households), while the other rural areas used a mix of river (20.7% of households) borehole water, both protected (4.7%) and unprotected (9.1%) and a small number of miscellaneous sources (see Table 1 of the Supporting Information).

**Sample Size.** Sample size was estimated based on comparison of two Poisson event rates in the presence of significant clustering. Since neither the underlying rates of dysentery nor the strength of clustering effects within households were known, we carried out a series of calculations based on rates of 1 to 10 days of dysentery per year and on different degrees of clustering effects. The projected sample of 1000 children was chosen as offering a 90% power to detect a 10% reduction in risk where the underlying rate was 5 episodes per child per year and clustering effects were strong ( $\rho = 0.2$ ). The sample provided more than 90% power to detect a 20% reduction in incidence for all rates of 2 episodes per child per year or greater

**Randomization.** After obtaining ethical approval from the Kenya Medical Research Institute households were identified using local information provided by health workers operating in the areas. Eligible households stored water in containers in-house, did not have a drinking water tap in the house or yard, and had at least one child (but not more than 5) between 6 months and 5 years old residing in the house. Field workers located the households on foot and recorded their addresses. A study area acronym and house number, linked to the Global Positioning System (GPS) coordinates of the household, was allocated to each household. The addresses and coordinates constituted the sample frame of households. Random numbers between zero and one were generated and allocated to the households. If the random number allocated to a household was less than 0.5 the household was randomized to the test group. If the allocated number was above 0.5 the house was randomized to the control group. Field workers were unaware of how the numbers were allocated.

**Sampling Issues.** The decision to use multistage (cluster) sampling method used in the study was a pragmatic one. No regional sample frame exists which would have allowed the identification of eligible households. The identification of eligible households within villages thus entailed a sampling procedure which selected villages and, within these villages, recruited households. There are two significant sources of clustering within the data: at village level, shared environmental factors such as water and sanitation as well as sociodemographic factors will cause households from each village to resemble each other. Furthermore, recruitment of more than one child per household generates further clustering within the data, since children within the same household will share environmental factors affecting health to a greater extent than children from different households within the same village. This required the use of robust (Huber-White)

variance estimation in order to correct for the statistical effects of clustering on estimates of precision.

**Presurvey.** Details of the study and what would be expected of each household and the children during the study were provided verbally and in writing in the local language to parents or carers. Written informed consent was obtained from the head of the household or the carer. Household selection, during which participants were trained at home to complete diarrhea diaries and the use of SODIS was undertaken by field workers that are well trained in aspects of community work and data collection. In addition a field manual provided clear instructions on all the procedures executed during the field study. The presurvey was completed three months prior to the start of the main survey. Household information with regard basic hygiene and water use practices and sanitation were also collected (see Table 1 of the Supporting Information). Field data were captured using hand-held computers and scanned barcodes to link records. The data were downloaded into a database and checked for completeness and consistency before analysis.

Two 2-L PET bottles were provided for each child in the intervention group. Carers of children in the intervention group were instructed to fill one bottle and place it in full, unobscured sunlight for a minimum of 6 h every day. In practice most bottles were exposed for longer than 6 h since parents or guardians usually placed the bottle outdoors early in the morning and brought it in at the end of the day. Consequently children in the intervention group drank from a bottle which had been exposed to sunlight on the previous day. Treated water was consumed on the day after exposure. To minimize the possibility of regrowth of partially inactivated bacteria carers were instructed to store the water for a maximum of 48 h. Carers were advised that, where possible, children in the intervention group should drink disinfected water directly from the SODIS bottle rather than from a cup or other container which might have presented a risk of recontamination of the water. Children in the control group were not provided with SODIS bottles and instead were instructed to maintain their usual practices.

**Anthropometry.** Formal anthropometric standardization to determine the precision and accuracy of each person taking height and weight measurements was not conducted because anthropometry was not the main focus of the study. However, field supervisors, who took the measurements, attended a week-long training session in South Africa during which the use of the equipment (standard adult digital battery operated weighing scales, stature meter and rollameter) was demonstrated and practiced. Special attention was given to the basic anthropometric principles such as calibration of the scales, accuracy when taking measurements, measuring techniques, and ensuring that correct data were recorded. Babies weighing less than 10 to 15 kg were weighed in the arms of the mother or carer. The weight of the babies was calculated in the laboratory. Older children were weighed standing unsupported on the adult scale. In either case the child was shoeless, wearing only a minimum of light clothing. A plank was used as a smooth horizontal position for the scales, stature meter, and the rollameter. The stature meter was always set up against a sturdy vertical wall or door frame. Attention was given to the position of the feet, knees, and position of the head of the subjects when using either the stature or rollameter (see Figures 1 and 2 of the Supporting Information). A manual provided detailed illustrated information and instructions on conducting anthropometry. An initial pilot scale study in South

Africa and second pilot scale study undertaken in Kenya provided further practical sessions.

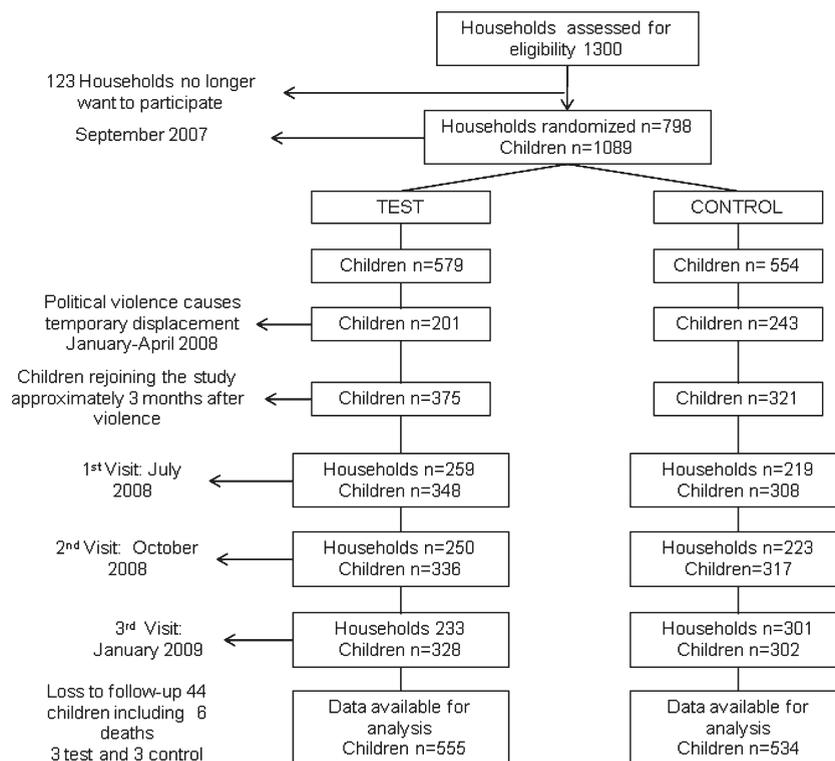
**Health Outcome.** The primary health outcome of the study was days on which the child had dysentery, defined according to Baqui, as any loose stool which contained blood or mucus.<sup>36</sup> A dysentery diarrhea day was defined as a single day in which one or more stools contained either blood or mucus. One or more consecutive dysentery diarrhea days occurring followed by three consecutive days on which neither dysentery nor nondysentery diarrhea occurred constituted a dysentery episode. Nondysentery diarrhea was defined as three or more loose or watery stools on the same day without blood or mucus, while an episode was characterized by three consecutive days on which neither dysentery nor nondysentery diarrhea occurred. Nondysentery diarrhea days and dysentery diarrhea days were recorded daily using pictorial diaries developed by Gundry and colleagues,<sup>33</sup> which record the number and consistency of the child's stools. Diarrheal incidence was recorded daily for both control and test children for 17 months.

**Monitoring.** Three monitoring visits to determine the microbial water quality and anthropometry were undertaken (July 2008, October 2008, and January 2009). Each visit included all households, but carers and children were often absent from their homes. This was particularly so during holidays when children are sent away to live with relatives or grandparents. Attempts to obtain data from these households included additional follow-up visits, but the long distances between the study areas made this an expensive and unfeasible procedure. As a result we were unable to collect data from every household for each of the three visits. Between monitoring visits trained field staff visited participating households every two weeks to collect diarrheal diaries. The diaries were checked for discrepancies and corrected when possible. Problems raised by the participants were resolved during these visits. Compliance was measured from the collection of the pictorial diarrheal diaries and by recording the responses of household caregivers during monitoring visits, every three months. On these occasions caregivers were asked (i) whether they were using SODIS and (ii) whether it was possible to collect a water sample from the SODIS bottle that was in use. Between monitoring visits field staff regularly reminded the SODIS group about the technique and inquired if they were still using it.

Water from the storage containers and SODIS bottles were collected in commercially available 100 mL sample bottles containing sodium thiosulfate to neutralize any residual chlorine in the water. Samples were transported on ice and analyzed on the same day using the Colilert-18 Quantitray, most probable number (MPN) method<sup>37</sup> to quantify *E. coli*. The maximum possible count obtainable using the 0–200 cell forming units per 100 mL Quanti-tray is >200.5 and the minimum <1.

**Statistical Methods.** Data were analyzed with Stata/SE, Release 11. Stata's robust variance estimation routines for clustered data, implemented in the *svy* procedures, were used to adjust for the effects of the multistage sample design, with children sampled within houses, and stratified by village (6 units).

Initial analysis confirmed that incidence rates of dysentery were overdispersed, making a Poisson regression inappropriate. Generalized negative binomial regression was used to calculate incidence rate ratios. Generalized negative binomial regression allows for variation in disease rates between individuals who have the same risk factor profile and allows this variation to be modeled as a function of predictor variables.



**Figure 1.** Flow diagram showing the course of the intervention.

*E. coli* data were transformed to a log scale and analyzed using interval regression. This allows values of zero to be analyzed as representing <1 colony forming unit (CFU) and values above the upper threshold of the system (>200.5) to be analyzed as representing a value greater than the threshold. The advantage of this method is that it allows the presence of values which are interval-censored (not known precisely but known to lie in a defined interval). This method overcomes the unreasonable assumptions frequently made when analyzing water quality data that a) values which are greater than the highest readable value are equal to that value and b) that samples which show no CFUs indicate that the water from which the sample was taken contains zero *E. coli*. Interval regression also overcomes the problem of expressing readings of zero on a logarithmic scale, since such values are simply expressed as being less than 1, rather than truly zero. Analysis of faecal coliform concentrations also used robust variance estimation to adjust for clustering of data within households.

Anthropometry measures were analyzed by using fractional polynomial quantile regression to estimate the fiftieth and tenth centiles of weight-for-age and height-for-age. This approach was adopted rather than using z-scores based on means and standard deviations on the grounds that such an approach assumes a normal distribution of data which is unlikely in socially deprived conditions, and the use of published norms may fail to take into account the empirical growth trajectories of the study population. By using the extensive data available, we were able to construct empirical growth curves that best fitted the study population.

The number of months drinking SODIS water was taken as the predictor variable to indicate the effect of SODIS on weight for age. Since the time on SODIS is zero for all measures taken from control children, the regression estimates the effect of duration of

SODIS use on anthropometric variables. We chose to estimate growth curves directly from the data because anthropometry norms developed for one population may be inappropriate for another.

## RESULTS

There were 765 households, with 404 (53%) randomized to solar disinfection. The types of water sources (combining the spring, dug well protected and unprotected and the canal and other; see Table 1 of the Supporting Information) used by the test and control groups were not statistically significantly different ( $\chi^2 = 4.394$ ,  $df = 4$ ,  $P = 0.355$ ). Almost all (92%) had access to a toilet, of which the majority (89%) were pit latrines. Only 7% of participants had access to a flush toilet. A median of 15 people shared a toilet. Sharing of toilets was evident in both the peri-urban areas where residents were provided with public toilets and the rural areas where one toilet in a yard was often shared with neighboring households. Hygiene levels determined by hand washing at critical times were high and not statistically significantly different between the test and control group for example, before eating ( $\chi^2 = 0.017$ ,  $df = 1$ ,  $P = 0.897$ ), before preparing food, ( $\chi^2 = 1.410$ ,  $df = 1$ ,  $P = 0.234$ ), after changing a baby's nappy ( $\chi^2 = 1.737$ ,  $df = 1$ ,  $P = 0.1875$ ), and after using the toilet ( $\chi^2 = 2.000$ ,  $df = 1$ ,  $P = 0.157$ ).

**Loss to Follow-up.** Six of the participating children died during the study period. Of these, three were in the intervention and three in the control groups. Cause of death is unknown for two of the three children in each group. One child in the intervention group died of diarrhea and one child in the control group died of pneumonia. Post election violence caused displacement of households in February 2008 resulting in a temporary loss of 444 children directly after the upheaval.

**Table 1. Unadjusted Annual Rates of Dysentery and Nondysentery Diarrhoea Days and Episodes**

group	dysentery		nondysentery diarrhea	
	days	episodes	days	episodes
control	5.20	2.02	10.89	4.75
test (SODIS)	3.34	1.31	8.07	3.65

Many households returned to their homes once the violence ended, and at the end of the study 24 children in the test group and 20 in the control group were completely lost to follow-up. The displacement of a large proportion of the study sample meant that many would have changed water source, sanitation facilities, and living conditions on several occasions during the study, making use of baseline data on these variables inappropriate for analysis of disease rates. A flow diagram showing the course of the intervention is provided in Figure 1.

The total number of children randomized was 1089, with 555 (51%) randomized to solar disinfection. The intervention and control groups did not differ with respect to either age ( $P = 0.980$ ,  $t$  test) or sex ( $P = 0.744$ , Chi-squared test). Median duration of diarrhea recording was 11 months; 9% of participants had less than 3 months, 75% had 17 months or less, and 15% had 17 or 18 months. Intervention and control groups did not differ in the number of days of diarrhea data recorded ( $t$  test,  $P = 0.492$ ).

Table 1 shows the unadjusted annual rates of dysentery- and nondysentery days and episodes for the test and control group of children. Rates of dysentery were related to age. Compared with children under 1 year, children aged 1 had an incidence rate ratio of 0.72 ( $P = 0.109$ ) for days of dysentery, children aged 2 an incidence rate of 0.52 ( $P = 0.001$ ), children aged 3 an incidence rate of 0.45 ( $P < 0.001$ ), and children aged 4 a rate of 0.29 ( $P < 0.001$ ). Likewise, nondysentery diarrhea incidence fell with age. Compared with children under 1 year, children aged 1 had an incidence rate ratio of 0.68 ( $P = 0.003$ ) for days of nondysentery diarrhea, children aged 2 an incidence rate of 0.67 ( $P = 0.002$ ), children aged 3 an incidence rate of 0.52 ( $P < 0.001$ ), and children aged 4 a rate of 0.47 ( $P < 0.001$ ). Children drinking water from standpipes were at somewhat lower risk of dysentery with an incidence rate ratio 0.77 for days of dysentery, but the associated confidence interval was wide (0.41–1.4). However, water source was adjusted for in the analysis of the effect of SODIS in view of the absolute effect size.

Table 2 shows the incidence rate ratios for each end point with estimates adjusted for water source (standpipe versus other water source), study area (entered as 5 dummy variables), and child age in whole years (4 dummy variables). Dispersion was parameterized by study area (5 dummy variables). All diarrhea end points were significantly reduced by use of solar disinfection, with reductions of roughly 50% in the incidence of dysentery and approximately 30% in the incidence of nondysentery diarrhea.

We used interval regression to compare *E. coli* concentrations in storage and SODIS bottle water in intervention households. *E. coli* concentrations were transformed to  $\log_{10}$  units as described in the Methods section before analysis. There were data available on 516 households at visit 1 (24 to 34 weeks from trial start), and 468 households at both visit 2 (34 to 40 weeks) and visit 3 (47 to 55 weeks). 50% of samples from stored household water had 10 CFU/100 mL or less; however, 23% had 100 CFU/mL or more. We compared storage water quality in control

**Table 2. Incidence Rate Ratios for Dysentery and Nondysentery Days and Episodes with Estimates Adjusted for Water Source, Study Area, and Child Age**

end point	incidence rate ratio	95% Ci	sig
dysentery days	0.56	0.40 to 0.79	<0.001
dysentery episodes	0.55	0.42 to 0.73	<0.001
nondysentery diarrhea days	0.70	0.59 to 0.84	<0.001
nondysentery diarrhea episodes	0.73	0.63 to 0.84	<0.001

and SODIS households using interval regression. *E. coli* concentrations did not differ over the follow-up period between control and SODIS households ( $z = -1.56$ ,  $P = 0.119$ ).

Water samples from SODIS bottles showed lower concentrations of *E. coli* at each visit, as shown in Table 3. The use of interval regression requires transformation of the data to logarithmic units. The values for storage water, back-transformed, correspond to geometric mean values of 8.4, 5.1, and 3.2 CFU/100 mL at the three time points, while the geometric mean values for the SODIS bottle samples represent 0.3, 0.2, and 0.1 CFU/100 mL, respectively. The coefficients for the difference correspond to the ratio between the storage and SODIS samples, which are 31, 30, and 22 at the three follow-ups, respectively.

Height and weight measurements were available on 656 children at visit 1, 653 at visit 2, and 632 at visit 3. There was no significant difference between SODIS and control groups in the numbers of measurements made at each visit (Chi-squared test,  $P = 0.972$ ). We examined height-for-age and weight-for-age by modeling the effects of age on each parameter as a two-term fractional polynomial, having verified that no significant improvement in fit was obtained by modeling age as three parameters. The effect of SODIS was modeled by converting the length of time on SODIS to a fraction of a year, allowing calculation of the effect of a year on SODIS. Median weight in the children in the control group at age 1 was 10.0 kg, 25th percentile 9.2, 75th percentile 11.1 kg. At age 5, median weight was 16.4 kg, 25th percentile 14.9, 75th percentile 17.8 kg. Median height-for-age was significantly increased in those on SODIS, corresponding to an average of 0.8 cm over a 1-year period over the group as a whole (95% CI 0.7 to 1.6 cm,  $P = 0.031$ ). Although median weight-for-age was similarly higher in those on SODIS, corresponding to a 0.23 kg difference in weight after a year on SODIS, the confidence interval spanned zero and the effect fell short of statistical significance (95% CI  $-0.02$  to 0.47 kg,  $P = 0.068$ ). An examination of weight for height revealed no significant effect of length of time on SODIS ( $P = 0.351$ ).

## DISCUSSION

This study adds to the evidence of the effectiveness of solar disinfection as a public health measure to reduce the risk of childhood dysentery. SODIS was associated with a reduction of 44% in the incidence of dysentery days and a reduction of 30% in nondysentery diarrhea days. The use of diarrheal diaries allows dysentery and nondysentery diarrhea to be analyzed separately. In addition, the use of diaries allows analysis using either days or episodes. This is important, as the mortality risk associated with diarrheal disease in children is associated with dysentery rather than nondysentery diarrhea.<sup>38</sup> Bloody diarrhea in children is a sign of intestinal infection caused by invasive enteric bacteria often associated with *Shigella*. Of the *Shigella* species pathogenic to man, *Shigella boydii*, *S. flexneri*, *S. sonnei*, and *S. dysenteriae* type 1,

**Table 3. *E. coli* Concentrations (log<sub>10</sub> cfu/100 mL units) in Untreated Water Storage Containers and SODIS Bottles at Each Follow-up Visit<sup>a</sup>**

visit	<i>E. coli</i> , storage container water (log <sub>10</sub> cfu/100 mL)	<i>E. coli</i> , SODIS bottle (log <sub>10</sub> cfu/ 100 mL)	difference (95% CI) (log <sub>10</sub> cfu/ 100 mL)	sig
1	0.923	-0.562	-1.48 (-1.73 to -1.24)	<0.001
2	0.707	-0.770	-1.48 (-1.70 to -1.26)	<0.001
3	0.501	-0.847	-1.35 (-1.62 to -1.08)	<0.001
all visits	0.723	-0.727	-1.45 (-1.60 to -1.30)	<0.001

<sup>a</sup> Mean levels and confidence intervals calculated by interval regression.

*S. flexneri* is the main cause for endemic shigellosis in developing countries<sup>39</sup> *S. dysenteriae* type 1 is associated with epidemic and endemic shigellosis<sup>40</sup> Most endemic shigellosis occurs in children between 6 months and 3 years of age.<sup>41,42</sup> Shigellosis also causes loss of important micronutrients for example zinc<sup>43</sup> and vitamin A,<sup>44</sup> contributing to the nutritional deterioration of children and consequently adversely affect growth.<sup>45</sup>

The etiology of diarrheal illness among the study population during this intervention is not certain. However, several of the authors conducted a study of prevalence of pathogens in the stools of rural Maasai children under age 5 years within the current study area in the mid 1990s.<sup>46</sup> The most common pathogens isolated from the 70 samples at that time were *Giardia lamblia* (31%), *Entamoeba histolytica* (23%), enteropathogenic *Escherichia coli* (13%) *Strongyloides stercoralis* (4%), *Blastocystis hominis* (3%), and *Cryptosporidium sp* (3%). Although all samples were screened for *Campylobacter* and rotavirus, neither pathogen was detected. While no information was available regarding shigellosis within this population, the presence of dysentery causing pathogen *E. histolytica* indicated that amoebic dysentery would not be unexpected. Co-infection with enteropathogens was common with two, three, and four species detected in 18.6%, 1.4%, and 1.4%, respectively, of the same samples studied. However, no pathogens were isolated from 47.2% of the samples. More recently a four year laboratory-based surveillance for bloody diarrhea at five clinics in Western Kenya analyzed 451 stools for the presence of *Shigella*. *Shigella* was the most common pathogen, 198 (44%) of the isolates of which 97 (22%) were *S. flexneri*, 41 (9%) *S. dysenteriae* type 1, 13 (3%) *S. boydii*, and 8 (2%) *S. sonnei*. *Campylobacter* (33 isolates), nontyphoidal *Salmonella* (15 isolates), and a single *Vibrio cholera* O1 were also isolated. *Shigella* was the main cause of bloody diarrhea, and the most common isolate was *S. flexneri*.<sup>47</sup> Other studies conducted in African countries reported similar results.<sup>48,49</sup>

Although much evidence exists on how improving the water quality at the point-of-use dramatically improves water quality and subsequently reduces diarrhea as much as 40% at household levels,<sup>50-53</sup> Schmidt and Cairncross<sup>6</sup> concluded that the true effect size, for specifically home water treatment interventions is strongly biased. Confirmation of bias seems apparent in published blinded home-based water quality trials that failed to show any significant effect on diarrheal disease reduction.<sup>54-56</sup> Schmidt and Cairncross<sup>6</sup> suggested that household water treatment intervention studies should either be blinded or include, as the primary outcome measure, an objective outcome such as mortality, weight gain, or growth. These types of measurements cannot easily be influenced by bias and therefore have the ability to show whether the effect size can truly be attributed to the intervention or not. This trial addresses the concern that

reported associations between SODIS and diarrheal disease may be due to biased reporting on the part of participants, due to the unblinded nature of the trials. The fact that while SODIS and control communities did not differ in their source water quality, but water samples taken from SODIS bottles had lower bacterial levels, provides plausible support for the association being causal. More importantly, however, this is the first trial to show evidence of the effects of SODIS on childhood anthropometry, with a statistically significant difference in the height-for-age of children on SODIS (0.8 cm 95% CI 0.7 cm to 1.6 cm,  $P = 0.031$ ) compared with children in the control group. These findings should go some way toward alleviating the concern expressed by some commentators that the lower rates of dysentery associated with SODIS are the product of biased reporting by parents rather than reflective of genuinely decreased incidence. The failure to find a significant difference in weight for age may suggest that the observed effect in height may be a false positive finding. However, the considerably greater measurement error entailed in measuring child weight compared with child height may have meant that the study had greater statistical power to detect effects on height than on weight. We should add that the recommendation made by some critics that SODIS be tested in a double-blind fashion reveals a lack of awareness of the conditions in which the communities live who most would benefit from household water treatment. The essential simplicity of SODIS, and the low labor cost, would be lost in the complex organization of a double-blind trial with daily deliveries of anonymized bottles of water, making the trial of questionable external validity, even supposing the resources and organization could be mustered. The gain in height shown in this study is consistent with an effect on child health mediated through the significant reductions in reported dysentery and nondysentery diarrhea. While we cannot rule out observer bias in the measuring of children, the effects demonstrated here are small and unlikely to be detectable by field staff in individual children. Indeed, field staff reported in feedback sessions that they were disappointed by the lack of any apparent difference in the growth of children in the SODIS arm, making biased reporting less likely.

Compliance or the motivation to adhere in a sustainable way to the protocols set for water quality interventions is greatly influenced by human behavior and has been problematic in previous SODIS studies.<sup>28,29</sup> Furthermore, assessing compliance in trials of this sort is problematic. Observing whether participants have SODIS bottles on their roof suffers from the problem that once field staff appear in a community, bottles appear rapidly on roofs on which they had not been previously. This form of courtesy bias also affects self-reported use of SODIS. More significantly, households that are more compliant with the trial protocol are likely to differ from less compliant households in other health behaviors, potentially biasing any analysis of the

effect of compliance. In a previous report, we used compliance with diarrheal data recording as a measure of participant motivation, which allowed comparison between intervention and control groups adjusted for the potential bias associated with degree of compliance. We reported that participants who were more than 75% compliant with diarrhea recording were likely to benefit from SODIS, but below this level there was no statistically significant benefit.<sup>30</sup>

In the present study, participants maintained good compliance in spite of very difficult circumstances created by political violence that broke out after elections in December 2007. However, compliance was partly dependent upon external factors, due to the displacement of a significant proportion of the study population, and the data available do not allow us to replicate our previous analysis which used completeness of diarrhea recording as a proxy for protocol compliance.

Compliance is driven by socio-economic circumstances, belief, education, the perceived need and benefits of an intervention, the general opinion of the community, compatibility of the intervention to existing values and past experiences, the degree to which results are visible<sup>57</sup> study design and the procedures followed to implement and communicate an intervention.<sup>58,59</sup> Different cultural and geographical settings naturally elicit different responses to a new idea such as a water quality intervention. In addition unexpected external factors, for example political upheaval, as experienced in Kenya or an infectious disease outbreak can derail adherence to any water quality intervention. Factors that contributed to the good compliance in this study are the need for clean water, poverty (UNICEF estimates that in Kenya, gross national income per capita in 2009 was US\$770, and 20% of the population are below the international poverty line of US\$1.25 per day<sup>60</sup>), and subsequently the inability to pay for medical treatment. Anecdotal information confirmed that SODIS water bottles were sought after items and carers believed that their children had fewer incidences of diarrhea reducing costs for medical treatment. In addition the study was extremely well managed by well informed, educated, and positive field coordinators, and participant motivation was probably enhanced by the remarkable role that the field staff played in providing aid during the ethnic violence and its aftermath, despite personal danger. These characteristics have been shown to be important aspects for the success of a water quality intervention.<sup>58</sup>

The present study adds to the growing literature on the utility of SODIS in the reduction of risk of diarrheal disease. The unanswered questions now are the factors which affect adherence to SODIS, and the comparative merits of SODIS and other household water treatment methods such as filtration and chlorination, and, most importantly, the question of how to introduce household water treatment into communities in such a way as to make sustained changes to behavior.

## ■ ASSOCIATED CONTENT

📄 **Supporting Information.** Table 1 and Figures 1 and 2. This material is available free of charge via the Internet at <http://pubs.acs.org>.

## ■ AUTHOR INFORMATION

### Corresponding Author

\*Phone: +353 1 4022207. E-mail: [kmcguigan@rcsi.ie](mailto:kmcguigan@rcsi.ie).

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