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Use, microbiological effectiveness and health impact of a household water filter intervention in rural Rwanda – a matched cohort study

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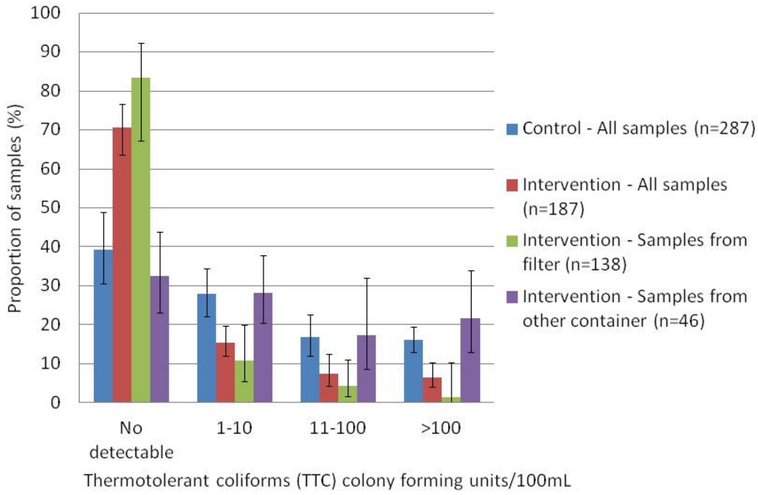
Graphical abstract



ABSTRACT

Unsafe drinking water is a substantial health risk contributing to child diarrhoea. We investigated impacts of a program that provided a water filter to households in rural Rwandan villages. We assessed drinking water quality and reported diarrhoea 12-24 months after intervention delivery among 269 households in the poorest tertile with a child under 5 from 9 intervention villages and 9 matched control villages. We also documented filter coverage and use. In Round 1 (12-18 months after delivery), 97.4% of intervention households reported receiving the filter, 84.5% were working, and 86.0% of working filters contained water. Sensors confirmed half of households with working filters filled them at least once every other day on average. Coverage and usage was similar in Round 2 (19-24 months after delivery). The odds of detecting faecal indicator bacteria in drinking water were 78% lower in the intervention arm than the control arm (odds ratio (OR) 0.22, 95% credible interval (CrI) 0.10-0.39, p<0.001). The intervention arm

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also had 50% lower odds of reported diarrhoea among children <5 than the control arm (OR=0.50, 95% CrI 0.23-0.90, p=0.03). The protective effect of the filter is also suggested by reduced odds of reported diarrhoea-related visits to community health workers or clinics, although these did not reach statistical significance.

KEYWORDS: household water treatment; water quality; faecal contamination; Rwanda

INTRODUCTION

Unsafe drinking water and household air pollution are two significant environmental health risks and contribute to diarrhoea and pneumonia, two major causes of death for children under 5 years of age (GBD 2015 Risk Factors Collaborators, 2016; Liu et al., 2014; Prüss-Ustün et al., 2014). In 2011, an estimated 700,000 deaths among children under 5 were due to diarrhoea (Fischer Walker et al., 2013b). In Rwanda, diarrhoea is a leading contributor to mortality in children under 5 years and is second after pneumonia, accounting for 9% of deaths in this age group (Liu et al., 2014), and unsafe water is estimated to be the third leading risk factor for overall disease (GBD 2015 Risk Factors Collaborators, 2016).

The 2014-15 Rwanda Demographic and Health Survey estimated 27.6% of the population use unimproved drinking water sources, with the majority residing in rural areas (National Institute of Statistics of Rwanda (NISR) et al., 2015). Access to improved water sources does not

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necessarily result in consumption of safe drinking water since not all improved sources are free of microbiological contamination (Bain et al., 2014). Moreover, since water is often collected and stored within the household after collection, additional contamination can occur during transit and storage (Wright et al., 2004). A recent nationally representative study found that more than 75% of households had drinking water with detectable thermotolerant coliforms (TTC), exceeding World Health Organization (WHO) guidelines for drinking water (Kirby et al., 2016; WHO, 2011).

There is increasing evidence that household drinking water quality is a determinant of diarrhoea (Hodge et al., 2016; Luby et al., 2015), and efforts to improve drinking water quality, such as by using filters, may reduce diarrhoea (Clasen et al., 2015; Wolf et al., 2014). Household water treatment is recommended by the WHO as an intermediate step towards ensuring safe drinking water supply and is part of a 7-point plan for comprehensive diarrhoea control (UNICEF/WHO, 2009; WHO, 2007). However, most of the studies to date have been short-term studies and use of interventions can change over time (Hunter, 2009). A recent systematic review and meta-analysis found that while shorter-term (<12 months) trials yielded protective effects from household water treatment interventions, none of the four trials with follow-up exceeding 12 months reported an effect on diarrhoea (Clasen et al., 2015). This could be due to a combination of declining usage over time, as well as non-exclusive use of the filter for consumption of drinking water. Moreover the health impact among non-blinded trials may be exaggerated due to reporting bias (Clasen et al., 2015). There is a lack of evidence regarding the long-term effectiveness of these technologies, particularly within a programmatic, scalable context.

In October 2012, a public-private partnership between the Rwanda Ministry of Health and DelAgua Health provided portable biomass-burning “rocket” cookstoves and household water filters to all households (1,943) in 15 villages located in 11 of Rwanda’s 30 districts. The

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intervention was distributed at a central location within each village and accompanied by behaviour change messaging and monitoring conducted by trained community health workers (CHWs) through quarterly-biannual visits (Barstow et al., 2014). A 5-month household randomized controlled trial (RCT) was conducted in three of the villages to assess the intervention's impact on household drinking water quality and household air pollution. The trial showed high uptake of the filter and was associated with a 97.5% reduction in TTC in drinking water despite non-exclusive use (Rosa et al., 2014b; Thomas et al., 2013a). However, the study did not assess health impact, and evidence for the sustained uptake and effectiveness of the intervention outside of a short-term intensive trial remains unclear.

We undertook a matched-cohort study to assess medium-term uptake of the filter 12-24 months after intervention receipt in order to determine its impact on faecal contamination of drinking water in the home and child diarrhoea. We used a matched cohort design since the intervention was pre-existing and was not randomly allocated to households or villages. The matched cohort design seeks to minimise the risk of unmeasured confounders by matching on characteristics likely to impact outcomes of interest (Austin, 2011; Stuart, 2010). This design has been used in other studies of pre-existing interventions where randomization is not possible (Arnold et al., 2009, 2010; Ercumen et al., 2015a).

MATERIALS AND METHODS

Village selection and matching

This study was based in the Southern and Western provinces of Rwanda, where most of the study population are engaged in agriculture. The setting is primarily rural, with study villages ranging from 1400-2500m in elevation. The area experiences two rainy seasons, with the "short rains" typically in September, October, November and December, and the "long rains" typically

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in March, April and May (Rwanda Meteorology Agency, 2016). Of the 15 villages that received the intervention in October 2012, nine were purposely selected for follow-up in this study. Three of the original 15 villages were excluded due to the previous RCT (Rosa et al., 2014b), and 3 were excluded due to low number of estimated eligible households and programmatic development activities.

Village-level matching was performed using a combination of restriction, propensity score matching, and rapid assessment (Arnold et al., 2009, 2010). Intervention villages were first exact matched to non-bordering potential control villages within the same health centre catchment area (sub-district). A post-intervention structured phone survey was then conducted in July 2013 and administered to one CHW from all intervention and potential control villages. The phone survey contained categorical questions on cooking and drinking water practices within the village, including drinking water sources and household water treatment methods, which the CHW answered as percentages by estimation. Additionally, pre-intervention household survey data from the nine intervention villages, originally collected by village CHWs for programmatic purposes in October 2012, were aggregated by village for additional matching to the indicators collected by the phone survey. Finally, the 2012 National *Ubudehe* Database was accessed to obtain the proportion of households and average household size by *ubudehe* category for each village (Rwanda Ministry of Local Government, 2011). *Ubudehe* categories are based on socioeconomic designations for each household by the Rwanda government in collaboration with community members. There are six *ubudehe* categories, with *ubudehe* 1 and 2 households comprising approximately the poorest 30% of the population.

Village-level data were thus combined from the above three sources. For intervention village-level data, characteristics likely to change due to the intervention, such as water treatment and cooking practices, were derived from the DelAgua household survey since it assessed these

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practices prior to receipt of the intervention. All other village-level characteristics were derived for intervention and control villages from the CHW phone survey and National *Ubudehe* Database. Potential control villages were restricted based on the implementer's original intervention village selection criteria which was intended to represent a typical rural village's water service and energy use (Barstow et al., 2014). Villages were restricted if more than 20% of households had piped water, more than 60% used water treatment other than boiling, more than 20% used cooking fuel other than biomass or charcoal, or more than 20% used a non-traditional stove (Barstow et al., 2014). After restriction, the pool of potential control villages for each intervention village ranged from 6-61 (mean=23 villages).

Propensity score matching using probit regression was then conducted using different combinations of the village-level covariates described above, given their potential relationship to drinking water quality and household air pollution which were the primary outcomes of interest (Brookhart et al., 2006). The mean bias of each fitted model was examined in an iterative process across the range of potential matching variables in order to obtain optimal covariate balance for all available covariates between arms (Imbens and Rubin, 2015). Using the propensity score from the optimal model, each intervention village was then matched to a control village within the same health centre catchment area using the nearest neighbour method (Austin, 2009; Rosenbaum and Rubin, 1985). Propensity score matching was performed using the Stata add-on package PSMATCH2 (Leuven and Sianesi, 2003).

Lastly, a rapid assessment was conducted in each of the selected control villages after visiting its respective intervention village. The rapid assessment consisted of a transect to qualitatively observe similarity to its paired village, and an in-person meeting between the staff supervisor and village's chief and CHWs. During the in-person meeting, the supervisor confirmed key variables used in the matching, including estimated total number of households, children under

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5 years of age, percent of households using improved water supply, primary household fuel type, primary household stove type, household cook times, and water treatment practices. Additionally, the chief and CHWs were asked to describe any changes in the village since October 2012 that could affect the primary and secondary outcomes.

Enrolment and eligibility

Households were enrolled and visited once between November 2013 and May 2014 (Round 1) and visited a second time between May 2014 and November 2014 (Round 2). The first household visit attempt at each round was unannounced. In each village, we enrolled all consenting households with a child under 5 years of age that belonged to the poorest socio-economic tertile (*ubudehe* groups 1 and 2) according to the 2012 National *Ubudehe* Database which includes head of household names for each village (Rwanda Ministry of Local Government, 2011). The large-scale rollout of DelAgua Health's carbon credit-financed distribution programme, which started in late 2014, targeted *ubudehe* groups 1 and 2, so we were most interested in assessing the long-term uptake and impact of the pilot within this demographic group (Nagel et al., 2016). Participating control households received a water filter and stove after completion of the study.

Description of water treatment intervention

The intervention, described in detail elsewhere (Barstow et al., 2014), included a household water filter, an advanced cookstove, in-home training, instructional materials, and repeated household visits to monitor and reinforce behaviour change. The filter was the Vestergaard-Frandsen Lifestraw Family 2.0, a table-top microbiological purifier with 5.5 litres of built in storage (Barstow et al., 2014). The filter utilizes gravitational pressure to remove bacteria, viruses and protozoa as the water passes through hollow fibre membranes. In laboratory testing, an earlier version of the filter with the same filtration membrane was found to have a 6-

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log reduction for bacteria, 4-log reduction for viruses, and 3-log reduction for protozoan cysts, and thus meets EPA standards (Clasen et al., 2009). The filter is designed to provide sufficient drinking water for a household for at least three years without replacing any consumables (Clasen et al., 2009). More recently, in results from the first round of the WHO International Scheme to Evaluate Household Water Treatment Technologies, the Lifestraw 2.0 was ranked 2 out of 3 stars offering “Comprehensive protection” (removing at least 2 $\log_{10}$ of bacteria, at least 3 $\log_{10}$ of viruses and at least 2 $\log_{10}$ of protozoa) (WHO, 2016).

Household survey

The field and laboratory team used for data collection and lab assays were trained and worked under the supervision of the study authors; they did not participate in the delivery or promotion of the intervention. At each visit, a household survey was administered to the primary cook of the household consisting of questions addressing household demographics and characteristics related to sanitation, hygiene, and drinking water practices. A socioeconomic status (SES) indicator was developed using polychoric principal component analysis (PCA) (Kolenikov and Angeles, 2009) based on household characteristics and durable goods ownership (household electricity, flooring material, wall material, radio, mobile phone, and bicycle ownership). The continuous PCA variable was divided into quintiles, and the variance explained by the first principal component was 0.535. Usage and condition of the filter was assessed using self-reported and observational indicators including frequency of use, whether the filter appeared to be accessible and in use (based on filter location and signs of non-use such as dirt/dust in and on the filter), and whether water was in the filter.

Primary and secondary outcome

The primary outcome for this study was household drinking water quality according to TTC in colony forming units (CFU) per 100mL, a WHO approved indicator of drinking water quality (WHO, 2011). Secondary outcomes included reported and observed use of the filter and primary

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caregiver-reported diarrhoea within the previous 7 days for children under 5 years of age. Diarrhoea was defined as three or more loose stools within a 24-h period, with a loose stool defined as any that can take the shape of a container (WHO, 2005). Additional self-reported outcomes according to the respondent included whether care from a CHW or health facility was sought for diarrhoea within the previous 7 days, and whether care was sought within the previous 3 months. Toothache was included as a negative control (Lipsitch et al., 2010).

Water quality testing

At the end of each visit, a 100mL sample of water a child under 5 would drink, be it directly from the water filter or other storage container, was collected and assessed for TTC using the membrane filtration technique (APHA, 2001). If a child under 5 was too young to drink water, the water the primary cook would drink was sampled. Source water quality was collected within 24 hours of the collection of a household sample. All water samples were collected in sterile Whirl-Pak bags (Nasco, Fort Atkinson, WI). After collection, samples were put on ice and processed within six hours of collection. Water samples were assayed for TTC on membrane lauryl sulphate medium (Oxoid Limited, Basingstoke, Hampshire, UK) and incubated for 18 hours at 44°C. Plates that yielded in excess of 300 CFU were deemed too numerous to count and were assigned a value of 300 CFU. One lab blank using distilled water and one duplicate were typically processed each sampling day and assessed for quality control purposes.

Sensors

In a random subsample of 79 households in Round 1 and 73 households in Round 2, use of the filter was monitored by temporarily replacing the householder's filter with an identical filter fitted with a cellular-reporting SweetSense usage sensor (Thomas et al., 2013b) (Figure 1). Households were eligible for sensor monitoring if the filter they owned was reported to be

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working properly at the time of the survey. Up to 21 households in each of the nine intervention villages were randomly selected to participate.

The sensored water filter was calibrated to detect changes in pressure in the upper container, indicating filling of the filter. The usage algorithms have been validated and described elsewhere (Thomas et al., 2013b). Sensor-equipped filters were deployed to households within two weeks after the household survey was conducted. Households were informed the sensor would collect performance data of the filter, but not told they would detect changes in water volume or frequency of use. Consenting households had the sensored water filter for a period of 7-30 days. During this monitoring period, the household's original water filter they had originally received was temporarily locked to prevent use. Sensor data were uploaded and interpreted as described elsewhere (Thomas et al., 2013a). The deployment and retrieval days were not included in analyses to reduce potential reactivity and have whole-day samples.

Precipitation data

In order to control for the potential impact of precipitation on water quality and diarrhoea (Kirby et al., 2016; Levy et al., 2016; Mukabutera et al., 2016), total precipitation within the previous 10 days to each household's survey date was included in analyses as a potential confounder (Ercumen et al., 2015b). Data were downloaded in Network Common Data Format (NetCDF) for each village centroid from Climate Hazards Group InfraRed Precipitation with Station data 2.0 (CHIRPS) (Funk et al., 2015), which comprises daily gridded precipitation data derived from satellite and in-situ station data at 0.05 degree spatial resolution (approximately 5.3km). Precipitation data were converted from NetCDF into raster format and joined to village centroid locations using ArcGIS 10.3 (ESRI, Redmond, CA, USA).

Sample size and study power

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In the design phase of this study, sample size calculations were based on the number of households needed to observe a 40% reduction in personal exposure to fine particulates among cooks in order to evaluate the impact of the improved cookstove component of the intervention. Thus, for the outcomes of household water quality and child diarrhoea we calculated minimum detectable effect size post-hoc using inputs (proportions in the control condition and intracluster correlation coefficients (ICC)) derived from the study data. Given a 61% prevalence of water samples with > 0 TTC/100mL in the control households, a within-village ICC of 0.05, a within-household (over time) ICC=.07, an average of 15 households per village, 9 villages per arm, and 15% attrition, the sample size allowed for a detectable 32% reduction from 61% to 42% of samples with TTC contamination, with 80% power. Minimum detectable effect for diarrhoea assumes one child per household. Given a 20% prevalence of diarrhoea in the control households, a within village ICC of 0.01, a within-child (over time) ICC of 0.05, an average of 15 households per village, 9 villages per arm, and 15% attrition, we were powered for a 50% reduction from 20% to 10% prevalence at 80% power.

Data Analysis

In order to compare the balance of household characteristics between arms, the standardized difference was calculated (Arnold et al., 2009; Rubin, 2007). The standardized difference is the difference of the means in terms of standard deviations, with a value of 0 indicating equal means and a value of 1 indicating a one standard deviation difference (Austin, 2011). Descriptive statistics, means, and cluster-robust confidence intervals of water quality measurements were adjusted for village-level clustering, which was the highest level of clustering in the data (Bottomley et al., 2016). Due to the skewed nature of the water quality TTC counts, Williams means are presented. To calculate the Williams mean, a value of 1 TTC was added to all water quality values, the geometric mean was calculated, and then 1 was subtracted (Alexander, 2012; Rosa et al., 2014b)

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We examined differences in water quality and 7-day reported diarrhoea between the control and intervention households using Bayesian multilevel logistic regression to account for the longitudinal, hierarchical data structure. For reported diarrhoea diarrhoea-related medical care visits, we fitted a 4-level, random intercept model, with two observations (level 1) per child (level 2), who were clustered within households (level 3) and villages (level 4). Models of household drinking water quality were 3-level random intercept models, with observations (level 1) nested within households (level 2) and villages (level 3). The dependent variables for water quality models were binary indicators of any detectable TTC/100mL vs. no detectable TTC/100mL and a separate model evaluating >10 TTC/100mL) vs. <10 TTC/100mL. Models were adjusted for individual, household, and village-level characteristics, and model coefficients were exponentiated to yield odds ratios.

Models were estimated using Markov Chain Monte Carlo (MCMC) with the Metropolis-Hastings algorithm. For multilevel models with discrete outcomes, MCMC methods yield unbiased estimates of both fixed and random model parameters and are robust to small numbers of clusters and small sample sizes (Browne and Draper, 2006; McNeish and Stapleton, 2016). We used diffuse, non-informative priors and estimated starting values for the MCMC chain using penalized quasi-likelihood. Given the complexity of the models, we used orthogonal parameterization to improve chain mixing and specified a burn-in length of 50,000 with a chain length of 2,000,000. We assessed chain mixing by visually examining traceplots and autocorrelation plots and convergence using the Raftery-Lewis and Brooks-Draper diagnostics (Browne, 2009). We obtained the means, 2.5%, and 97.5% values of the posterior distribution to calculate the point estimates and 95% credible intervals (CrI) of the true model parameters. The 95% CrI can thus be interpreted as the interval within which there is a 95% chance the true population values are included. All analyses were conducted using MLWin Version 2.1 (Browne,

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2009; Rasbash et al., 2009) and Stata 14 (College Station, TX) with the RunMlWin add-on package (Leckie et al., 2013).

Ethics and Consent

Primary cooks gave written informed consent to participate in the study. If the respondent could not sign their name, they supplied a thumbprint and a literate witness signed on their behalf after ensuring comprehension. This study was approved by LSHTM Ethics (6457) and Rwanda National Ethics Committees (494/RNEC/2013). This study was registered at ClinicalTrials.gov (NCT01998282).

RESULTS

Village matching

After restriction according to pre-defined characteristics, CHW phone surveys resulted in 201 potential control villages out of 336 villages that were within the same health centre catchment areas as intervention villages. Propensity score matching resulted in 9 potential control villages that were visited and confirmed during rapid assessment. Median bias, a summary indicator of the distribution of the absolute value of the standardized percentage bias measures of the individual matching variables, was 27.8 prior to matching, and reduced to 7.2 after matching (Table S1), indicating improved balance among potential confounders (Rosenbaum and Rubin, 1985). Bias was reduced in all variables except mean daily cooking times, which is unlikely to be a confounder of drinking water quality or diarrhoea.

Table 1 shows balance of household and child characteristics at enrolment between the intervention and control arms. Overall, the arms were well balanced on demographic, sanitation, hygiene, and water practice characteristics. However, source drinking water quality showed

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signs of slight imbalance, with a higher proportion of samples in the intervention arm having higher TTC contamination than controls (Table 1). Treatment of household water was higher in the intervention arm, and travel time to health facility also appeared to be imbalanced, with intervention households reporting less travel time than control households (Table 1).

Study participants

Overall, 269 households were enrolled into the study, with 113 households in the intervention arm and 156 in the control arm (Table 1). There were no reported refusals at enrolment or follow-up. Approximately 6 months after enrolment, 144 control households (92.3%) and 91 intervention households (80.5%) were followed-up and surveyed as part of Round 2 (Figure S1). There was one reported child death in between Round 1 and Round 2 surveys.

Filter coverage and use

In Round 1 (enrolment), 97.4% of intervention households reported receiving the intervention filter (Table 2). Of these households, 94.6% of households had the filter in the household at the time of visit, and 84.6% of filters were reported to be working. Coverage was similar at Round 2 (Table 2). With the exception of one household in Round 2, all households with a working filter reported they were currently using it (Table 2).

Of households with a working filter, over 85% of households in each round reported using the filter on the day of survey or previous day, and over 80% had water in the filter. Among all intervention households with drinking water stored in the home at time of visit (105 in Round 1, 81 in Round 2), 76 households (72.4%) indicated a child's drinking water would come from the filter and had water in it in Round 1, and 63 households (77.8%) in Round 2. Of the 91 intervention households that had a working filter at both round 1 and round 2, 54 (59.3%) reported using the filter on the day of visit or previous day at both visits, and 47 (51.6%) had

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water in the filter at both visits. Sensors confirmed usage of the filter, with 50.0% of households using the filter at least once on at least half of the days in which sensor data was available in Round 1, and 36.8% in Round 2 (Table 2).

Of households reporting they currently use the filter, 17.2% of respondents reported drinking unfiltered water the day of the visit or the previous day in Round 1, and 9.3% in Round 2 (Table 2). Respondents were more likely to report ever drinking unfiltered water when away from the household (33.3% in Round 1, 26.7% in Round 2) compared to when at their household (16.1% in Round 1, 21.3% in Round 2). Among children under 5 residing in households reporting current filter usage, approximately 10% drank unfiltered water the day of the survey or previous day in both Round 1 and Round 2 (according to primary caretaker) (Table 2). A higher proportion of households reported they had a child under 5 who ever drank unfiltered when away from the household compared to at the household (Table 2).

<u>Water quality</u>

A total of 478 household drinking water samples were collected (Table 3). In Round 1, 108 water samples were collected from intervention, and 149 from control households. In Round 2, 81 water samples were collected from intervention, and 140 from control households. Four samples were lost between the point of collection and the processing lab due to improper storage of the sample. In the intervention arm, 74.1% of households reported treating the water sample, compared to 1.3% of control households.

Using combined data from both rounds, household drinking water quality in control households overall had significantly worse water quality than intervention households, with a Williams mean of 6.3 TTC/100mL (95% CI, 4.6-8.5) compared to 1.3 TTC/100mL (95% CI, 0.9-1.9, $p<0.001$) in the

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intervention arm (Table 3). Within the intervention arm, households with drinking water from filter storage containers had less TTC contamination (WM 0.5, 95% CI 0.1-1.0) than intervention households that stored their water in another container (WM 8.7, 95% CI 4.7-15.4, $p<0.001$) (Table 3). Overall, 39.4% of control households had no detectable TTC (95% CI, 30.6-48.9%), compared with 70.6% of intervention households (95% CI, 63.7-76.7%) (Figure 2). Of 91 intervention households that provided water samples in both Round 1 and Round 2, 55 households (60.4%) had no detectable TTC at both visits, while of 144 control households with water samples in both rounds, 27 households (18.8%) had no detectable TTC.

Controlling for water source, toilet type, and rainfall within the previous 10 days, the odds of having detectable TTC were significantly reduced in the intervention arm, with an OR of 0.22 (95% CrI 0.10-0.39, $p<0.001$). A further sensitivity analysis among a subsample of households (276 total observations) was conducted, controlling for source water quality instead of source type since source type may not be an adequate proxy for source quality. This sensitivity analysis found there was an OR of 0.17 (95% CrI 0.04-0.35, $p<0.001$) controlling for source water quality (log TTC), demonstrating the effect of the filter on water quality remained protective despite the possible role of source water quality as a confounder.

Similarly, the odds ratio of having drinking water with more than 10 TTC/100mL in the intervention arm compared to control arm was 0.34 (95% CrI 0.18-0.56, $p<0.001$). Controlling for source water quality instead of reported water source, there was an OR of 0.26 (95% CrI 0.10-0.50, $p=0.001$) with source water quality as log TTC.

Child diarrhoea

Overall, one-week prevalence for reported diarrhoea was 19.3% in the control arm and 12.5% in the intervention arm, with greatest difference between the two arms occurring in Round 2

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(Table S2). Controlling for SES, age in months, gender, water source (improved vs. unimproved), and toilet type (improved vs. unimproved), and rainfall within the previous 10 days, children in the intervention arm had 50% lower odds of diarrhoea compared to children in the control arm (OR=0.50, 95% CrI 0.23-0.90, p=0.03). Separate models for seeking care from a CHW for diarrhoea within the last 7 days and seeking care for diarrhoea at a health facility within the last 7 days were not estimable due to low number of cases. Controlling for SES, age in months, gender, water source, toilet type, rainfall within the previous 10 days, and reported travel time to health facility, the odds ratio of seeking care from a CHW or at a health facility for diarrhoea within the last 7 days in intervention compared to control was 0.54 (95% CrI 0.18-1.21, p=0.13). The odds ratio of seeking care for diarrhoea at a health facility within the last 3 months was 0.60 (95% CrI 0.27-1.11, p=0.11), controlling for SES, age in months, gender, water source, toilet type, and reported travel time to health facility. Prevalence of the negative control of toothache among children under 5 within the previous 7 days was similar between control and intervention arms (overall, 3.9% and 3.8% respectively).

DISCUSSION

Previous research has shown household water filters to be protective against diarrhoea in the short term, but studies with follow up >12 months were not effective against diarrhoea (Clasen et al., 2015). The majority of studies have been small and conducted within the context of intensive research trials rather than at-scale programmes as delivered. This study found high coverage and continued use of a household water filter 12-24 months following intervention delivery. This was accompanied by improved household drinking water quality and reduced one-week prevalence of self-reported diarrhoea among children under 5 years.

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The levels of coverage and use of the filter were significantly higher than those reported on a large-scale intervention involving previous versions of the LifeStraw filter in Kenya (Pickering et al., 2015). This may be due in part to improvements in the design of the filter, from a hanging version (model 1.0) used in previous studies to the tabletop version (2.0) used here. The previous version may have been difficult to use; it also had no water storage chamber. The difference in effect may have also benefited from consistent engagement by the programmatic team. This included technical support, transport of broken filters between households and regional repair centres, involvement of CHWs who lived in the targeted communities, and dynamic and repeated behaviour change messaging and materials (Barstow et al., 2014). Most instances of non-use in the intervention arm were due to breakage or perceived breakage. The necessary backwashing frequency and cleaning frequency seemed to be key messages that were not followed consistently, and this led to clogged and unusable filters, as noted in previous studies (Barstow et al., 2014; Rosa et al., 2014b).

In addition to self-reported and observed usage, filter usage was confirmed by the sensor-equipped filters. Sensors may offer a more objective measure of usage and are able to provide usage statistics over an extended period of time, although they may still be subject to bias due to reactivity. Although households were not told the explicit nature of the sensor, it is possible that usage increased due to observer bias and other factors related to the presence of research staff in the village during the monitoring period (Arnold et al., 2015). A recent study among similar households in Rwanda demonstrated reactivity when households knew the sensor was present and measured filter usage, with households appearing to increase their usage for at least 30 days (Thomas et al., 2016). In this study, sensors were in households for 7-30 days due to logistical constraints, and it is possible the sensors do not reflect long-term usage. The range in the number of days sensors were deployed within households was largely dependent upon the number of study households within the intervention village and its matched control village,

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resulting in differing amounts of time study personnel (and sensors) were in each village. This further diminishes the generalizability of usage data generated by the sensors. The mean volume filtered per day and the overall less than 50% of household sensor deployments that were adherent (defined as at least one filter fill on at least half of analysable transmit days) suggests consumption of filtered water is below WHO recommendations (Grandjean, 2005). This may be due to under-consumption of water and/or preference for other types of beverages, as well as consumption of non-treated water both at and away from the household, challenges identified in earlier evaluations of the intervention (Barstow et al., 2014; Rosa et al., 2014b).

Consistent with potential under-consumption of filtered water as indicated by the sensors, this study found non-exclusive consumption of filtered water by both children and adults, particularly whilst away from the household. Since these behaviours were self-reported, non-compliance is likely underestimated, particularly for children who were not always supervised by the survey respondent (Rosa et al., 2016, 2014a). Previous work has identified non-exclusive and inconsistent use of household water treatment products as challenges in this and other low-income settings (Barstow et al., 2014; Boisson et al., 2013; Clasen et al., 2015; Peletz et al., 2012; Rosa et al., 2014b). This behaviour can diminish the health gains that are possible (Brown and Clasen, 2012; Enger et al., 2013; Hunter et al., 2009). Future research and behaviour change efforts should focus on ways to maximize the availability of filtered water and sustain exclusive and consistent use, both within and outside of the household.

Drinking water quality in the intervention arm was significantly less contaminated than in the control arm in both rounds and overall. The observed reductions in TTC contamination is consistent with other field-based studies of the LifeStraw filter, including version 1.0, a hanging model (Boisson et al., 2010; Peletz et al., 2013, 2012) and version 2.0, the tabletop model (Rosa et al., 2014b). Levels of faecal contamination in the control arm and in intervention households

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whose sample did not come from the LifeStraw were similar to other studies in Rwanda among households not using a LifeStraw filter (Kirby et al., 2016; Rosa et al., 2014b). Within the intervention arm, those who reported consuming water directly from the filter had significantly improved water quality compared to households that stored their water in other containers.

This study found significant reduced odds of child diarrhoea within the previous week among children in the intervention arm compared to the control arm. The magnitude of effect was similar to other filter studies. A recent systematic review found point-of-use water filters to reduce the risk of diarrhoea by about half, both for all ages (RR 0.48, 95%CI 0.38 to 0.59; 18 trials) and for children under five years of age (RR 0.49, 95% CI 0.38 to 0.62) (Clasen et al., 2015). This included 3 trials of LifeStraw filters that yielded a pooled reduction of 31% (RR 0.69, 95% CI 0.51 to 0.93).

This study has several limitations. We cannot exclude the possibility of courtesy bias that can occur with a non-blinded intervention, both for reported intervention usage and reported health impacts. A systematic review of household water treatment found that while non-blinded trials generally reported a protective effect, blinded trials generally did not (Clasen et al., 2015). There was no impact on the negative control of toothache, suggesting courtesy bias may have a limited role, although additional negative controls such as bruising/scraping and earache could have strengthened this check. It is also possible the implementer's health education and behaviour change messaging influenced respondent responses regarding health symptoms and/or usage behaviour, as reduced risk of diarrhoea was described as a benefit of consistent filter usage. Thus the effect on diarrhoea is potentially exaggerated, and there remains a need for more objective outcomes to overcome the weaknesses of this self-reported outcome (Clasen and Boisson, 2015), such as biomarkers of recent infection (Priest et al., 2006). A larger randomized study with confirmed health facility diagnoses of diarrhoea and other objective measures would

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help determine whether the filter is effective at preventing clinically significant cases of diarrhoea.

In some villages, study teams were present in the village for over a month and some households could have anticipated household visits by study personnel. Additionally, the implementers remained programmatically engaged with communities throughout the study. This could have influenced household behaviours and responses (Arnold et al., 2015; McCarney et al., 2007; Zwane et al., 2011). There was also high attrition in this study (12.6%), particularly among the intervention arm (19.5%). Reasons for this are unclear, although intervention villages with the lowest follow-up rates were visited during the July and August planting season (Table S3). The loss to follow-up is not believed to be due to unmeasured confounders or factors relevant to our outcomes of interest, and an analysis of household and child characteristics with complete vs. incomplete follow-up did not reveal notable differences (Table S4).

Additionally, we cannot rule out the potential role of unmeasured confounders that could impact water quality and diarrhoea since the intervention and control villages were not randomly selected. Possible confounders such as hygiene and sanitation characteristics were not accounted for in the matching procedure, although these characteristics were similar between the intervention and control arms. Timely household- or village-level census data could have improved the matching considerably, although there was good balance between the arms on key characteristics. Despite continued susceptibility to unmeasured confounding, the matched cohort design seeks to provide an unbiased counterfactual approximating a randomized design. Because the approach can be used to evaluate previously-delivered interventions, it may reduce the risk present in prospective randomized controlled trials where the intervention being evaluated is not delivered or embraced as intended. Its purpose is to match on potential confounders at the design phase in order to achieve a valid comparison group, reducing the bias

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and strengthening causal inference without relying on post-hoc modelling assumptions (Arnold et al. 2010)."

Lastly, this was a combined intervention of both a water filter and an advanced cookstove. While this paper has focused on diarrhoea and water quality as outcomes, we cannot rule out the possibility that the stove influenced the diarrhoea results. For example, the stove component of the intervention could have reduced immune system vulnerability to respiratory infections (Lee et al., 2015) and co-morbidity with diarrhoea, although reduced risk of diarrhoea is more likely to reduce pneumonia than vice versa (Ashraf et al., 2013; Fischer Walker et al., 2013a; Schmidt et al., 2009). Nevertheless, these results should be interpreted within the context of a combined intervention, although the causal pathway of improved drinking water due to the filter in turn resulting in reduced diarrhoea remains the most plausible explanation for our findings. Future research should examine the separate and combined impacts of household-based WASH and energy interventions.

Notwithstanding these limitations, this study does provide support for the potential value of scaling up the intervention. In particular, it demonstrates that use continues at high levels for up to 24 months—a major concern raised about point-of-use water quality interventions from previous research (Clasen et al., 2015). It also shows that that this study population was exposed to unsafe drinking water throughout this period, a finding consistent with a previous cross-sectional study (Kirby et al., 2016) and that the intervention filter was effective in significantly reducing this exposure during this longer follow up period. The implementers have now delivered filters and stoves to the poorest 30% (*ubudehe* 1 and 2) of households throughout Western Province (Barstow et al., 2016). A randomized controlled trial to assess the impact of this larger scale roll out is currently underway (Nagel et al., 2016). Given the impact on water quality and diarrhoea observed in this matched cohort study 12-24 months after delivery, there

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is the potential for this intervention to improve household water quality and child health at scale.

Conflict of Interest

E.A.T. has a commercial equity interest in a university-owned start-up that is commercializing the sensors described. E.A.T., L.I and M.U were employees of DelAgua Health Rwanda (Implementation), Ltd during the study.

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Figure 1 Sweetsense sensor affixed to Lifestraw filter (photo courtesy of Evan Thomas).

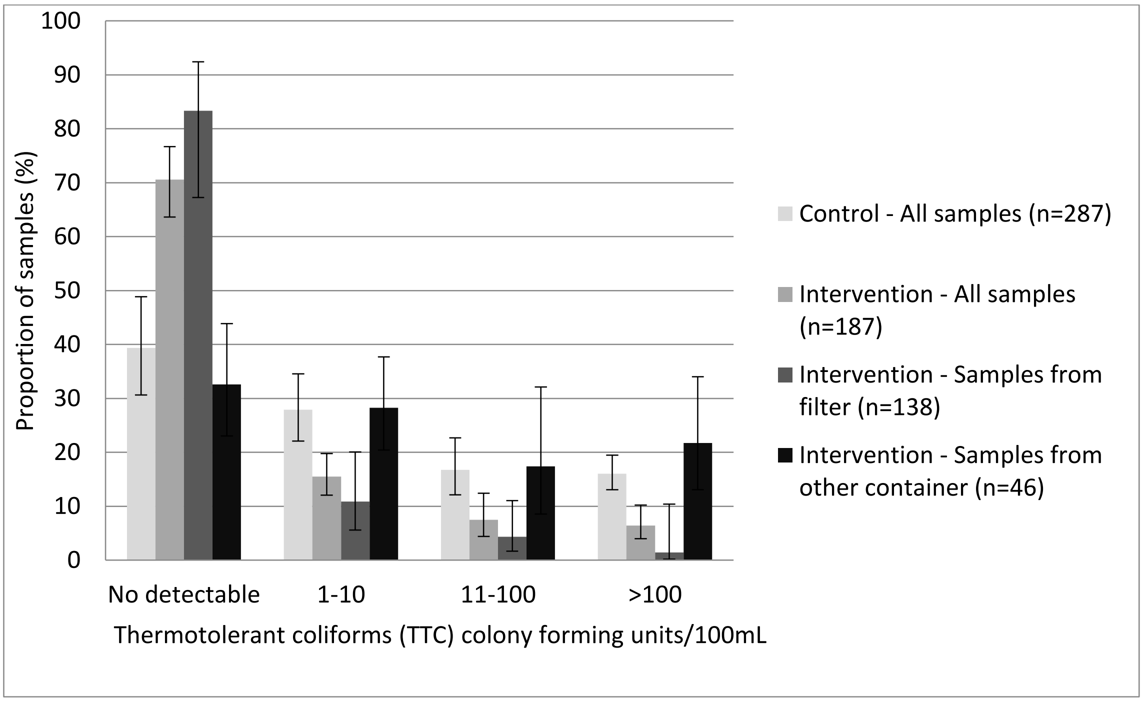

Figure 2 Proportion of control and intervention household drinking water samples by level of faecal contamination (CFU/100mL) and water storage location with cluster-robust 95% confidence intervals. (Note: Three intervention water samples were from an unknown storage location.)

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Table 1 Intervention and control household characteristics at enrollment.

Household characteristics	Intervention (n=113 hh) %hh	Control (n=156 hh) %hh	Standardized difference
Mean number of occupants per household	5.07	5.35	-0.151
Mean number of females 18+ per household	1.23	1.35	-0.190
Mean number of males 18+ per household	0.82	0.83	-0.018
Mean number of children under 5 per household	1.31	1.24	0.126
Female respondent	100.0	100.0	.
Mean age of respondent	35.34	37.40	-0.160
Respondent never attended school	36.3	36.5	-0.005
Respondent completed primary	14.2	16.0	-0.052
Respondent completed some secondary or higher	4.4	4.5	-0.003
Floor type -- earth/sand	93.8	90.4	0.127
Has electricity	2.7	8.3	-0.251
Has radio	33.6	35.3	-0.034
Has mobile phone	25.7	34.6	-0.196
Has mattress	27.4	35.9	-0.183
Has bicycle	1.8	3.8	-0.126
Owns land	90.3	85.9	0.135
Owns household	83.2	90.4	-0.214
Owns animals	46.9	44.9	0.041
Mean reported one-way travel time to health facility (min)	45.6	63.6	-0.451
Method of reaching facility – only on foot	96.5	98.7	-0.148
Has dedicated handwashing location after defecation	0.9	1.3	-0.038
Toilet type – Improved[1]	36.3	30.8	0.117
Share toilet	16.0	14.6	0.039
Drinking water stored in household 1 day or less	92.6	97.3	-0.217
Current water source - public tap / borehole	23.9	25.0	-0.026
Current water source - protected spring	68.1	59.6	0.178
Current water source – Improved[1]	92.9	85.9	0.230
Fetch water daily	85.7	90.2	-0.138
Roundtrip water-fetching time (min)	26.65	27.59	-0.039
Has drinking water available at time of visit	96.5	95.5	0.048
	N=93 households[2]	**N=105 households[2]**	
Source drinking water quality - no detectable TTC	58.1	64.8	-0.138
Source drinking water quality <11 TTC/100mL	64.5	93.3	-0.755
Source drinking water quality <101 TTC/100mL	89.2	99.0	-0.427
	N=147 children	**N=193 children**	
Mean child age (months)	31.06	30.68	0.023
Child gender -- female	53.7	52.8	0.018

[1]According to WHO/UNICEF Joint Monitoring Programme (JMP) for Water Supply and Sanitation guidelines (WHO/UNICEF, 2006)
[2]Households matched to source water sample +/- 1 day of survey date.

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Table 2 Reported and observed filter coverage, use and exclusive use among intervention households.

	Round 1 N (%) N=113 households	Round 2 N (%) N=91 households	Overall N (%) N=204 household observations
Coverage			
Received filter	110 (97.4)	89 (97.8)	199 (97.6)
Currently has filter[1]	104 (94.6)	85 (95.5)	189 (95.0)
Filter broken[1]	15 (13.6)	12 (13.5)	27 (13.6)
Filter away for repair[1]	4 (3.6)	3 (3.4)	7 (3.5)
Household currently has working filter[1]	93 (84.5)	76 (85.4)	169 (84.9)
Observed and reported use	**N=93 households**	**N=76 households**	**N=169 household observations**
Reports currently using filter	93 (100.0)	75 (98.7)	168 (99.4)
Reports filter last used on day of visit or previous day	86 (92.5)	67 (88.2)	153 (90.5)
Filter looks in use (based on accessibility and presence of dirt/dust on filter)	88 (94.6)	69 (90.8)	157 (92.9)
Has water in the filter	80 (86.0)	62 (81.6)	142 (84.0)
Sensor-derived use[2]	**N=45 households**	**N=39 households**	**N=84 household observations**
Filter filled on at least half of days with sensor data (% of households) [3]	22 (50.0)	14 (36.8)	36 (45.9)
Filter filled on a least one third of days with sensor data (% of households)	35 (79.5)	21 (55.3)	56 (68.3)
Mean (SD) filter fills per day of sensor data per household	0.8 (0.5)	0.8 (0.7)	0.8 (.6)
Mean (SD) litres treated per day of sensor data per household	2.2 (1.4)	1.6 (1.3)	1.9 (1.4)
Mean (SD) litres per fill event	2.9 (1.8)	2.14(1.7)	2.6 (1.8)
Reported exclusive use[4]	**N=93 households**	**N=75 households**	**N=168 household observations**
Respondent drank unfiltered water today[4]	8 (8.6)	4 (5.3)	12 (7.1)
Respondent drank unfiltered water yesterday[4]	12 (12.9)	6 (8.0)	18 (10.7)
Respondent drank unfiltered water today or yesterday[4]	16 (17.2)	7 (9.3)	23 (13.7)
Respondent ever drinks unfiltered water while at home[4]	15 (16.1)	16 (21.3)	31 (18.5)
Respondent ever drinks unfiltered water while away from home[4]	31 (33.3)	20 (26.7)	51 (30.4)
Child drank unfiltered water today[4, 5]	9 (7.4)	8 (8.2)	17 (7.8)
Child drank unfiltered water yesterday[4,5]	9 (7.4)	8 (8.2)	17 (7.8)
Child drank unfiltered water either today or yesterday[4,5]	13 (10.7)	9 (9.3)	22 (10.1)
Household has child under 5 who ever drinks	23 (24.7)	25 (33.3)	48 (28.6)

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unfiltered water while at home[4]			
Household has child under 5 who ever drinks unfiltered water while away from home[4]	28 (30.1)	25 (33.3)	53 (31.6)

[1]Only if household received Lifestraw filter
[2]Sensors were deployed in 79 hh in Round 1 and 73 hh in Round 2, for a mean of 16.3 days (SD 7.5, range 8-36 days). Due to mobile network challenges, sensor failure, and other technical faults, data was usable from 45 households in Round 1 and 39 households in Round 2.
[3]Day classified as transmit day if the sensor transmitted data to a central server at least once (not including the partial deployment and retrieval days). A mean of 12.9 days per deployment were useable for analysis (SD 7.7, range 0-34 days).
[4] Only if household reported using filter
[5]For each child under 5 residing in household reportedly using filter. N=121 children in Round 1, N=97 children in Round 2.

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Table 3 Household drinking water quality (TTC/100mL) with cluster-robust 95% confidence intervals (CI) in control and intervention households at each round, according to water storage location.

	Control – overall			**Intervention – overall**			**Intervention –sample from filter**			**Intervention – sample from other container**		
Round	**N**	**AM (95% CI)**	**WM (95% CI)**	**N**	**AM (95% CI)**	**WM (95% CI)**	**N**	**AM (95% CI)**	**WM (95% CI)**	**N**	**AM (95% CI)**	**WM (95% CI)**
1	149	51.9 (28.8-75.0)	4.5 (2.5-7.5)	106	31.4 (13.0-49.9)	1.7 (1.1-2.5)	75	5.8 (-1.4-13.0)	0.5 (0.2-1.1)	28	103.3 (35.5-171.1)	11.9 (5.2-25.5)
2	138	121.5 (65.5-177.6)	9.0 (5.9-13.5	81	19.7 (1.6-37.8)	0.9 (0.4-1.7)	63	3.0 (-2.0-7.9)	0.4 (0.0-1.1)	18	78.3 (21.1-135.6)	5.2 (2.5-10.1)
All	287	85.4 (62.1-108.7)	6.3 (4.6-8.5)	187	26.3 (12.1-40.6)	1.3 (0.9-1.9)	138	4.5 (-1.6-10.6)	0.5 (0.1-1.0)	46	93.5 (37.9-149.1)	8.7 (4.7-15.4)

AM=arithmetic mean, WM=Williams mean.
Note: Three intervention water samples were from an unknown storage location.