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High Compliance Randomized Controlled Field Trial of Solar Disinfection of Drinking Water and Its Impact on Childhood Diarrhea in Rural Cambodia

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Supporting Information

ABSTRACT: Recent solar disinfection (SODIS) studies in Bolivia and South Africa have reported compliance rates below 35% resulting in no overall statistically significant benefit associated with disease rates. In this study, we report the results of a 1 year randomized controlled trial investigating the effect of SODIS of drinking water on the incidence of dysentery and nondysentery diarrhea among children of age 6 months to 5 years living in rural communities in Cambodia. We compared 426 children in 375 households using SODIS with 502 children in 407 households with no intervention. Study compliance was greater than 90% with only 5% of children having less than 10 months of follow-up and 2.3% having less than 6 months. Adjusted for water source type, children in the SODIS group had a reduced incidence of dysentery, with an incidence rate ratio (IRR) of 0.50 (95% CI 0.27−0.93, $p = 0.029$). SODIS also had a protective effect against nondysentery diarrhea, with an IRR of 0.37 (95% CI 0.29−0.48, $p < 0.001$). This study suggests strongly that SODIS is an effective and culturally acceptable point-of-use water treatment method in the culture of rural Cambodia and may be of benefit among similar communities in neighboring South East Asian countries.

INTRODUCTION

Solar disinfection (SODIS) is a point-of-use household water treatment and storage intervention that has been the topic of much study in the past 15 years. The method involves filling transparent containers with biologically contaminated water and exposing the containers to direct sunlight. The resulting thermal (temperature >45 °C) and optical (UV-A light) pathogen inactivation processes produce water that is considered microbiologically safe to drink after ≥6 h exposure.[1−3] PET bottles have been the transparent container of choice due to their availability in most communities, robustness, lightweight, and efficient transmittance of UV-A.[4] While a large body of research has proven how effective the technique is within the laboratory environment,[4−12] published field-based trials of its efficacy in human populations are much scarcer.[13−19]

From a cost and technology perspective, SODIS is an attractive solution to the problem of household treatment and storage of drinking water, since it costs very little to implement[20] and requires minimal training or specialized equipment, usually a discarded plastic drink bottle is all that is required. Therefore, it is of concern that several recent trials have reported low compliance levels for SODIS field studies. A trial of solar disinfection in Bolivia by Mäusezahl and colleagues in a setting of very low compliance failed to show a statistically significant reduction in diarrheal disease, although a reduction in diarrhea was observed for both the test and control communities.[16] Despite intensive health promotion activity, compliance with SODIS in this trial was the lowest reported in any SODIS study at 32%, and the relative risk of diarrhea was 0.81 (95% confidence interval 0.59−1.12). A study of SODIS in a South African periurban environment by du Preez and co-workers in 2009[19] also reported low compliance levels. Dysentery incidence rates were lower in those drinking solar disinfected water (incidence rate ratio 0.64, 95% CI 0.39−1.0, $P = 0.071$) but not statistically significant. 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, $P = 0.014$). However, there was no significant reduction in risk at lower

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levels of motivation. A statistically significant reduction in dysentery was achieved only in households with higher motivation, showing that motivation is a significant determinant for measurable health gains.

The results reported in the current study are from one of a series of similar trials funded by the Irish government (HRB project no. GHRA-2006-001) and the EU (contract no. FP6-2006-INCO−DEV-3−031650), which were carried out simultaneously in Cambodia, Zimbabwe, Kenya (ClinicalTrials.gov Registration: NCT01306383), and South Africa (ClinicalTrials.gov Registration: NCT01082107), as part of the EU FP7 SODISWATER project. One of the primary aims of this project was to examine the health impact of SODIS on similar size cohorts in a variety of socio-economic and environmental settings. Cambodia was chosen for several reasons: (i) very little data were available for rural SODIS users outside the African continent, particularly with regard to impact on incidence of dysentery; (ii) no SODIS trial had been attempted in South East Asia at the time that funding was sought; (iii) it was expected that the spectrum of waterborne pathogens in South East Asia would differ significantly from that encountered in previous African studies; (iv) we were keen to explore whether the social, community, and cultural influences in Cambodia might have an effect on protocol compliance or adherence rates compared with the other SODISWATER locations in S. Africa, Kenya, and Zimbabwe. The results of the South African arm of this study have already been reported elsewhere.[19]

PARTICIPANTS AND METHODS

Ethics Statement. Ethical approval was obtained from the National Ethics Committee for Health Research, Ministry of Health, Royal Government of Cambodia on November 3, 2006 via a letter no. 104 NECHR. Permission to conduct the study was obtained from the national, local authorities, and community leaders.

Study Sites. The trial was based among rural subsistence farming communities in the provinces of Prey Veng (PV) and Svey Rieng (SR) in the South East of Cambodia toward the border with Vietnam (see Supporting Information, Figure 1). Specifically the study occurred in the districts of Ba Phnom (PV), Kampong Trabaek (PV), Me Sang (PV), and Romeas Haek (SR), within a 40 km radius of the village of Me Sang (11°10″ N, 105°44″ E).

Prey Veng and Svay Rieng are among the poorest provinces of Cambodia, based on population below poverty line. These provinces are a part of the Mekong river flood zone and have recurring floods. Both are also susceptible to droughts when the rainy season either starts late or ends early. Prey Veng and Svay Rieng provinces have mortality rates in children aged under 5 years of 143 and 110 per 1000 live births, respectively, which is much higher than the national average of 83. Similarly, the prevalence of diarrhea with blood among the children under the age of 5 years was found to be higher in Prey Veng (3.1) and Svay Rieng (3.3) compared to the national average (2.5).[21]

Eligible Households. Households were recruited on a village-by-village basis. Adults from eligible households were invited to come to a village briefing meeting to introduce SODIS and the trial. Eligible households were permanent households within the village boundaries with children aged between six months and five years who were normally resident there. Households already using other methods of water treatment such as ceramic filtration were excluded. At the briefing meeting, householders who were interested in taking part in the study were identified. These households were then randomized using a raffle system into control and intervention households. Control households were assured that if SODIS offered a significant reduction in risk of diarrheal disease, they would be trained and given bottles and corrugated iron sheets at the end of the study period.

Written informed consent was obtained from the household head or carer of the children of the participating households after details of the study were explained to them. Oral rehydration salts were provided to carers of children with persistent diarrhea. Field staff were provided with a manual describing all the project procedures and were thoroughly trained about SODIS, the scope and aim of the project, ethical conduct, data capturing on the hard copy forms, and evaluation of the correctness of data on diarrhea incidence reported daily by parents or carers. A database was developed to enter all the hard copy data collected from the field and the staff were thoroughly trained in cleaning the data collected in the hard copy as well as the data that was entered manually into the database. Field staff visited households at least every two weeks to collect and distribute diarrheal diaries and to assist with difficulties experienced with completion of the diaries. Field staff were supported by the community leaders and key members of the community during the monitoring process to encourage households to do SODIS.

Baseline Information. Almost all of the households (97%) obtained water from unprotected boreholes. An important subgroup of these, 25%, drew water from shallow tube wells fitted with hand pumps. The remainder used unprotected wells or surface ponds (see Figures 2 and 3 in the Supporting Information). Water was stored at the dwelling before drinking in 95% of the households. Of the households who stored their water, 71% stored it in large 300 L lidded cement containers (sample shown in Figure 4 in the Supporting Information) while 23% used plastic containers of varying volume. 84% of the households used the water from storage for drinking as well as for other purposes in the households. 69% of the households did not treat water before drinking. Of those households who treated their water, 73% boiled it sometimes (i.e., not on a regular basis and usually only when a child was ill), 9% used ceramic or biosand filters, and 14% used other methods such as filtering through clothes and/or mixing herbs in the water.

The person responsible for cooking regularly washed their hands in 94% of the households. Out of the households, 72% wash their hands only with water, and 25% use soap. The members of 97% of the households wash their hands before eating. Of these households, 73% use only water, and 22% use soap. 93% of the carers reported that their children wash their hands before eating. Of these children, 77% used only water, and 22% used soap. 49% of the carers interviewed said that they washed their hands after changing soiled clothes of the children. Only 7% of the households have access to latrines; the majority of households use open fields for defecation.

Sampling and Surveillance. The primary health outcome of the study was days on which the child had dysentery, defined, according to Baqui, as any loose stool that contained blood or mucus.[22] Nondysentery diarrhea was defined as three or more loose or watery stools on the same day. A dysentery episode was defined, following Baqui, as one or more consecutive dysentery days followed by three consecutive days on which neither dysentery nor nondysentery diarrhea occurs. A nondysentery diarrhea episode was similarly defined.

Diarrhea was recorded using pictorial diaries similar to those used in the South African study but translated into Khmer, the local language. These were used to record the child's stools each day using a "smiley face" for normal stools and a "sad face" for each loose or watery stool passed. A checkbox is ticked if any stool contains blood or mucus.[23] Follow up started in March 2009 and ended in March 2010.The parents or carers in every participating household were given verbal and written information on the disease concept and a simple explanation of the solar disinfection process and its effect on the microbial quality of their drinking water and subsequently the health of their children. They were trained in the use of SODIS and the completion of diarrhea diaries. Baseline household information with regard to basic hygiene, sanitation, and water use practices was also collected. Intervention households were provided with two transparent 2 L plastic bottles for each child participating in the study and a sheet of corrugated iron on which to place these to expose them to sunlight (see Figure 5 in the Supporting Information). Carers 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 adhered to a "first thing in the morning, last thing in the evening" regimen. Consequently, each child in the intervention group drank from a bottle that had been solar disinfected on the previous day. Treated water was consumed on the day after exposure and never allowed to stay in the container for more than 48 h so that the possibility of regrowth of partially inactivated bacteria was minimized. Carers were advised that, where possible, children in the intervention group should drink directly from the bottle rather than filling a cup or other container, which may have presented a risk of recontamination of the treated water.

Carers for each child in the control group were not provided with SODIS bottles and instead were instructed to maintain their usual practices for collecting and storing drinking water. The main study took place over a 12 month period during which diarrheal incidence was recorded daily for both control and test children using a pictorial daily diarrhea diary that was completed by the caregiver for each child and collected on a regular two week cycle. Water from the storage containers and SODIS bottles was collected every 3 months in commercially available 100 mL sample bottles to test water quality in the SODIS (intervention) and storage (control and intervention) containers. Samples were transported on ice and water quality analysis occurred on the same day.

At the time of diary collection, intervention group 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. Field staff regularly reminded the SODIS group about the technique and inquired if they were still using the technique.

Qualitative Evaluation. In a qualitative evaluation of the study, carried out six months after study completion, a purposive sample of 26 members of the community was interviewed. This included both those in the SODIS and control groups ($N = 22$) as well as four villagers who had not taken part in the original study but had started using SODIS either during or soon after the study period, so-called "SODIS Self-Adopters". Interviews were conducted through a local translator. To minimize the intrusiveness of the process, notes were written up immediately after each interview by the interviewer and translator.

Table 1

group	mean days of data	mean days of dysentery	mean days of other diarrhea	number of children	number of households
control	381	0.27	15.0	426	375
SODIS	377	0.15	5.7	502	407

Statistical Methods. 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 in advance, we carried out a series of calculations based on rates of 1−10 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 days per child per year and clustering effects were strong ($\rho = 0.2$). The sample provided more than 90% power to detect a 20% reduction where baseline incidence rates were two days per child per year or greater.

Data were analyzed with Stata/SE, Release 11. Fecal coliform counts from the intervention and control groups, expressed on $\log_{10}$ units, were compared using interval regression, which allows estimation of means for data in which some values are above or below detection limits. Samples in which no fecal coliforms were observed were classed as "less than one colony forming unit (CFU) per 100 mL," and samples in which the maximum detectable value (5170 CFU/100 mL) was observed were classified as 5170 or greater. 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. Data were stratified on district (four levels) with the primary sample unit identified as village (19 units) and the second-stage sample unit of household.

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.

RESULTS

A total of 928 children participated in a 1 year trial (Table 1). Drop out was negligible, with only 5% of children having less than 10 months of follow-up and 2.3% having less than 6 months. There was no significant difference in follow-up rates in SODIS and control children.

The rate of dysentery was low overall; 7.8% of children in the control and 4.6% of children in the intervention group had one or more days of dysentery in the study period of just over a year. On the other hand, nondysentery diarrhea was common; 89% of control and 72% of SODIS children had one or more days of diarrhea in the study period.

Water supply type was an important determinant of dysentery. Children in houses using shallow hand-pumped tube wells had a significantly increased risk of dysentery with an incidence rate ratio (IRR) of 2.1 for days of dysentery (95% CI 1.2−3.9, $p = 0.033$). However, children in households with tube wells were not at increased risk of nondysentery diarrhea (IRR for days of nondysentery diarrhea = 0.90, 95% CI 0.72−1.1, $P = 0.389$).

Overdispersion of dysentery rates varied systematically by villages. Accordingly, dummy variables representing villages were used to model the dispersion parameter, alpha, to account for this. Adjusted for water source type, children in the SODIS group had a reduced incidence of days of dysentery, with an IRR of 0.50 (95% CI 0.27−0.93, $p = 0.029$). This risk reduction corresponds to a preventable fraction of 50% (95% CI 7−73%).

SODIS also had a protective effect against days of nondysentery diarrhea, with an IRR of 0.37 (95% CI 0.29−0.48, $p < 0.001$). The corresponding preventable fraction is 63% (95% CI 52−71%). We repeated this analysis using episodes of dysentery and nondysentery diarrhea and found reductions of similar size: for episodes of dysentery, the incidence rate ratio was 0.40 (95% CI 0.20−0.78, $P = 0.008$), and for episodes of nondysentery diarrhea, the ratio was 0.38 (95% CI 0.30−0.47, $P < 0.001$).

We used interval regression to examine the effect of SODIS on fecal coliform levels, with robust variance estimation based on clustering of observations within household. Over all three follow-up visits, drinking water samples from households in the control group had a mean of 1.68 $\log_{10}$ CFU per 100 mL, while those in the SODIS group had a mean of 0.83 $\log_{10}$ CFU per 100 mL, a difference of 0.85 $\log_{10}$ units (95% CI 0.70−1.0, $P < 0.001$). Transforming these values to CFU gives geometric mean values of 48 CFU per 100 mL in the control and 6.8 CFU per 100 mL in the SODIS group. The difference in fecal coliform levels was significant, and of a similar size, at all three follow-up visits (data not shown). Over the follow-up period, only 25.4% of water samples from SODIS households had ≥ 10 CFU per 100 mL, against 71.1% in controls, giving a relative risk of 0.14 for the presence of ≥ 10 CFU per 100 mL associated with SODIS (95% CI 0.11−0.18, $P < 0.001$, adjusted for clustering within household).

DISCUSSION

The trial adds to the evidence of the utility of SODIS in the prevention of diarrheal disease. While the earliest studies[13−15] were carried out in areas of high incidence, leaving a doubt as to the effectiveness of the method in settings of lower incidence,[16,19] this study, by way of contrast, is in a setting with a low incidence of dysentery, although this must be set in the context of a significant incidence of nondysentery diarrheal disease.

Despite the low incidence of dysentery, SODIS was associated with a 50% reduction in risk, and with an even greater reduction in risk of nondysentery diarrhea. This reduction was paralleled by an observed reduction in the faecal contamination of drinking water, with three-quarters of SODIS water samples falling below 10 CFU per 100 mL, against less than a third of control samples. This improvement in water quality was seen at all three follow-up visits.

The trial was marked by a high degree of motivation on the part of the participants. In a previous paper,[19] we reported that participants in a SODIS trial in South Africa only achieved a significant reduction in dysentery if they had at least 75% compliance with the trial protocol. In this study, more than 95% of participants would have met this criterion, both in the SODIS and control groups. The reasons for the high level of participant engagement with the project probably stem from two sources. First, the method of recruitment differed from previous trials: in this trial, participants were recruited from householders who attended an information meeting, and allocation to SODIS or control was done using a public "lucky draw", with those randomized to the control group given the promise of SODIS after the end of the trial. These circumstances ensured that the trial participants were the most motivated members of their community, and the allocation by lucky draw made SODIS a resource in the community where demand exceeded supply. We should point out that, in these rural communities, plastic bottles are in short supply. Several villages that we visited in the qualitative phase had adopted the policy of only buying soft drinks in 2 L clear bottles for festivities and functions in order to increase the available supply of bottles for SODIS later. Alternatively, members of the extended family who worked in the larger cities were asked to bring 2 L bottles back with them whenever they returned to their home village. In addition to receiving bottles, SODIS households also received a piece of galvanized sheeting on which to leave the bottles in the sunshine. This, again, increased the perceived value of the intervention.

The second feature that resulted in high participant motivation came to light during these qualitative interviews. Householders in this area have abundant supplies of water, with a water table that is close to ground level, unlike many arid regions where considerable time is expended in fetching water. However, faecal contamination is common, and water must be boiled to make it safe. Since the area is intensively farmed, fuel is scarce, and householders have to purchase it. As a result, boiling water is only feasible for young children. Householders who were interviewed spoke positively about the savings in both time and money resulting from not having to boil water. They also praised the taste of SODIS water, which they said tasted like boiled water. Thus, SODIS accorded with cultural perceptions of "good" water: it was purified by heating, and it tasted like boiled water, reinforcing their conviction that it must be safe to drink. It is notable that, during the interviews, we observed a significant number of households with ceramic or sand filters that were not in use. When asked about these, householders felt that, while filters took the dirt out of water, it did not taste like good, boiled water.

Like most studies in the literature, this study is nonblinded and relies on participant reporting of disease end points. Some authors have been critical of the potential for bias that is associated with these trial characteristics.[24,25] Courtesy bias, in particular, may lead participants to report the outcomes that they think the field staff wish to hear. However, as Hartinger and colleagues[26] point out, the use of a blinded design would negatively affect compliance and inhibit the community dynamics, both of which are known to play a significant role in the process of adoption of new methods.[27] However, it remains possible that the results of this study are influenced by courtesy bias, and in addition, the close fit between SODIS treated water and the cultural construct of "good" water may have caused a placebo effect that might have caused participants to underrecognize diarrhea. Against this, however, we can point to significant improvement in the bacteriological quality of drinking water associated with SODIS treatment, which would support the hypothesis that the reduction in reported diarrhea rates was due at least in some part to improvement in water quality.

SODIS training and equipment (bottles and galvanized sheeting) were given to all control group participants following the trial, and both field visits and interviews with householders and community health workers following the trial showed that SODIS was in use by the majority of both intervention and control households six months after the end of the trial and was being adopted by community members who had not participated in the trial. This suggests strongly that SODIS is a culturally acceptable point-of-use water treatment method in the culture of rural Cambodia and may be of benefit among similar communities in neighboring South East Asian countries.

It also suggests that programs to introduce SODIS in communities might consider the model used in this trial, where a group of the most motivated households is given SODIS initially. Householders in the SODIS group reported that members of the community were initially dubious about SODIS and that neighbors would come to ask them how they found it, whether they had observed any effect on health, and to find out what the water tasted like. The SODIS group acted as an early adopter group, disseminating knowledge about SODIS and normalizing its use within their communities, so that by the end of the trial the community perception of SODIS had been shaped by their positive experiences.

■ ASSOCIATED CONTENT

Supporting Information. Map of Cambodia showing the project areas and photographs of an unprotected borehole fitted with a hand pump, one of the surface pond water sources, a 300 L lidded cement water storage container, and the standard arrangement for SODIS exposure at a study household. This material is available free of charge via the Internet at http://pubs.acs.org.

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Notes

The authors have no proprietary, professional, financial, or other personal interest of any nature or kind in any product, service, and/or company that could be construed as influencing the position presented in, or the review of, this work.

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