Assessing use, exposure, and health impacts of a water filter and improved cookstove distribution programme in Rwanda

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Statement of Own Work

I, Miles Kirby, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Miles Kirby

Date: 20 January 2017

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****tikkun olam****

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Abstract

Background

Unsafe drinking water and household air pollution are leading risk factors for diarrhoea and pneumonia, two major causes of death for young children. Rural areas are vulnerable due to unsafe water supplies and biomass burned indoors for cooking. Household water filters and portable fuel-efficient cookstoves could reduce these risks, but there is limited evidence of long-term uptake and impact.

National Water Quality Study

To determine the extent of faecal contamination of household stored drinking water and associated risk factors in Rwanda, we conducted a nationally representative cross-sectional study. Only 24.9% (n=217) of household supplies met WHO Guidelines of no detectable faecal contamination (thermotolerant coliforms (TTC)). Risk factors for intermediate and/or high risk contamination (11-100 and 101+ TTC/100mL) included low population density, increased open waste disposal within a sector, lower elevation, water sources other than piped to household or rainwater/bottled, and occurrence of an extreme rain event the previous day. Thus, community-level factors are associated with stored household water quality; observed contamination poses a health risk in Rwanda.

Matched Cohort Study

We next conducted a matched-cohort study in 18 villages to assess uptake, exposure, and health impacts of a water filter and improved biomass cookstove intervention programme 13-24 months after receipt. Coverage and use of the filter and cookstove was high, but non-exclusive. The odds of detecting TTC were 78% lower in the intervention arm (OR 0.22, $p<0.001$), with 50% lower odds of reported diarrhoea among intervention children <5 (OR=0.50, $p=0.03$). The

intervention was associated with 43.4% lower fine particulate matter in kitchens ($p<0.001$), but geometric mean exposure remained above WHO targets for cooks (151 $\mu g/m^3$) and children (175 $\mu g/m^3$), and only marginally reduced among intervention cooks (22.2% lower, $p=0.06$). While the filter showed promise for health benefits, alternative household and community-level approaches for achieving clean, safe air are needed.

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List of abbreviations

ALRI	acute lower respiratory infection
AM	arithmetic mean
ARI	acute respiratory infection
CFU	colony forming unit
CHIRPS	Climate Hazards Group InfraRed Precipitation with Station data
CHW	community health worker
CI	confidence interval
CO	carbon monoxide
CrI	credible interval
DALYs	Disability adjusted life years
DHS	Demographic and Health Survey
exp	exponentiated
GM	geometric mean
GPS	global positioning system
h	hours
HAP	household air pollution
hh	households
HIV/AIDS	human immunodefficiency virus / acquired immune deficiency syndrome
HPEM	Harvard Personal Environmental Monitor (impactor)
ICC	intra-cluster correlation
ID	identification
IMCI	Integrated Management of Childhood Illness
IQR	interquartile range
ISO	International Organization for Standardization
IWA	International Workshop Agreements
JMP	Joint Monitoring Programme for Water and Sanitation
LPG	liquefied petroleum gas
LSE	linearized standard error
m	metres
max	maximum
MCMC	Markov chain Monte Carlo
MDG	Millennium Development Goal
mg	milligram
mg/m^3	milligrams per cubic metre
min	minimum
mL	milliliter
NCDs	non-communicable diseases
NetCDF	Network Common Data Form
NISR	National Institute of Statistics Rwanda
OR	odds radio
PM	particulate matter
$PM_{2.5}$	particulate matter <2.5 µm in aerodynamic diameter
PPM	parts per million

RCT	randomized controlled trial
RESPIRE	Randomized Exposure Study of Pollution Indoors and Respiratory Effects
SD	standard deviation
SES	socioeconomic status
TNTC	too numerous to count
TTC	thermotolerant coliforms
µg	micrograms
$\mu g/m^3$	micrograms per cubic metre
µm	micrometer
UCB-PATS	University of California, Berkeley Particle and Temperature Sensor
UNICEF	United Nations Children's Fund
WASH	Water, sanitation, and hygiene
WHO	World Health Organization
WM	Williams mean

Chapter 1. Introduction and Research Aims

1.1 Project overview

This study will examine an improved cookstove and water filter distribution program in rural Rwanda. The program is a partnership between Rwanda Ministry of Health and DelAgua Health, a for-profit organization which seeks to address environmental health concerns with a pay-for-performance model following a carbon offset scheme (Edwards et al., 2004; Johnson et al., 2009). By developing interventions that reduce the need for fuel wood used for water treatment and cooking, DelAgua Health seeks to obtain carbon credits by participating in the United Nations Clean Development Mechanism (Thomas, 2012). Carbon credits are awarded for demonstrable adoption of such technologies over a designated time period (Haigler, 2011), and there is incentive for the implementer to distribute at scale, monitor uptake and ensure correct use over time (Simon et al., 2012). This type of market-based approach can provide funding and promote accountability by requiring monitoring of large stove and water treatment programs (Shrimali et al., 2011).

London School of Hygiene and Tropical Medicine (LSHTM) (Dr. Thomas Clasen, PI) was commissioned by DelAgua to undertake a four-year research programme agreed with the Rwanda Ministry of Health to (i) assess the adoption (use) of the interventions, (ii) evaluate the impact of the intervention on exposure to contaminated drinking water and household air pollution (HAP), and (iii) conduct a health impact evaluation of a large-scale roll out of the programme. We started this work with a randomized controlled trial of a pilot programme (Phase IA) (Rosa et al., 2014). The research described in this thesis represents the next phase of

the work (Phase IB) and includes (i) scoping the country-wide exposure to contaminated drinking water in Rwanda by conducting a rapid drinking water quality assessment, (ii) assessing the longer-term (year two) use of the intervention hardware, (iii) evaluating the impact of the intervention on drinking water quality and personal-level exposure to HAP, in preparation for a large-scale randomized controlled trial (Phase II) (Nagel et al., 2016; Thomas et al., 2016). The papers from Phase IA and Phase II, which I have contributed to since beginning the PhD at London School of Hygiene and Tropical Medicine (LSHTM), are included as appendices.

1.2 Research aims

The overall aim of this research is to assess the uptake and exposure impact of water filters and improved cook stoves distributed for free in rural Rwanda and to provide information to inform the design of a large scale health impact evaluation of the intervention. The specific objectives of this research are:

i) To determine the level of faecal contamination of household drinking water nationally and risk factors associated therewith.

ii) To evaluate the medium-term use of a water filter and improved cookstove provided to lower-income populations with a child under 5 years of age in rural Rwanda.

iii) To assess the impact of the intervention on drinking water and household air pollution.

Thesis questions:

a) To what degree is household drinking water faecally contaminated nationally in Rwanda, and what household and community-level factors are associated with household microbial water quality (Chapter 3)?

b) To what extent is the intervention stove and water filter used by this population 13-24 months after they have been received (Chapter 4 and Chapter 5)?

c) Is the intervention associated with improvements in drinking water quality (Chapter 4)?

d) Is the intervention associated with improvements in cooking area fine particulate matter ($PM_{2.5}$) and personal exposure to $PM_{2.5}$ and carbon monoxide (CO) (Chapter 5)?

e) What is the burden of respiratory infection and diarrhoea illness in children under 5 according to caretaker self-report (Chapter 4 and Chapter 5)?

1.3 Responsibilities of Investigators

Unless stated otherwise, I was responsible for all research covered by this thesis, with guidance from Thomas Clasen, Corey Nagel, Ghislaine Rosa, Jill Baumgartner, Michael Johnson, W.P. Schmidt, and Evan Thomas. Throughout the thesis, use of the pronoun “we” refers to work that was conducted by the author, Miles Kirby, with guidance from his supervisors.

I lived in Rwanda from April 2013-December 2014. From April 2013-June 2013, I designed and managed a national cross-sectional study to assess drinking water quality, source water quality, household water treatment practices, and cooking practices. Due to the pilot nature of this work, this work is not included in the thesis. From July 2013-September 2013, I was involved in preparations for the matched cohort study (Chapter 4 and Chapter 5). These included study design, submitting ethics applications, writing, programming, and piloting the survey tools, procurement of all materials including new personal exposure assessment equipment, training

staff, and field testing and refining the study procedures. I also designed the matching procedure and obtained all data necessary for propensity score matching, which was performed by Corey Nagel. From October 2013-November 2014, I directly supervised the matched cohort data collection team. These included frequent visits to project offices and study households for quality assurance purposes. From November 2014-May 2015, I designed and remotely managed a national household drinking water quality study (Chapter 3).

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Chapter 2. Literature Review

2.1 Drinking water quality

2.1.1 Access to safe water

An estimated 663 million people do not have access to an improved drinking water source (defined to include piped water to the dwelling, plot or yard, as well as public taps/standpipes, tubewells or boreholes, protected dug wells, protected springs, and rainwater collection) (WHO/UNICEF, 2015). However, water from improved water sources is not necessarily of safe microbiological quality and can contain faecal contamination (Bain et al., 2014a, 2014b; Shaheed et al., 2014). An estimated 1.8 billion people use a water source that has faecal or chemical contamination (Onda et al., 2012), with the burden particularly high in Africa (Bain et al., 2014a).

A recent meta-analysis showed piped water was safer at both the source and household compared to other water source types (Shields et al., 2015). Sub-national inequalities, including urban and rural differences and differential access to types of improved water sources such as piped water are commonplace (Bain et al., 2014c; Fuller et al., 2015; Luh et al., 2013; Pullan et al., 2014; WHO/UNICEF, 2015; Yu et al., 2014). Although rural drinking water sources tend to be more contaminated than urban sources (Bain et al., 2014b), definitions of what constitutes urban and rural settings are often broad and do not necessarily take into account population density, socioeconomic differences, and access to services which can vary significantly (Christenson et al., 2014). Within urban settings, there can be high heterogeneity of vulnerability to poor drinking water quality (Elala et al., 2011; Yongsi, 2010).

2.1.2 Water storage issues

Moreover, in these hygiene-challenged environments, even water that is safe at the source frequently can become contaminated from faecal pathogens during collection, transport and storage in the home (Trevett et al., 2005; Wright et al., 2004). Even households that have access to piped tap water may store their water leading to water quality contamination (Baker et al., 2013). Post-treatment contamination can also occur at point-of-consumption, via contaminated drinking cups (Rufener et al., 2010). Unsafe storage can be the dominant contamination pathway in urban settings (Machdar et al., 2013), although intermittent supply, system deficiencies and poor condition of improved sources also increase risk of contamination and illness (Ercumen et al., 2014; Shaheed et al., 2014). This suggests that in absence of safely managed piped water, there is a need to improve water quality and safely store water at a household level immediately prior to consumption.

2.1.3 Water quality testing by suppliers in Africa

Water quality testing by suppliers and public health surveillance agencies in sub-Saharan Africa is less frequent in rural areas and among small water suppliers (Peletz et al., 2016). This trend is seen in other low-income settings, and is primarily due to high costs and lack of resources including field testing capacity and laboratory resources (Crocker and Bartram, 2014). When water is tested by agencies in sub-Saharan Africa, piped sources relative to other sources are most frequently tested (Kumpel et al., 2016). In a study examining nearly 43,000 microbial water quality tests from seven countries, piped sources were less frequently contaminated than non-piped sources, while protected sources such as protected springs and protected dug wells showed presence of faecal indicator bacteria of 39% and 65% respectively (Kumpel et al., 2016). Piped water sources in low-resource settings are additionally subject to intermittent supply due to a wide variety of institutional, mechanical, environmental, and human influences (Galaitsi et

al., 2016). Intermittent supplies can increase water contamination in these systems (Kumpel and Nelson, 2016).

2.1.4 Health impacts of unsafe water

Globally, an estimated 1.25 million deaths and 75 million disability-adjusted life years (DALYs) are attributable annually to obtaining water from unsafe sources (GBD 2015 Risk Factors Collaborators, 2016). Most of the deaths are from diarrhoea, especially among young children exposed to faecal contamination in drinking water (Prüss-Ustün et al., 2014). Diarrhoea is a leading cause of mortality in children under 5, accounting for an estimated 9% of overall deaths (Liu et al., 2014). In 2011, an estimated 700,000 deaths among children under 5 were due to diarrhoea (Fischer Walker et al., 2013c).

Diarrhoea in young children less than 2 years of age can lead to linear growth faltering from 2-7 years of age, likely continuing beyond (Moore et al., 2001). Diarrhoea can lead to undernutrition, which in turn can lead to increased frequency and duration of diarrhoea episodes (Guerrant et al., 1992). Evidence from a cohort study in Brazil suggests early childhood diarrhoea, independent of malnutrition and stunting, has been associated with cognitive development impairment later in life (Pinkerton et al., 2016).

A recent systematic review and analysis found no association between faecal coliform levels in drinking water and diarrhoea, although the review noted heterogeneity and evidence of publication bias (Gruber et al., 2014). However, there is increasing evidence that household drinking water quality is a determinant of diarrhoea (Hodge et al., 2016; Levy, 2015; Luby et al., 2015). A recent review compiling 45,052 observations found that log10 increases in TTC/100mL above 10 TTC/100mL increased the odds of both child and all ages diarrhoea (Hodge et al.,

2016). Another large study examining *E. coli* contamination found a relationship between log10 increases and subsequent diarrhoea using 12,192 monthly follow-up visits over a 2-year period (Luby et al., 2015). A more recent study in Bangladesh gives further evidence for a relationship between *E.coli* in drinking water and diarrhoea, based on prospective measurements and more reliable two-day diarrhoea recall; cross-sectional data in this study found no association (Ercumen et al., 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). In Rwanda, unsafe drinking water is currently ranked third as a risk factor for disease (GBD 2015 Risk Factors Collaborators, 2016). There have been few studies of water quality in Rwanda, but none on a national scale. Rosa et al. (Rosa et al., 2014) conducted repeated samples over a 5-month period in 3 villages in Western and Northern province and found high faecal contamination levels (Rosa et al., 2014). A study in Rusizi district (Western Province) also found faecal contamination of household drinking water supplies, although most samples were not highly contaminated (Sinharoy et al., 2016). Another study looked at differences between a river used as a water source and 20 stored water samples after household water treatment (Uwimpuhwe et al., 2014). Other water quality assessments in Rwanda have found high faecal contamination of surface water partly due to anthropogenic influence, and these sources are sometimes used as water sources (Sekomo et al., 2012; Wronski et al., 2015).

2.2 Factors affecting drinking water quality

Faecally contaminated drinking water is usually associated with two major factors: poor hygiene (especially failure to wash hands after defecation) or poor sanitation. However, a variety of additional factors are associated with the faecal contamination of drinking water.

2.2.1. Hygiene and Sanitation

Contaminated hands may be a pathway for stored drinking water contamination (Mattioli et al., 2014; Pickering et al., 2010; Schriewer et al., 2015). Transmission can occur through contact with contaminated soil, food or other surfaces such as toys (Mattioli et al., 2014; Pickering et al., 2012, 2011; Torondel et al., 2015). Domestic animal exposure can result in increased contamination on hands as well as contaminated water leading to diarrhoeal illness (George et al., 2015; Schriewer et al., 2015; Zambrano et al., 2014). Hands frequently come in contact with contaminated soil, food or other surfaces and can contaminate water supplies (Mattioli et al., 2014; Pickering et al., 2012, 2011).

Evidence of sanitation conditions adversely affecting water quality is mixed. Surfaces within and around toilets can be a source of pathogens (Pickering et al., 2012). A cross-sectional study in urban slums in India found no impact of shared sanitation on drinking water, although shared facilities were less likely to be clean or functional (Heijnen et al., 2015). Another study in Tanzania did not find any association between latrines with slab and soil faecal bacteria, though this could have been due to a low sample size (Pickering et al., 2012).

In some settings, animal-associated faecal contamination of water, soil, and hands may be more dominant than human-associated faecal contamination (Boehm et al., 2016; Harris et al., 2016).

A study in Bangladesh evaluating provision and promotion of child feces removal tools and toilets found that ruminant faecal contamination was prevalent within the household environment including drinking water, and was associated with animal ownership (Boehm et al., 2016). In a study in Uganda, dumping of solid waste into the bush was a contributor to chemical and biological contamination (Nsubuga et al., 2004), while another study found that latrines within 50m of pumps or wells increased risk of virus detection (Verheyen et al., 2009). Groundwater contamination has been observed downstream of latrines, although there is mixed evidence on how far contamination can reach and is likely very context specific (Graham and Polizzotto, 2013). For example, a study in Kenya found increased latrine density was associated with groundwater contamination (nitrate and chloride), but not faecal contamination (Wright et al., 2013).

2.2.2 Population density

Studies have found an increase in enteric infection with increased housing density (Halpenny et al., 2012), potentially due to person-to-person transmission and increased social connectedness (Bates et al., 2007). Sources of faecal contamination may contaminate surface water sources used for drinking or other household uses, and can also contaminate groundwater and/or water sources with poor infrastructure (Godfrey et al., 2006; Howard et al., 2003; Kulabako et al., 2007; Nsubuga et al., 2004). Increased population density has been associated with increased contamination of protected springs (Nsubuga et al., 2004), potentially through increased latrine density or unsafe sanitation (Escamilla et al., 2013). On the other hand, a recent study examining population density in Guatemala found no effect of population density on enteric infection (Jarquin et al., 2016).

2.2.3 Solid Waste disposal

Household waste is an important contributor to household water quality, and may be partially dependent on the disposal practices of one's neighbours. Many households in Rwanda and other low-income countries have limited waste removal services, and this is a challenge in both urban and rural settings. Household solid waste can contain numerous pathogens, and may include child feces and other sources of faecal waste (Majorin et al., 2014; Rego et al., 2007). Lack of solid waste removal has been associated with health risks including *Giardia* (Prado et al., 2003). When dumped in the bush, farmland, or rivers, this source of faecal contamination may contaminate surface water sources used for drinking, and contaminate groundwater or water sources with poor infrastructure (Kulabako et al., 2007). For example, protected springs can still be vulnerable to contamination due to structural issues, as was found in a study in Kampala (Howard et al., 2003). Sanitary inspection of water sources is recommended in order to to target structural improvements, and WHO risk-of-contamination scoring is a tool that has shown a strong relationship with health-related indicators (Mushi et al., 2012).

2.2.4 Livestock density

A number of studies have found associations between livestock density and enteric illness (Febriani et al., 2009; Frank et al., 2008; Graziani et al., 2015; Jagai et al., 2010). In New Zealand, livestock density was associated with increased risk of Cryptosporidiosis in children under 5 (Lal et al., 2016). *Giardia* and *Cryptosporidium* prevalence has been found to be greater in areas with reduced population density compared to higher density areas (Jagai et al., 2010; Pollock et al., 2010). This may be due to reduced livestock ownership in urban areas. A study of a river in Kenya found cattle to be the dominant source of faecal contamination and Cryptosporidium in the environment (Jenkins et al., 2009). A systematic review of studies conducted in high-income

settings found distinct seasonal variations in human zoonotic enteric infections (Lal et al., 2012); thus, the impact of livestock on water quality and diarrhoea may be mediated by climatic factors.

Presence of livestock within the home can also impact drinking water quality. Chickens often enter houses and can come in close proximity with water storage containers, as well as other surfaces that human hands come in contact with. Avian feces can contain high levels of pathogens (Oberhelman et al., 2003), and close proximity has been associated with increased *Campylobacter*-related diarrhoea (Oberhelman et al., 2006). A study in Zimbabwe found children ingested chicken feces and contaminated soil (Ngure et al., 2013), and domestic animal exposure has been associated with environmental enteropathy and stunting, as well as contamination on caregivers hands (George et al., 2015). Faecal contamination on hands and animal proximity may in turn result in increased risk of stored water contamination.

2.2.5 Altitude

One study in Rwanda identified increased altitude as protective against diarrhoea, and this was partly attributed to drainage and accumulation of solid waste, flies and faecal matter at lower altitudes (Uwizeye et al., 2014). Higher altitude may be indicative of fewer sources of animal and human waste in the watershed, although temperature, which varies with altitude in Rwanda, can affect faecal indicator growth. A review recently identified higher altitude areas as having reduced faecal indicator growth and prevalence in the environment relative to lower elevations (Rochelle-Newall et al., 2015).

2.2.6 Rainfall

Water sources, including a range of improved water sources, are susceptible to greater contamination during the wet season, and this pattern has been found in both urban and rural settings and in different climate zones (Kostyla et al., 2015). During the rainy season, storm water runoff can increase, and contamination can infiltrate into groundwater (Nsubuga et al., 2004). Impacts from acute precipitation events can also impact water quality. For example, previous day rainfall resulted in increased faecal contamination of protected springs in Kampala (Howard et al., 2003) and wells in Mozambique (Godfrey et al., 2006). Rainfall may additionally mediate the impact of unimproved water sources and unimproved sanitation on diarrhoea (Bhavnani et al., 2014). The impact of open waste disposal, as well as presence of other faecal sources such as human/animal faeces, may be aggravated by extreme rainfall events which can result in a "flush effect" (Levy et al., 2009), particularly in environments with rapid groundwater recharge. Other studies in Rwanda have identified increased rainfall as a risk factor for water source contamination (Gasana et al., 2002) and groundwater contamination (Nigatu et al., 2015).

2.3 Point of use water treatment

2.3.1 General

Household water treatment and safe storage is recommended by the World Health Organization (WHO) to address the risks associated with source water quality and household recontamination (UNICEF/WHO, 2009; WHO, 2007). Household water treatment methods include boiling (Brown and Sobsey, 2012; Rosa et al., 2010), chlorine (Arnold and Colford Jr, 2007; Boisson et al., 2013), flocculation, sedimentation and disinfection (Souter et al., 2003), solar disinfection (SODIS) (Mäusezahl et al., 2009; Rose et al., 2006) and filtration (Clasen et al., 2015, 2004; Stauber et al., 2012). In several review studies, point of use water treatment has been shown to improve

water quality and reduce diarrhoea (Clasen et al., 2015; Fewtrell et al., 2005; Waddington et al., 2009; Wolf et al., 2014). However, many of these studies were non-blinded and relied on self-reported diarrhoea which is subject to courtesy bias (Schmidt and Cairncross, 2009). As blinded trials of these interventions present ethical issues (Clasen and Boisson, 2015), there is a need for more objective outcomes to overcome the weaknesses of self-reported outcomes such as biomarkers of recent infection (Priest et al., 2006).

Of various water treatment methods available, filtration is considered one of the best options (Hunter, 2009; Clasen 2015). A meta-regression examining different household water treatment methods in developing countries found that ceramic filters were most effective, and likely to remain effective over time (Hunter, 2009). Another study found that ceramic and biosand filters were the most effective as well as sustainable and acceptable (Sobsey et al., 2008), although this study and the review by Hunter (2009) occurred before the development of advanced ultrafiltration filters (Clasen et al., 2009). A recent study highlights rotavirus, *Shigella, Cryptosporidium,* and *Enteropathogenic E. coli* contributing the most to moderate-to-severe diarrhoea in children, with *Cryptosporidium* most associated with increased death among children 12-23 months (Kotloff et al., 2012). Unlike some other common treatment methods such as chlorine (Korich et al., 1990), most filters are effective against these bacteria and protozoa. At the same time, most water filters, including ceramic candle filters, are not effective in removing viruses from drinking water (Sobsey, 2002).

2.3.2 Lifestraw filter

For the Rwanda project, DelAgua selected the Lifestraw ® Family Filter 2.0, a tabletop gravity-based filter that employs hollow-fibre membranes as the microbiological barrier and includes

safe storage for product water (Figure 1). The filter was selected because it is effective against all classes of microbial pathogens (including viruses) and is designed to provide sufficient drinking water for a household for at least three years without replacing any consumables (Clasen et al., 2009). There have been a few studies examining the impact of the Lifestraw 1.0, an earlier version of the filter that required users to hang it in homes and did not include safe storage. These included a randomized placebo-controlled trial in Democratic Republic of Congo (DRC) (Boisson et al., 2010) and a randomized controlled trial in Zambia that also included safe storage (Peletz et al., 2012). The study in DRC found microbiological effectiveness but low uptake, and did not find an effect on diarrhoea (Boisson et al., 2010). The Zambia study, conducted among a population living with human immunodefficiency virus / acquired immune deficiency syndrome (HIV/AIDS), found high uptake and reductions in diarrhoea among both children under 2 and all household members (Peletz et al., 2012). One year later there was similar high uptake and microbiological reductions, although this population may be more likely to engage in consistent use (Peletz et al., 2013).

Figure 1 Lifestraw Family Filter 2.0 (photo courtesy of Thomas Clasen)

2.3.3 Correct, consistent and sustained use

A major challenge facing household water treatment interventions is correct, consistent use. Despite uptake demonstrated during field trials, usage of household water treatment interventions tends to diminish over time (Arnold and Colford Jr, 2007; Boisson et al., 2013; Waddington et al., 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.

Studies utilizing quantitative microbial risk assessment modelling have shown that high compliance and consistent use of treated drinking water are necessary to achieve health benefits (Brown and Clasen, 2012; Enger et al., 2013, 2012; Hunter et al., 2009), and even a small reduction in adherence can substantially offset positive health gains (Brown and Clasen, 2012). There is therefore a need to carefully measure compliance of household water treatment interventions (Enger et al., 2013), and factors affecting longer-term drinking water practices.

Sub-optimal use of the Lifestraw Filter 1.0 was recently reported in a study in Kenya (Pickering et al., 2016). The investigators found that that usage of the filter declined over time among households with pregnant women, dropping to 19% 2-3 years following the initial free distribution. As noted above, this filter has been fully redesigned in an effort to improve use and protect treated water. A pilot randomized control trial in Rwanda using this new tabletop version found high microbiological effectiveness and high uptake, although non-exclusive use (Rosa et al., 2014).

There are several factors affecting filter usage and performance (Ojomo et al., 2015). People may be less likely to treat their water at home when source water is perceived as being clean (Arnold et al., 2013), or they may not want to wait for water filtration to occur (Boisson et al., 2010). Untreated water may also be preferred when away from the home (Boisson et al., 2010; Rosa et al., 2014). User maintenance and operation can impact filter performance and increase risk of exposure (Baumgartner et al., 2007). General household hygiene practices may also influence proper filter maintenance and operation, as well as diarrhoea (Divelbiss et al., 2013). Despite a promising variety of trials confirming beneficial impacts of filters on water quality and diarrhoea, there is a need for long-term follow-up in order to assess filter performance and how to maximize consistent, exclusive use (Clasen et al., 2015).

2.4 Household air pollution

2.4.1 Biomass usage

An estimated forty percent of the world's population uses solid fuels such as wood, crop residues, charcoal and coal for cooking and household energy needs (Bonjour et al., 2013). While the proportion of global population cooking with biomass has decreased since 1980, around 2.8 billion continue to cook with biomass, and this has remained relatively stable due to population growth (Bonjour et al., 2013). Southeast Asia and Africa are most dependent on solid fuel use, with an estimated 60%-77% of Africa's population relying on solid fuels (Bonjour et al., 2013; Rehfuess et al., 2006). Only 0.3% of households in Rwanda use liquefied petroleum gas (LPG), with the majority relying on solid fuel such as wood, straw/shrubs/grass, and charcoal (98.1%) (National Institute of Statistics of Rwanda (NISR) et al., 2015). Only 20.9% of households cook outdoors, with the remainder primarily cooking in a separate building (53.3%) or in the house (24.3%) (National Institute of Statistics of Rwanda (NISR) et al., 2015).

Burning of solid fuels on traditional inefficient stoves results in incomplete combustion. Products of incomplete combustion include particulate matter (PM) and carbon monoxide (CO) in addition to more than 250 compounds, many of which are known to be harmful to health (Bruce et al., 2000; Naeher et al., 2007). Fine particulate matter <2.5 micrometers in aerodynamic diameter ($PM_{2.5}$) is considered to an indicator of health risk in air pollution exposure measurement (Clark et al., 2013b; Naeher et al., 2007; Williams et al., 2015). Given PM2.5 measurement difficulties in public health research, CO has been used as a proxy of PM2.5 with varying success (Dionisio et al., 2012b; Klasen et al., 2015; McCracken et al., 2013; Northcross et al., 2010). Despite evidence that PM2.5 and CO may not correlate well with each other in certain settings, CO remains an important health indicator of exposure and is associated with acute and chronic health effects (Penney et al., 2010; Yang et al., 2004).

2.4.2 Health impacts of household air pollution

Household air pollution (HAP) is estimated to have resulted in 2.9 million deaths and 85.6 million DALYs in 2015 (GBD 2015 Risk Factors Collaborators, 2016). Numerous health impacts have been associated with HAP (Bruce et al., 2015b; Fullerton et al., 2008; Smith et al., 2014). There is strong evidence for the adverse impact of household air pollution (HAP) on respiratory infections (Gordon et al., 2014), particularly for children who are vulnerable to acute lower respiratory illness (Dherani et al., 2008; Gordon et al., 2014; Po et al., 2011). Each year an estimated 1.3 million child deaths are due to pneumonia (Fischer Walker et al., 2013c).

Strong evidence has also been reported for chronic obstructive pulmonary disorder and chronic bronchitis (Assad et al., 2015; Hu et al., 2010; Kurmi et al., 2010; Mortimer et al., 2012). More

tentative evidence exists for nasopharyngeal and laryngeal cancer as well as lung cancer and stroke (Bruce et al., 2015a; Gordon et al., 2014; Kurmi et al., 2012a; Raspanti et al., 2016). Exposures early in life may result in increased risk for some of these diseases in adulthood (Kurmi et al., 2012b). Emerging evidence suggests there may be an impact on blinding and other eye conditions (Ravilla et al., 2016; West et al., 2013) as well as tuberculosis (Jafta et al., 2015; Lin et al., 2014; Sumpter and Chandramohan, 2013). A recent meta-analysis indicates HAP associations with cancers of the cervix as well as upper aero-digestive tract (Josyula et al., 2015). Other non-disease related injuries can occur, such as burns from stoves (Peck et al., 2008) and sexual violence during fuel collection (Patrick, 2007). Much uncertainty exists about exposure-response for these outcomes, and misclassification is possible (Assad et al., 2015; Bruce et al., 2015b; Gordon et al., 2014).

Child survival outcomes such as low birth weight, preterm birth, still birth, and perinatal mortality are also associated with solid fuel use (Amegah et al., 2014; Epstein et al., 2013; Patel et al., 2015; Pope et al., 2010; Wylie et al., 2014). One recently hypothesized mechanism for adverse health outcomes is fetal thrombotic vasculopathy, due to observed associations in Tanzania that was recently observed with increasing $PM_{2.5}$ and CO exposures (Wylie et al., 2016).

Globally, systolic blood pressure is highest in low and middle income countries (Danaei et al., 2011). Hypertension is an important risk factor for cardiovascular disease (Lewington et al., 2002; Vasan et al., 2001), and leads to one of the highest burdens of disease (GBD 2015 Risk Factors Collaborators, 2016). Cross sectional studies examining the impact of biomass smoke on blood pressure suggest an association with elevated blood pressure (Baumgartner et al., 2011; Burroughs Peña et al., 2015; Clark et al., 2011; Quinn et al., 2016).

Reductions of blood pressure due to changes in HAP have been observed in a couple of studies. The RESPIRE intervention study found a 3.7mm Hg reduction in systolic blood pressure and a 3.0mm Hg reduction in diastolic blood pressure among women over 38 years old after receiving vented cookstoves (McCracken et al., 2007). A stove intervention study in Nicaragua found a reduction in systolic blood pressure, but only for women over 40 years or obese women (Clark et al., 2013a). Although only small effect sizes have been observed, reductions can have a large impact at a population level. For example, a 2 mm Hg reduction in population average systolic blood pressure could reduce mortality by 10% (Lewington et al., 2002).

Although biological mechanisms responsible for all of these illnesses are not precisely defined, a number of physiologic impacts from biomass exposure have been identified. These include oxidative stress, pulmonary inflammation, and platelet activation (Dutta et al., 2013; Kurmi et al., 2013; Sussan et al., 2013). Sub-mechanisms may include dose-dependent inflammation, altered phagocytosis in human macrophages, and impacts on innate immunity (Lee et al., 2015; Rylance et al., 2015). Biomass impacts on atherosclerotic plaques, carotid intima-media thickness, and higher blood pressure have also been observed (Painschab et al., 2013). Recent work has characterized increased biomarkers of endothelial inflammation among adults with chronic exposure to biomass smoke (Caravedo et al., 2015).

2.4.3 Potential interventions for improving household air pollution

Clean fuel and improved cookstoves

There are three main approaches to reducing HAP: transitioning to cleaner fuel, changing to cleaner cookstoves, and increasing ventilation. Moving to cleaner fuels in many rural settings is unlikely to happen in the near-term due to high costs and lack of supply (Ezzati and Kammen, 2002). Improving fuel efficiency and reducing emissions using current fuel types is therefore an interim option (Kshirsagar and Kalamkar, 2014). However, adoption and sustained consistent use of improved stoves at scale is a challenge, and is enabled and hindered by a range of factors that are related to the technology as well as household and institutional determinants (Debbi et al., 2014; Rehfuess et al., 2014).

Improved cookstoves are often tested in a laboratory setting, though these results are not necessarily indicative of what will be achieved in a real world setting during a household's normal cooking activities (Johnson et al., 2010; Roden et al., 2009). In one study, cookstove emissions were three times higher during actual cooking in Honduras than simulated cooking emissions in a laboratory setting (Roden et al., 2009). Factors such as lighting technique, fuel addition, and wood type also affect emissions (Roden et al., 2009).

Ventilation/cooking location

The success of improved cookstoves may also partly be mediated by cooking location and ventilation (Bruce et al., 2004). In a test kitchen simulation, PM 1-hour concentrations were lowered by 93% and 98% when opening a door and window respectively (Grabow et al., 2013). For those cooking with biomass, the highest reduction may come from cooking outdoors as opposed to improving a cooking device , with one study finding acute respiratory infection (ARI) due to biomass smoke could be reduced by 50% if cooking moves outdoors (Akunne et al., 2006). This is due in part to increased dispersion outdoors compared to indoor environments

with limited ventilation (Balakrishnan et al., 2004). Another study using survival analysis found that cooking outdoors was similar to transitioning to a cleaner fuel, but that cooking with stove ventilation was most linked to child acute lower respiratory infection (ALRI) mortality (Rehfuess et al., 2009). Laboratory tests examining mutagenicity indicate even the most efficient biomass stoves available, known as forced-draft or fan-assisted stoves (e.g. Philips) will still result in poor indoor air quality in the absence of ventilation (Mutlu et al., 2016).

The importance of ventilation and cooking location has also been shown in personal exposure studies. Lower carbon monoxide exposure among children has been found among households cooking outdoors (Barnes et al., 2006). Another study found that ventilation had an impact on personal and indoor respirable PM, as well as indoor carbon monoxide (Clark et al., 2010). Moving cooking outdoors may also have an adverse effect if children spend more time outdoors, and air pollution is known to spread from cooking areas into living areas (Dasgupta et al., 2006).

Heating and lighting

Within the household, there are other sources of HAP besides cooking, including lighting as well as heating, with potential seasonal relationships contributing to personal exposure and ambient levels (Dionisio et al., 2012a; Jin et al., 2006; Ni et al., 2016; Pennise et al., 2009). Kerosene is an emerging concern (Lam et al., 2012) and is used for lighting, cooking, and heating. It is particularly hazardous, and has been associated with kitchen concentrations and personal exposure to black carbon (Van Vliet et al., 2013) in addition to particulate matter (Apple et al., 2010). Kerosene use has also been associated with low birth weight and potentially neonatal death (Epstein et al., 2013).

2.4.4 Improved cookstoves and impact on HAP

Improved cookstoves have been found to reduce kitchen concentrations of particulate matter and carbon monoxide (Clark et al., 2013b; Ezzati et al., 2000a; Pennise et al., 2009; Thomas et al., 2015). Personal exposure studies have also demonstrated an impact, although usually there are greater reductions in kitchen emissions than personal exposures (Cynthia et al., 2008; Smith et al., 2014). Women and children tend to be more exposed due to spending more time in cooking areas (Gordon et al., 2014; Siddiqui et al., 2009). However, average 24-hr exposures can still be high among those not involved in cooking (Balakrishnan et al., 2002) and health impacts are possible among these household members.

An improved stove in Guatemala reduced CO exposures by 90%, 61%, and 52% in kitchens, mothers, and children 0-18 months (Smith et al., 2010). Similarly, an improved stove in Mexico resulted in a 74% reduction in kitchen PM concentrations, but personal exposure was only reduced by 35% (Cynthia et al., 2008). A non-portable rocket mud stove study in Kenya reduced fuel use and both kitchen and personal CO, although levels were still high and unlikely to impact health (Ochieng et al., 2013a, 2013b). Factors to improve rocket stove performance included fuel drying, cooking away from the main house, and behaviour change, such as reducing smouldering (Ochieng et al., 2013b). Indeed smoldering can substantially contribute to HAP, particularly with traditional stove designs; an improved portable stove may have the greatest reduction (Ezzati et al., 2000b). In Rwanda, a randomized controlled trial involving a portable rocket stove found a mean 24-hour $PM_{2.5}$ reduction of 46%, although for the approximately 25% users cooking outside, reductions were 73% (Rosa et al., 2014). More advanced cookstoves such as fan-assisted biomass stoves show promise, and have potential to substantially reduce cooking area concentrations and personal exposures.

However, most improved cookstove studies have failed to reduce kitchen concentrations or personal exposures below WHO guidelines of 10 µg/m^3 and the interim WHO target of 35 µg/m^3 (Clark et al., 2013b; Thomas et al., 2015; WHO, 2014). Substantial reductions that approach the guideline levels are likely necessary to achieve health impact for acute respiratory infections (Burnett et al., 2014; Ezzati and Kammen, 2001; Smith et al., 2011) and cardiovascular disease (Baumgartner et al., 2012; Pope III et al., 2011). In fact, evidence of negative health impacts still exists below the WHO Guideline (Wellenius et al., 2012). Moreover, though evidence is placed on PM2.5 reductions, more efficient improved combustion cookstoves may produce higher emissions of ultrafine particles that could present health risks (Just et al., 2013).

Many improved cookstove intervention studies report improved respiratory symptoms and fewer eye or back problems, although self-reported symptoms are subject to courtesy bias (Schmidt et al., 2011). With high reductions in exposure and high compliance, improved cookstoves have been associated with several objective health impacts. These include reduced risk of severe pneumonia (Smith et al., 2011), reduced blood pressure (Alexander et al., 2015; Clark et al., 2013a; McCracken et al., 2007) and improved lung function similar to smoking cessation (Romieu et al., 2009; Smith-Sivertsen et al., 2009).

2.4.5 Ecozoom stove

The intervention stove is a portable rocket stove design known as an Ecozoom Dura stove (Figure 2). The stove's internal chamber allows for improved combustion and channelled air flow resulting in reduced emissions. The stove included a stick support used to increase airflow and a pot skirt to improve thermal efficiency. Although full testing according to the International

Organization for Standardization (ISO) and International Workshop Agreements (IWA) has not occurred (ISO/IWA, 2012), laboratory results for water boiling tests suggest it is likely Tier 2 for the ISO/IWA fuel efficiency, total emissions, indoor emissions (Aprovecho Research Center, 2012; Ballinger et al., 2013). Since Tier 4 includes the highest performing optimal cooking solutions, the Tier 2 status of this and other similar rocket stoves suggests potential for only modest reductions in HAP (Jetter et al., 2012; Mutlu et al., 2016; Still et al., 2015). Nevertheless, epidemiological studies have suggested the potential for positive health impacts provided that use is optimized (Johnson and Chiang 2015).

Figure 2 Ecozoom Dura cookstove (photo courtesy of Thomas Clasen)

2.4.6 Sustained use/ stacking

Like household water treatment interventions, a major challenge of cookstove interventions is optimizing use. In respect of stoves, this is known as “stacking” behavior, or the continued use of traditional stoves despite the presence of an improved cookstove (Burwen and Levine, 2012; Ruiz-Mercado et al., 2011; Ruiz-Mercado and Masera, 2015). When traditional stoves continue to be used, there may be minimal impact of the improved stove on HAP (Edwards et al., 2007; Johnson and Chiang, 2015). Even if benefits are initially detected from an improved stove

implementation, these can diminish over time in the presence of stove stacking (Hanna et al., 2012; Pine et al., 2011; Romieu et al., 2009), even when traditional stoves are used as secondary stoves (Pennise et al., 2009).

One method to ascertain use of traditional and intervention stoves is through the use of sensors. Sensors have been used in numerous stove evaluation studies, including in Uganda (Hankey et al., 2015), Kenya (Lozier et al., 2016), Ghana (Piedrahita et al., 2016), and Mexico (Ruiz-Mercado et al., 2008). A study in India found that intervention stove usage reduced over time until approximately 200 days after initial receipt (Pillarisetti et al., 2014), while a study in Kenya saw improved stove usage decrease over a period of 12 days(Lozier et al., 2016). In other studies, stove use increased after delivery and then leveled off (Ruiz-Mercado et al., 2008). Usage on portable intervention stoves within Rwanda indicated consistent use, although self-reported use was higher (Thomas et al., 2013). Sensors have also been used on improved stoves in humanitarian settings. A study in South Sudan indicated use of an improved stove was over-reported, although usage increased after a follow-up survey and was sustained for two weeks of observation (Wilson et al., 2016).

2.5 Current HAP intervention trials

Several trials are currently underway to assess the impact of improved cookstoves on HAP and health. A randomized trial in Ghana examining low birthweight and physician-assessed severe pneumonia has recently been completed in Ghana, consisting of two biomass-burning highly efficient BioLite gasifier (fan-assisted forced draft) stoves in one arm, LPG stove with fuel supply in another arm, and a control arm (Jack et al., 2015). Another study in Ghana is also examining the impact of the Philips gasifier stove on personal exposure, cooking area, health-related

biomarkers, and local to regional air quality (Dickinson et al., 2015; Piedrahita et al., 2017). Two trials that recently finished were based in Nepal and used a cluster-randomized stepped wedge approach to investigate the impact of a biomass stove with chimney as well as LPG on ALRI and birthweight (Tielsch et al., 2014). Preliminary results suggest the biomass stove intervention may have contributed towards a reduction in ALRI incidence, although kitchen $PM_{2.5}$ concentrations remained high and secular trends likely minimized observable effects (Tielsch et al., 2016). Another trial that is examining low birthweight, premature birth, and other adverse birth outcomes is based in Nigeria, and seeks to transition intervention households from mainly traditional kerosene stoves to bioethanol. Although health results are forthcoming, the study has found high uptake given the liquid-to-liquid transition, with very little stacking and consistent usage according to stove use monitors (Northcross et al., 2016). In Rwanda, a study examining severe acute respiratory illness and diarrhoea of a combined rocket stove and water filter intervention has recently completed (Nagel et al., 2016), and analysis is in progress. Finally, an ongoing cluster-randomized trial in Malawi is investigating whether the provision of two fan-assisted Phillips biomass stoves reduces incidence of healthcare provider-diagnosed pneumonia following the IMCI protocol ("Cooking and Pneumonia Study (CAPS)," 2016).

2.6 Combined cookstove and water treatment studies

Three household intervention studies have focused on combined cooking and drinking water technologies. Two projects have involved the combination of improved stove and HWT within the same device, although these studies have had low compliance and low acceptability overall (Christen et al., 2009; Gupta et al., 2008). A more recent cluster-randomized study design paper in Peru has separated the interventions out and also added a kitchen sink (Hartinger et al., 2011). The pilot indicated high uptake of the stove, reduced fuel consumption, and a preference for solar treated water taste (Hartinger et al., 2012). A nested cross-sectional study highlights

the issue of maintenance and functionality, finding only well-performing cookstoves reduced emissions, with non-significant reduced personal exposures (Hartinger et al., 2013). Results of the trial indicate the combined intervention had a slight but non-significant impact on childhood diarrhoea, and no effects on respiratory health or growth outcomes (Hartinger et al., 2016).

2.7 Comorbidity

Children with diarrhoea or respiratory infections may have immune system vulnerability to infections (Lee et al., 2015). Some studies have suggested that reduced diarrhoea risk can reduce risk of ALRI (Ashraf et al., 2013; Fischer Walker et al., 2013a; Schmidt et al., 2009). A study in Israel among Bedouin children found that nutritional status and diarrhoeal illness are risk factors for pneumonia (Coles et al., 2005). Furthermore, reduced diarrhoea may improve clinical outcomes associated with severe pneumonia (Chisti et al., 2016; Leung et al., 2015), and is also associated with malnutrition, a risk factor for pneumonia (Chisti et al., 2009; Howie et al., 2016; Le Roux et al., 2015). Stunting is associated with poor pneumonia outcomes (Moschovis et al., 2015). Mortality among children may be increased when both diarrhoea and ALRI are present (Fischer Walker et al., 2013b).

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Chapter 3. Faecal contamination of household drinking water in Rwanda: A national cross-sectional study

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SECTION A – Student Details

Student	Miles Kirby
Principal Supervisor	Thomas Clasen
Thesis Title	Assessing use, exposure, and health impacts of a water filter and improved cookstove distribution programme in Rwanda

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	Science of the Total Environment		
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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	With input from co-authors, I designed the study. I organized and supervised collection of data and samples, managed daily operations, supervised lab work, and cleaned the data. I analysed the data and I wrote the paper.

Student Signature: Miles Kirby **Date:** 11 November 2016

Supervisor Signature: _____ **Date:** 11 November 2016

Faecal contamination of household drinking water in Rwanda: A national cross-sectional study

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ABSTRACT

Unsafe drinking water is a leading cause of morbidity and mortality, especially among young children in low-income settings. We conducted a national survey in Rwanda to determine the level of faecal contamination of household drinking water and risk factors associated therewith. Drinking water samples were collected from a nationally representative sample of 870 households and assessed for thermotolerant coliforms (TTC), a World Health Organization (WHO)-approved indicator of faecal contamination. Potential household and community-level determinants of household drinking water quality derived from household surveys, the 2012 Rwanda Population and Housing Census, and a precipitation dataset were assessed using multivariate logistic regression. Widespread faecal contamination was present, and only 24.9% (95% CI 20.9-29.4%, n=217) of household samples met WHO Guidelines of having no detectable TTC contamination, while 42.5% (95% CI 38.0-47.1%, n = 361) of samples had >100 TTC/100mL and considered high risk. Sub-national differences were observed, with poorer water quality in rural areas and Eastern province. In multivariate analyses, there was evidence for an association between detectable contamination and increased open waste disposal in a sector, lower elevation, and water sources other than piped to household or rainwater/bottled. Risk factors for intermediate/high risk contamination (>10 TTC/100mL) included low population density, increased open waste disposal, lower elevation, water sources other than piped to household or rainwater/bottled, and occurrence of an extreme rain event the previous day. Modelling suggests non-household-based risk factors are determinants of water quality in this setting, and these results suggest a substantial proportion of Rwanda's population are exposed to faecal contamination through drinking water.

Keywords: water quality, faecal contamination, Rwanda, precipitation

HIGHLIGHTS:

- Nationally representative study of household drinking water quality in Rwanda
- More than 75% of houses had detectable TTC contamination in their drinking water
- Houses using surface compared to other sources had highest odds of TTC contamination
- Houses not using piped or rain/bottle sources had increased odds of TTC contamination
- Extreme rain, elevation and open waste dumping were risk factors of TTC contamination

1. INTRODUCTION

Globally, an estimated 1.25 million deaths and 75 million disability-adjusted life years (DALYs) are attributable annually to obtaining water from unsafe sources (Forouzanfar et al., 2015). Most of the deaths are from diarrhoea, especially among young children exposed to faecal contamination in drinking water (Prüss-Ustün et al., 2014). In Rwanda, unsafe water is currently ranked third as a risk-factor for disease (Forouzanfar et al., 2015), and diarrhoea is a leading cause of mortality in children under 5, accounting for an estimated 9% of overall deaths (Liu et al., 2014).

While the UN celebrated the achievement of the Millennium Development Goal (MDG) for water in 2012, unsafe drinking water is still the eighth leading risk factor for disease globally (Forouzanfar et al., 2015). An estimated 663 million people do not have access to an improved drinking water source (defined to include piped water to the dwelling, plot or yard, as well as public taps/standpipes, tubewells or boreholes, protected dug wells, protected springs, and rainwater collection) (WHO/UNICEF, 2015a). However, water from improved water sources is not necessarily free of faecal contamination (Bain et al., 2014b; Shaheed et al., 2014), with an estimated 1.8 billion people using a source that has faecal contamination, particularly in Africa (Bain et al., 2014a). Moreover, in these hygiene-challenged environments, even water that is safe at the source frequently becomes contaminated from faecal pathogens during collection, transport and storage in the home (Trevett et al., 2005; Wright et al., 2004).

Furthermore, safe water source coverage is not always equitable. Subnational inequalities, including urban and rural differences and differential access to types of improved water sources such as piped water are commonplace (Bain et al., 2014c; Fuller et al., 2015; Luh et al., 2013;

Pullan et al., 2014; Yu et al., 2014). In Rwanda, 76% of the population has access to an improved drinking water source, with 9% having access to piped water onto premises. However, while 85% of the urban population has access to improved drinking water sources including 28% having access to water piped onto premises, access for the rural population is only 57% and 2% respectively ((NISR) and (MINECOFIN), 2014).

With the adoption of the Sustainable Development Goals and specifically Target 6.1 of achieving universal and equitable access to safe and affordable drinking water for all by 2030, there is a need to incorporate water quality testing at sources and households (WHO/UNICEF, 2015b). In cooperation with the Rwanda Ministry of Health and DelAgua Health Rwanda—a private company distributing water filters and cookstoves financed by carbon credits (Barstow et al., 2014)—we conducted a national cross-sectional study to assess the faecal contamination of drinking water at the household level. In addition to testing water quality, potential risk factors for water quality were assessed at a household level and analyzed along with potential community-level determinants.

2. MATERIALS AND METHODS

2.1. Study setting

The study was conducted in all five provinces and 30 districts of Rwanda from 22 February to 4 April 2015, which included dry and rainy periods. In general, Eastern and Southern provinces are relatively drier and warmer compared to Northern and Western provinces, with increasing elevation and hilly terrain moving east to west. While most of the country is rural, Kigali City province is predominantly urban.

2.2. Sample size calculation

The primary outcome of interest was a national estimate of faecal contamination of drinking water at the household level. For this purpose, we used thermotolerant coliforms (TTC), a WHO-approved indicator of faecal contamination (WHO, 2011). We used a Monte Carlo simulation in order to generate within-village variance and between-village variance estimates necessary for sample size calculations (Chakraborty et al., 2009). Based on previously collected water quality data from Rwanda (Rosa et al., 2014b), we estimated an average within-village proportion of households with TTC-free drinking water of 40%, with a range of 0% to 100% as parameters for the simulation, as well as average size of a village and variation in size of villages based on a national database (Rwanda Ministry of Local Government, 2011). The variance components and intra-cluster correlation (ICC) were averaged across 1000 simulation runs to yield an ICC of 0.248, a within-village variance of 0.173 and a between-village variance of 0.057. Using the within-village and between village variance outputs from the simulation, we then calculated sample size. Setting a constant of 6 households to be sampled per village due to logistical considerations, we estimated a total of 144 villages (n=864 households) would be required to generate a national-level estimate of faecal contamination in household water quality with 90% confidence with a 10% relative precision. One additional village was added to buffer against potential sample loss.

2.3. Sample selection

To construct a nationally representative sample of households, a stratified two-stage cluster sample design was developed. Prior to sample selection, the population was stratified by geographic district (n=30 districts) and urban/rural status. Within each district, households were designated as urban or rural according to the village's urban or rural classification by the Rwanda Housing Authority Urban Status Final Report (RHA, 2012). As the intention was to have a binary indicator of urban status, peri-urban households were classified as urban households in the sample allocation. Proportional allocation was used to determine a stratum-specific sample size

based on the number of urban and rural households in each district derived from the 2012 national *ubudehe* database, which includes head of household names for each village (Rwanda Ministry of Local Government, 2011). In the first sampling stage, villages were randomly sampled from each stratum with probability proportional to estimated size (number of households). In the second stage, 6 primary households were randomly selected per village. Backup households were randomly pre-selected prior to data collection in case enumerators were unable to locate a primary household or the household member declined to participate. Community health workers were consulted prior to initiating surveys within a village in order to confirm the residency status and location of randomly selected households.

2.4. Eligibility criteria

Households were eligible to participate in the study if the house did not have a Lifestraw Family water filter provided by DelAgua Health Ltd., had drinking water present for sampling at the time of enumerator visit, and had a household member 16 years of age or older present that could answer the survey questions.

2.5. Household survey

Enumerators sought to survey the primary cook in each household, but if the cook was not present another adult 16 years of age who was willing to participate was surveyed. After providing informed consent, the respondent was asked to respond to a short pre-piloted survey in Kinyarwanda, a national language and spoken by all study households. The survey covered self-reported and observed household demographics, sanitation and hygiene facilities, water source type and household drinking water practices. We also asked questions on the respondent's self-reported diarrhoea and reported diarrhoea among any children under 5 years of age residing in the house. A socioeconomic status indicator was developed using polychoric

principal component analysis based on household materials and durable goods ownership (Kolenikov and Angeles, 2009).

2.6. Water sampling and analysis

At the end of each household survey, a drinking water sample was collected in a sterile Whirl-Pak bag (Nasco, Fort Atkinson, WI USA) containing a tablet of sodium thiosulphate to neutralize any halogen disinfectant. Respondents were asked to show where a child under 5 would get their drinking water, or where the respondent would if there was no child under 5 in the household, and the respondent dispensed the water from either their storage or serving container directly into the sample bag. The respondent also answered questions about whether that particular water sample had been treated and what type of source it had been collected from. Samples were placed on ice and processed in a mobile laboratory within 6 h of collection to assess levels of TTC. The mobile water sampling laboratory was set up in different locations throughout the study to minimize the time from sample collection to sample processing and membrane filtration. The lab was either set up in two separate offices or in hotel rooms; all rooms used for laboratory processing and analysis had a table that was cleaned with 75% ethanol and then covered with tinfoil to minimize risk of cross-contamination. Assays were performed using the membrane filtration technique on membrane lauryl sulphate medium (Oxoid Limited, Basingstoke, Hampshire, UK) using an Oxfam-DelAgua field incubator (Robens Institute, University of Surrey, Guilford, Surrey, UK). Plates that yielded colony forming units (CFUs) that were too numerous to count were given a level of 300 TTC for purposes of analysis (Rosa et al., 2014b). On average 24 water samples were processed each day (SD 7.2), with a range of 6-36 samples. For quality assurance, a lab blank was processed each sampling day using distilled water, and 1-2 sample duplicates were performed per day depending on incubator capacity.

2.7. Census data

In order to assess potential community-level determinants of drinking water quality, we accessed publicly available data from the Rwanda Population and Housing Census 2012, which was conducted August 2012. District profiles, which contain aggregate Census results for each sector (containing approximately 35 villages), were downloaded from the National Institute of Statistics Rwanda website ((NISR), 2014). A high-risk sanitation coverage indicator was created comprised of percentage of households in a sector with a public pit latrine or percentage of households practicing open defecation (in contrast to households using private pit latrine or flush toilet/WC system). “Other” and “not stated” types of toilet facilities could not be classified and did not contribute to the high-risk sanitation coverage percentage. For bivariate analysis, quartiles of the higher risk sanitation coverage indicator (% of sector) were used. Percentages of households within sectors disposing of their waste “in the bush”, “on the farms”, or “in the river/stream/drain/gutter” were combined to derive a percentage of households within a sector practicing open waste disposal. Other waste disposal such as “compost dumping”, “private dust bins”, and “public refuse bins” were considered contained disposal methods, while “other” and “not stated” could not be classified. For bivariate analysis, quartiles of the open waste disposal indicator (% of sector) were used. Lastly, population density (inhabitants/km^2), as reported by Rwanda Census 2012 for each sector, was collapsed into quartiles for inclusion in analyses. Water source coverage according to the census was not included in analyses since this was assessed during the household survey specifically for the collected water sample.

2.8. Precipitation data

Precipitation data for previous 7 days prior to each household’s survey date were downloaded in NetCDF format for each household location 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 household/village centroid locations using ArcGIS 10.3 (ESRI, Redmond, CA, USA). If the house had an inaccurate GPS location (outside of its village boundary), rainfall for the household was calculated according to its village centroid coordinates. Occurrence of an extreme rainfall event in the day previous to the survey date was calculated as a binary variable according to whether that day's rainfall exceeded the 90th percentile for all observed daily precipitation at all household/village locations over the survey period (Carlton et al., 2014; Howard et al., 2003). Thus, an extreme event was determined to have occurred if rainfall exceeded 2.53 cm on the previous day.

2.9. Statistical analysis

All analyses were conducted in Stata 14 (Stata Corporation, College Station, TX, USA). Because of a multi-modal distribution of TTC counts for water quality, Williams means (Alexander, 2012), medians, and interquartile ranges are presented as measures of central tendency. National and sub-national level estimates of water quality were weighted and adjusted for the complex sample design. For bivariate and multivariate analyses, we used logistic regression with two different water quality indicator outcomes: i) detection of TTC contamination vs no detection of TTC contamination and ii) intermediate/high risk vs. no detection of TTC contamination/low risk (>10 TTC/100 mL vs <=10 TTC/100 mL) (WHO, 2011). The choice to examine determinants of drinking water quality for the latter categorization was based on a recent meta-analysis of drinking water quality and diarrhoea which showed a marked increase in disease risk for households with drinking water having >10 TTC/100mL (Hodge et al., 2016), as well as a previously proposed intermediate post-2015 MDG monitoring target of <10 CFU of *E. coli* per 100 mL (WHO/UNICEF, 2013). Final model selection using multivariate analysis was based on the inclusion of variables with p-values of <0.10 in bivariate analysis. Model performance was assessed by constructing a confusion matrix based on predictive probabilities using

postestimation commands in Stata. All regression analyses incorporated sampling weights and cluster-robust standard errors were used in significance tests and the calculation of confidence intervals.

2.10. Ethics

The study was reviewed and approved by the ethics committee at the London School of Hygiene and Tropical Medicine (No. 9069) and Rwanda National Ethics Committee (No.460/2013). The protocol was also approved by the Rwanda National Institute of Statistics (Nº 0542/2015/10/NISR). Written informed consent to participate in the research was obtained from the male or female head of household, the primary cook of each participating household, or another adult respondent.

3. RESULTS

3.1. Study population

A total of 870 households from 145 villages and all 30 districts were sampled that met the eligibility criteria of currently having drinking water available at the household, not having a Lifestraw filter, and with a respondent at least 16 years of age. Target enrolment of 6 households per village was attained for all villages. There were no refusals, although 396 (45.5%) of households surveyed were backup houses because primary houses had either moved from the village, could not be identified from the sample frame *ubudehe* database, were not home at the time of the survey, or did not have drinking water available at the time of the survey. The elevation ranged from 962m to 2594 m, and previous week's rainfall ranged from 0 cm (78 households) to 8.22 cm (6 households). 88.9% of respondents were female, and 75% of surveyed villages were rural. Additional household and community characteristics are found in Table 1.

Table 1 Survey respondent and village/household characteristics.

	N (households)[a]	%
Province		
Kigali City	78	9.0
Southern	234	26.9
Western	180	20.7
Northern	156	17.9
Eastern	222	25.5
Total	870	100.0
Village status		
Rural	654	75.2
Peri-urban	108	12.4
Urban	108	12.4
Respondent characteristics		
Female	773	88.9
Years of education mean (SD)	3.9 (3.7)	-
Age mean in years (SD)	42.5 (16.1)	-
Household characteristics		
Mean household elevation in metres (SD)	1771 (287)	-
Household members mean (SD)	4.7 (2.2)	-
Children under 5 years mean (SD)	0.5 (0.7)	-
Dirt/animal dung flooring	683	78.5
Evidence of cow kept on plot	360	41.4
Owns 1 or more chickens	170	19.5
Water, sanitation and hygiene characteristics		
Hand washing		
Has dedicated hand washing location after defecation	64	7.4
Soap present at a designated handwashing location after defecation	15	1.7
Toilet type		
Pit latrine with slab	279	32.1
Pit latrine without slab	557	64.0
Other improved toilet (ventilated pit, composting, flush/pour flush)	18	2.1
No toilet	16	1.8
Reported drinking water source of collected sample		
Piped water into yard/plot[b]	41	4.7
Public tap/standpipe[b]	226	26.0
Hand pump (borehole)[b]	13	1.5
Protected spring[b]	361	41.5
Protected well[b]	2	0.2
Rainwater[b]	54	6.2
Bottled water[b]	4	0.5
Unprotected spring[c]	73	8.4

Surface water[c]	96	11.0
Reported household water treatment of collected sample		
None	778	89.6
Boiled	84	9.7
Other (filtered, chlorinated, boiled & chlorinated)	6	0.7
Precipitation characteristics		
Extreme rain event in previous day (>=2.53cm)	46	5.3
Mean precipitation in previous 7 days in cm (SD)	2.63 (1.85)	-

[a]Except where mean and standard deviation indicated
[b]Improved water sources according to WHO/UNICEF Joint Monitoring Programme (JMP) for Water Supply and Sanitation guidelines (WHO/UNICEF, 2006). Bottled water determined to be improved given village availability of improved sources for cooking and personal hygiene as well as type of bottle.
[c]Unimproved water sources according to JMP guidelines.

3.2. Water quality results

Drinking water samples were collected from 870 households. Of these samples, one was lost during transit, one was too turbid to process, and two samples' plates could not be read after incubation; these are counted as missing. Nationally, Williams mean water quality was 34.1 TTC/100mL (95% CI 26.0-44.7), with Eastern Province having the highest contamination compared to other provinces (123.9 TTC/100mL, 95% CI 84.1-182.3 TTC/100mL) (Table 2). In addition to regional differences, there was evidence that households in urban villages had lower levels of water contamination than households in rural villages. Rural samples had a Williams mean of 41.5 TTC/100mL (95% CI 30.9-55.7 TTC/100mL), while urban samples had a Williams mean of 11.3 TTC/100mL (95% CI 4.6-26.1 TTC/100mL). Although water source type was self-reported and could be subject to misclassification, particularly protected vs. unprotected springs, there was evidence that household samples fetched from surface water sources were more contaminated than other source types. Drinking water samples reportedly fetched from piped to household premises sources were the least contaminated overall, although not completely free of contamination (Table 2).

Table 2 Household drinking water quality by province, village status, and reported water source type.

	n	Williams mean (TTC/100 mL)	Lower 95% CI	Upper 95% CI	Median (TTC/100 mL)	IQR (TTC/100 mL)
Rwanda	866	34.1	26.0	44.7	38	0-600
Kigali City Province	78	18.1	6.7	46.4	15	0-392
Southern Province	233	29.7	19.2	45.6	24	2-294
Western Province	179	27.8	14.3	53.0	26	2-504
Northern Province	156	11.0	4.8	23.9	5.5	0-216
Eastern Province	220	123.9	84.1	182.3	261	32.5-600
Village status						
Rural	652	41.5	30.9	55.7	44.5	2-600
Peri-urban	106	28.3	12.7	61.5	34	2-600
Urban	108	11.3	4.6	26.1	6	0-328
Reported water source type						
Piped water into yard/plot[a]	40	4.3	1.9	8.5	0	0-83
Standpipe/borehole[a]	239	27.1	15.2	47.7	26	2-490
Protected spring/well[a]	362	29.6	18.5	47.1	26	2-340
Rain/bottled water[a]	57	19.6	8.2	45.0	26	0-408
Unprotected spring[b]	73	30.5	11.6	77.9	16	0-600
Surface water[b]	95	259.5	164.9	408.1	600	70-1500

[a]Improved water sources according to JMP guidelines (WHO/UNICEF, 2006). Bottled water (n=4) determined to be improved given village availability of improved sources for cooking and personal hygiene as well as type of bottle.
[b]Unimproved water sources according to JMP guidelines.

Only 24.9% (95% CI 20.9-29.4%, n=217) of household water samples met WHO Guidelines of no detectable TTC contamination, while 42.5% (95% CI 38.0-47.1%, n=361) of samples were >100 TTC/100mL and considered high risk (Figure 1). Samples from Kigali City Province and Northern Province had the highest proportion of samples with no detectable TTC contamination (39.1%, 95% CI 23.3-57.5% and 38.8%, 95% CI 27.7-51.2% respectively) (Figure 1). Eastern province had the lowest proportion of samples meeting WHO guidelines, with only 12.3% (95% CI 8.0- 18.4%) of samples having no detectable TTC contamination. Eastern Province also had the highest proportion of samples with high risk contamination >100 TTC/100mL (63.5%, 95% CI 54.1-72.0%). Similar to the pattern observed for mean water quality differences, an estimated 44.1% of urban households had drinking water with no detectable TTC contamination (95% CI 29.6-59.6%), while peri-urban and rural houses had 23.7% (95% CI 14.1-37.0%) and 21.9% (95% CI 17.8-26.7%) respectively. Additionally, a higher proportion of rural samples (65.1%, 95% CI 59.7-70.1%), were at intermediate or high risk according to WHO Guidelines, compared to urban samples (41.8%, 95% CI 28.1-57.0%).

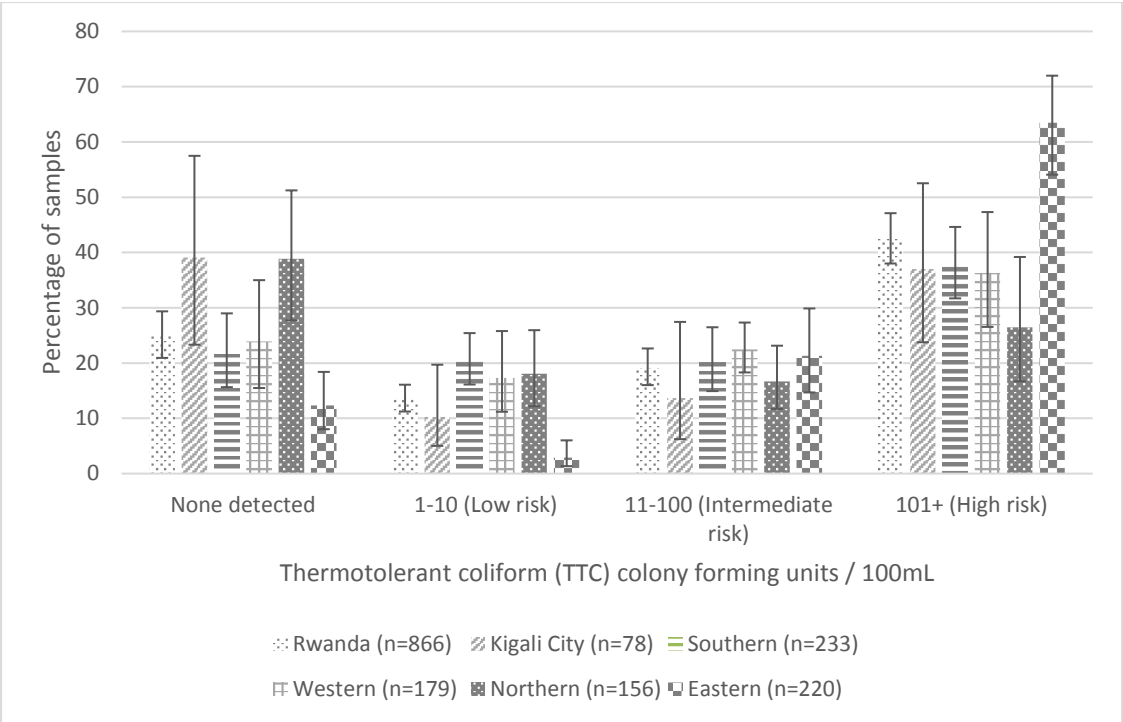

Figure 1 Household drinking water quality (thermotolerant coliform colony forming units/100mL) nationally and by province with 95% confidence intervals.

3.3. Factors associated with detectable TTC contamination (>=1 TTC/100mL)

In bivariate logistic regression analyses for detectable TTC contamination, household-level risk factors with p values <0.10 included having a dirt/animal dung floor, chicken ownership, not having soap at a dedicated handwashing location after defecation, having an unimproved toilet, not treating drinking water, and drinking water source, particularly surface sources such as streams, rivers, or lakes (Table S1). Household water storage practices were not associated with water quality, nor was reported time to fetch water, household size, SES, diarrhoea in the household in the previous week, toilet location, toilet sharing, or latrine cleanliness. Community-level risk factors that indicated increased odds of any water contamination included the percentage of houses within the sector disposing of solid waste into bush, farm or rivers (according to percentage quartiles). Increased elevation was associated with lower TTC counts, as was cumulative rainfall in the previous 7 days. Both increased population density (according

to quartiles) and village urban status were associated with lower TTC counts, with highest population density quartile (OR 0.38, 95% CI 0.20-0.74, p<0.001) and urban designation (OR 0.36, 95% CI 0.18-0.70, p=0.003) most protective relevant to lowest quartile and rural status respectively (Table S1). After further examination, only population density was included in multivariate analyses to avoid potential issues of collinearity, and because census-derived population density was more recent and had higher resolution than rural, peri-urban, and urban designations.

In the multivariate logistic regression model for risk factors of detectable TTC (Table 3), there was evidence that reported drinking water source is a determinant of household water quality, with surface water sources having the highest odds of contamination relative to piped water into yard/plot (OR 15.91, 95% CI 3.58-70.65, p<0.001). With the exception of rainwater/bottled water, water from other sources, including improved sources, had increased odds of contamination relative to piped water into yard plot. Public tap/borehole (OR 4.11, 95% CI 1.05-16.16, p=0.043), protected spring /well (OR 4.10, 95% CI 1.07-15.73, 0.040), and unprotected spring (OR 4.08, 95% CI 0.96-17.31, p=0.056) all had similar odds of detectable TTC contamination relative to piped water into yard/plot.

Increased percentage of households in a sector that openly disposed of solid waste was associated with significantly increased odds of detectable TTC contamination, relative to lowest quartile (corresponding to <21.4% of households in sector). There was also evidence that household elevation is associated with water quality. Households below 1500m had the highest odds of having detectable TTC contamination relative to households at above 2000m (OR 11.71, 95% CI 4.98-27.51, p<0.001), although the 95% CI overlapped with households between 1500 and 1999m (OR 5.47, 95% CI 2.92-10.23, p<0.001). There was no evidence that other factors such as sector population density, cumulative rainfall in previous 7 days, type of flooring, chicken

ownership, toilet type, presence of soap, and household water treatment were drivers of detectable TTC contamination in multivariate analyses. The model correctly predicted 665 (77.1%) cases.

3.4. Factors associated with intermediate/high risk contamination (>10 TTC/100mL)

In bivariate logistic regression analyses, determinants of intermediate/high risk drinking water quality with p values <0.10 were similar to determinants of the detectable TTC contamination model with a few exceptions (Table S1). Household-level risk factors included chicken ownership and having an unimproved toilet, but not floor type, presence of soap at handwashing location, or household water treatment, as was found for the detectable TTC contamination model. Community-level determinants included reported water source type, sector open waste disposal practices, and elevation, similar to the detectable TTC contamination model. Also similar to the detectable TTC contamination model, both increased population density and urban status were associated with lower TTC contamination in the intermediate/high risk contamination model, but only population density was included as described in 3.3. Two precipitation-related indicators were significantly associated with water quality: cumulative rainfall in the previous 7 days was protective, while an extreme rain event in the previous day increased odds of intermediate/high risk contamination. After further examination and to avoid potential issues of collinearity, seven-day cumulative rainfall was not included in the final intermediate/high risk contamination model as it was correlated with the occurrence of an extreme rain event on the previous day.

In the multivariate logistic regression analysis for determinants of intermediate/high risk contamination (Table 3), there was again evidence that the household's water source is a risk factor, with surface water having the highest odds relative to piped water to yard/plot (OR 19.19, 95% CI 6.73-54.70, p<0.001). Increased open solid waste disposal within the sector was

again also strongly associated with increased odds of intermediate/high risk contamination, and increased elevation was protective, with the highest odds of intermediate/high risk contamination in houses below 1500m (OR 11.95, 95% CI 5.79-24.63, $p<0.001$). In contrast with the detectable TTC contamination model, there was evidence that the highest quartile of sector population density in the sample, corresponding to >686 people/km^2, had lower odds of intermediate/high risk contamination relative to the lowest quartile of sector density of <386 people/km^2 (OR 0.48, 95% CI 0.25-0.89, $p=0.021$). There was no evidence that household factors such as chicken ownership or household toilet type increased odds of intermediate/high risk contamination, while the occurrence of an extreme rain event on the previous day significantly increased odds of intermediate/high risk contamination (OR 3.92, 95% CI 1.33-11.56, $p=0.014$). The model correctly predicted 599 (69.2%) cases.

Table 3 Multivariate logistic regression models for i) >=1 TTC/100mL vs no detectable TTC and ii) >10 TTC/100mL vs <=10 TTC/100mL.

	>=1 TTC/100mL vs no detectable TTC		>10 TTC/100mL vs <=10 TTC/100mL.	
	Adjusted OR (95% CI)	**p value**	**Adjusted OR (95% CI)**	**p value**
Sector waste dumped in bush/farm/river - First quartile (1.1-21.4% of households)	REF		REF	
Second quartile (21.5-29%)	2.55 (1.34-4.87)	0.005	2.06 (1.12-3.79)	0.020
Third quartile (29.1-39%)	2.39 (1.16-4.93)	0.019	1.60 (0.83-3.10)	0.16
Fourth quartile (39.1-55.5%)	2.84 (1.43-5.62)	0.003	1.88(0.97-3.66)	0.063
Sector density - First (55-385 people/km^2)	REF		REF	
Second quartile (386-499/km^2)	0.95 (0.48-1.91)	0.89	0.67 (0.37-1.18)	0.16
Third quartile (500-686/km^2)	1.06 (0.51-2.18)	0.88	0.71 (0.39-1.30)	0.27
Fourth quartile (687-24482/km^2)	0.80 (0.37-1.70)	0.55	0.48 (0.25-0.89)	0.021
Village rainfall in previous 7 days (cm)	1.04 (0.86-1.25)	0.71	-	-
No extreme village rain event in previous 1 day	-	-	REF	
Extreme village rain event in previous 1 day	-	-	3.92(1.33-11.56)	0.014
Elevation >=2000m	REF		REF	
1500-1999m	5.47 (2.92-10.23)	<0.001	5.20 (2.74-9.85)	<0.001
<1500m	11.71 (4.98-27.51)	<0.001	11.95 (5.79-24.63)	<0.001
Ceramic tile/cement/brick flooring	REF		-	-
Dirt/animal dung flooring	1.03 (0.63-1.69)	0.90	-	-
No chickens owned	REF		REF	

1 or more chickens owned	1.50 (0.91-2.48)	0.11	1.10 (0.72-1.69)	0.65
Soap present at designated handwashing location after defecation	REF		-	-
No soap present at designated location after defecation or no designated location	1.41 (0.52-3.86)	0.50	-	-
Improved toilet (pit latrine with slab or other improved type)	REF		REF	
Unimproved toilet (pit latrine without slab or none)	1.50 (0.93-2.40)	0.095	1.15 (0.78-1.70)	0.49
Piped water into yard/plot	REF		REF	
Public tap/borehole	4.11 (1.05-16.16)	0.043	4.01 (1.62-9.93)	0.003
Protected spring/well	4.10 (1.07-15.73)	0.040	3.64 (1.44-9.21)	0.007
Rainwater/bottled water	1.22 (0.29-5.19)	0.79	2.34 (0.75-7.25)	0.14
Unprotected spring	4.08 (0.96-17.31)	0.056	4.43 (1.53-12.81)	0.006
Surface water	15.91 (3.58-70.65)	<0.001	19.19 (6.73-54.70)	<0.001
Household treated water (JMP adequate)	REF		-	-
No household treatment	1.21 (0.56-2.63)	0.62	-	-

4. DISCUSSION

This is the first population-based, nationally representative assessment of household drinking water quality in Rwanda. We found widespread faecal contamination of household supplies, a finding that is consistent with studies of particular sub-populations in Rwanda (Rosa et al., 2014b; Uwimpuhwe et al., 2014). Faecal contamination of drinking water can have adverse health impacts and can contribute to diarrhoea (Hodge et al., 2016; Luby et al., 2015). These results suggest a substantial proportion of Rwanda's population are exposed to faecal contamination through this pathway.

Reported source of the sampled household drinking water was a major factor associated with water quality. Compared to piped water to yard/plot, all water source types (other than rainwater/bottled water) had increased odds of detectable and intermediate/high risk TTC contamination. These results are consistent with a recent meta-analysis that showed piped water was safer at both the source and household compared to other water source types (Shields et al., 2015), and that water from improved sources is not necessarily free of contamination and can still pose a health risk (Bain et al., 2014b). At substantial risk for detectable and intermediate/high risk TTC contamination are households utilizing surface sources, suggesting transitioning these households to improved water source types, particularly piped water, could lead to substantial improvements in water quality in this setting. Indeed, other water quality assessments in Rwanda have found high faecal contamination of surface water, partly due to anthropogenic influence (Sekomo et al., 2012; Wronski et al., 2015).

We found various community-level factors associated with increased faecal contamination of water at the household level. Households residing in sectors with high levels of open household solid waste disposal were at increased odds of detectable and intermediate/high risk TTC

contamination, although there did not appear to be increasing risk according to quartiles suggesting a potential threshold effect. Solid waste can contain numerous pathogens, and may include child faeces and other sources of faecal waste (Majorin et al., 2014; Rego et al., 2007). When openly disposed of into the environment, this source of faecal contamination may contaminate surface water sources used for drinking or other household uses, and contaminate groundwater and/or water sources with poor infrastructure (Godfrey et al., 2006; Howard et al., 2003; Kulabako et al., 2007; Nsubuga et al., 2004). Open household solid waste disposal may also lead to unsanitary environments around the household and other living environments and contribute towards other pathways of water contamination such as through contaminated hands and collection/storage vessels. The impact of open waste disposal, as well as presence of other faecal sources such as human/animal faeces, may be aggravated by extreme rainfall events which can result in a "flush effect" (Levy et al., 2009), particularly in environments with rapid groundwater recharge. Other studies in Rwanda have identified increased rainfall as a risk factor for water source contamination (Gasana et al., 2002) and groundwater contamination (Nigatu et al., 2015), and previous day rainfall resulted in increased TTC contamination of protected springs in Kampala (Howard et al., 2003) and wells in Mozambique (Godfrey et al., 2006). Globally, water sources, including a range of improved sources, are susceptible to greater contamination during the wet season, and this pattern has been found in both urban and rural settings and in different climate zones (Kostyla et al., 2015).

We also found that households at higher elevations had lower odds of detectable and intermediate/high risk TTC contamination. Higher elevations may characterize more pristine catchment areas, and have fewer sources of animal and human waste in the environment than is often present downstream or lower in watersheds. A recent study in Rwanda supports this, identifying elevation as protective against diarrhoea, partly attributed to drainage and accumulation of solid waste, flies and faecal matter at lower elevations (Uwizeye et al., 2014). Another study in Rwanda found increased elevation to be associated with improved surface

water quality (Wronski et al., 2015). Additionally, ambient temperature, which we did not include in our analyses, decreases with increased elevation in Rwanda, and may have reduced faecal indicator growth and prevalence in the environment relative to lower elevations (Rochelle-Newall et al., 2015).

Increased population density was also associated with reduced odds of intermediate/high risk TTC. Consistent with this finding, a major systematic review found rural drinking water sources to be of worse quality than urban drinking water sources (Bain et al., 2014b), and this pattern has also been observed in a national, randomized study of household drinking water in Peru (Miranda et al., 2010). In Rwanda, this pattern may be due to reduced livestock ownership in urban areas, which can be a substantial source of faecal contamination in the environment (Jenkins et al., 2009). In contrast, other studies have found increased population density to be associated with contaminated groundwater and drinking water contamination, potentially due to latrine density, poor waste management, unimproved sanitation, and other unmeasured factors (Escamilla et al., 2013; Nsubuga et al., 2004; Okotto-Okotto et al., 2015; Wright et al., 2013). More investigation is needed to arrive at a possible explanation for this finding.

Interestingly, household-level indicators did not appear to be determinants of faecal contamination of drinking water in this setting. We suspect that this is partly due to a low degree of variation in household water collection, storage, and serving practices. Most households fetch and store water in 20L jerricans on a fairly regular basis given proximity of water sources and year-round availability of water, and while additional contamination may occur in the household, these practices may have less impact on household water quality than determinants that affect source water quality in this setting. Household unimproved toilet type did not reach statistical significance, in contrast with a study in Tanzania that found increased presence of *E. coli* virulence genes (ECVG) in stored drinking water of households with

unimproved toilet types (Mattioli et al., 2013). Although other studies have found that domestic animal exposure can result in increased contamination on hands as well as contaminated water leading to diarrheal illness (George et al., 2015; Schriewer et al., 2015; Zambrano et al., 2014), we did not find significant associations for the limited range of livestock indicators we examined. Future research on animal proximity and contact with drinking water supplies, mechanisms of contamination, and ways to minimize this potential contamination pathway is warranted. Although presence of soap at a designated hand washing location after defecation was not significant in multivariate analysis, very few houses reported having a designated handwashing location. It is likely our use of this proxy indicator and this finding does not adequately account for hand cleanliness and may not reflect the role of hygiene on water quality in this setting (Pickering et al., 2010; Ram et al., 2011).Hands frequently come in contact with contaminated soil, food or other surfaces and can contaminate water supplies (Mattioli et al., 2014; Pickering et al., 2012, 2011). Of interest is our finding in bivariate analyses that recent diarrheal illness in either the child (if present) or respondent was not associated with water quality, although this may be due to low numbers of households with children under 5. Recent studies give evidence for the relationship between water quality and diarrhoea and thus this finding may be due to low sample size and timing of sample collection vs illness recall (Hodge et al., 2016; Luby et al., 2015). Lastly, although significant in bivariate analysis for detectable TTC contamination, reported household water treatment was not a significant determinant of drinking water quality in multivariate analysis. The majority of households that reported treating their water reported their method as boiling. Other research has shown that reported household water treatment is exaggerated, inconsistent and often ineffective (Rosa et al., 2014a). Moreover, without safe storage, treated water may be subject to recontamination, which may partly explain why a stronger protective effect was not observed (Wright et al., 2004).

There are a number of limitations to this study. This is a single cross-sectional study and was conducted over two months. While we cannot infer causality between the examined risk factors and drinking water quality, we have identified potential relationships worthy of further examination, perhaps using experimental study designs. This activity was conducted to assess household drinking water quality prior to receiving a Lifestraw filter. Since households were excluded if they had received a Lifestraw Filter from DelAgua Health or did not currently have drinking water in the house, this study population may not be representative of the general population. Evidence from a randomized trial found improved water quality in households that had received the Lifestraw filter from DelAgua Health (Rosa et al., 2014b), and thus water contamination may be overestimated in Western Province where DelAgua Health conducted a large-scale free distribution of filters to *ubudehe* 1 and 2 households in two thirds of the province. Additionally, initial sample size calculations were based on the need to obtain a single point estimate of national drinking water quality, although the sample size of 862 samples (for detection of TTC model) and 866 samples (for intermediate/high risk TTC contamination model) exceeds the commonly cited rule of thumb of at least 10 events per variable (Peduzzi et al., 1996). Although a range of geographic settings were included in the study, approximately half of the study was in the rainy season and the data collection team moved from one province to another due to logistical and timing constraints. This resulted in an imbalance of experienced climatic conditions between regions during sampling, and the results may reflect a season bias, particularly between regions (Wright et al., 2012). A more ideal study design would incorporate repeated measures of water quality in households and water sources under a range of climatic conditions. This would enable assessment of potential drivers over a longer time period to account for climatic variability and variations in exposures at household and community levels, and minimize risk of seasonal bias. Given multiple contamination pathways and concerns about faecal coliforms as a suitable faecal indicator for health (Gruber et al., 2014), detailed assessment of other sources of faecal contamination, such as through surface, soil, food, hand,

water source sampling, and microbial source tracking, would help to better characterize mechanisms and pathways of health-relevant drinking water contamination. This study utilized publicly available sector-level data from the Rwanda census which preceded water sampling by over two years and may not reflect current village conditions. The daily precipitation data also lacks geographic specificity, and may not accurately reflect rainfall amounts or occurrence of extreme events (Crétat et al., 2013; Funk et al., 2015). Future research seeking to examine community environmental and climatic determinants should incorporate village or watershed-level data, and in-situ temperature and precipitation measurement.

5. CONCLUSION

Unsafe drinking water quality is a major health concern in low-income countries, particularly for children under 5 years of age. This study found widespread faecal contamination of household drinking water supplies, with evidence of sub-national differences, household and community-level risk factors, and impact of extreme precipitation. As the first population-based, nationally representative assessment of household drinking water quality in Rwanda, these results highlight the need to reduce the risk of unsafe drinking water at both source and point of consumption.

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Author contributions.

Conceived and designed the experiments: MK, CN, LI, LZ, GR, TC. Performed the experiments: MK, LI, LZ. Analyzed the data: MK CN. Wrote the paper: MK TC.

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SUPPLEMENTARY INFORMATION

Table S 1 Unadjusted logistic regression analysis for i) >=1 TTC/100mL vs no detectable TTC and ii) >10 TTC/100mL vs <=10 TTC/100mL.

	N(%) or Mean (SD)	**>=1 TTC/100mL vs no detectable TTC**		**>10 TTC/100mL vs <=10 TTC/100mL**	
		Crude OR	**p value**	**Crude OR**	**p value**
Village/sector characteristics					
Rural village	652 (75.3)	REF		REF	
Peri-urban village	106 (12.2)	0.91 (0.45-1.81)	0.78	0.77 (0.44-1.37)	0.37
Urban village	108 (12.5)	0.36 (0.18-0.70)	0.003	0.39 (0.20-0.74)	0.005
Sector density - First quartile (55-385 people/km^2)	220 (25.4)	REF		REF	
Second quartile (386-499/km^2)	216 (24.9)	0.90 (0.44-1.85)	0.77	0.64 (0.33-1.23)	0.18
Third quartile (500-686/km^2)	221 (25.5)	0.64 (0.29-1.41)	0.27	0.50 (0.24-1.05)	0.065
Fourth quartile (687-24482/km^2)	209 (24.1)	0.38 (0.20-0.74)	<0.001	0.30 (0.17-0.55)	<0.001
Sector waste dumped in bush/farm/river - First quartile (1.1-21.4% of households)	227 (26.2)	REF		REF	
Second quartile (21.5-29%)	209 (24.1)	2.87 (1.49-5.54)	0.002	2.43 (1.25-4.73)	0.010
Third quartile (29.1-39%)	214 (24.7)	3.26 (1.70-6.25)	<0.001	2.39 (1.29-4.44)	0.006
Fourth quartile (39.1-55.5%)	216 (24.9)	4.82 (2.53-9.21)	<0.001	3.14 (1.75-5.62)	<0.001
Sector % unimproved toilet type (bush and shared pit latrine) – First quartile (1.7-5.6% of households)	222 (25.6)	REF		REF	
Second quartile (5.7-9%)	215 (24.8)	1.11 (0.53-2.35)	0.78	0.92 (0.44-1.92)	0.82
Third quartile (9-13.4%	214 (24.7)	1.17 (0.58-2.36)	0.67	1.03 (0.52-2.04)	0.92
Fourth quartile (13.5-64.8%)	215 (24.8)	0.85 (0.44-1.64)	0.62	0.73 (0.41-1.30)	0.29

Village rainfall in previous 7 days (cm)	2.6 (1.8)	0.83 (0.74-0.94)	0.004	0.89 (0.79-1.00)	0.047
No extreme village rain event in previous 1 day	820 (94.7)	REF		REF	
Extreme village rain event in previous 1 day	46 (5.3)	1.49 (0.48-4.60)	0.48	2.53 (0.97-6.63)	0.06
General household characteristics					
Household elevation >=2000m	157 (18.1)	REF		REF	
1500-1999m	492 (56.8)	4.70 (2.81-7.88)	<0.001	4.53 (2.62-7.83)	<0.001
<1500m	217 (25.1)	6.39 (3.07-13.31)	<0.001	8.61 (4.44-16.68)	<0.001
Number of household members	4.7 (2.2)	1.00 (0.92-1.09)	0.97	0.97 (0.91-1.05)	0.49
Number of children under 5 in household	0.5 (0.7)	1.16 (0.90-1.50)	0.25	1.09 (0.87-1.37)	0.45
Lowest SES quintile	174 (20.1)	REF		REF	
Low SES quintile	172 (19.9)	1.42 (0.85-2.36)	0.18	1.38 (0.91-2.10)	0.12
Middle SES quintile	174 (20.1)	1.06 (0.61-1.83)	0.84	1.30 (0.80-2.10)	0.29
High SES quintile	173 (20.0)	1.02 (0.59-1.78)	0.94	1.24 (0.73-2.10)	0.42
Highest SES quintile	173 (20.0)	0.64 (0.36-1.14)	0.13	0.88 (0.51-1.50)	0.63
Ceramic tile/cement/brick flooring	186 (21.5)	REF		REF	
Dirt/animal dung flooring	680 (78.5)	1.61 (1.01-2.57)	0.044	1.36 (0.89-2.07)	0.15
[No evidence of any] cow kept on plot	507 (58.6)	REF		REF	
[Evidence of] cow(s) kept on plot	359 (41.5)	1.02 (0.69-1.50)	0.91	1.10 (0.79-1.52)	0.58
No chickens owned	696 (80.4)	REF		REF	
1 or more chickens owned	170 (19.6)	1.94 (1.21-3.10)	0.006	1.45 (1.00-2.11)	0.052

No diarrhoea (child <5 or respondent)	763 (88.1)	REF		REF	
Diarrhoea (child <5 or respondent)	102 (11.8)	0.89 (0.54-1.48)	0.65	1.05 (0.63-1.77)	0.84
Household hygiene and sanitation characteristics					
Has dedicated handwashing location after defecation	64 (7.4)	REF		REF	
No designated handwashing location	802 (92.6)	1.32 (0.62-2.80)	0.47	1.06 (0.49-2.29)	0.89
Water present at designated handwashing location after defecation	43 (5.0)	REF		REF	
No water present at designated location after defecation or no designated location	821 (94.8)	1.17 (0.53-2.54)	0.70	1.17 (0.48-2.83)	0.73
Soap present at designated handwashing location after defecation	15 (1.7)	REF		REF	
No soap present at designated location or no designated location	849 (98.0)	2.33 (0.97-5.59)	0.058	1.22 (0.50-2.96)	0.65
Improved toilet (pit latrine with slab or other improved type)	296 (34.2)	REF		REF	
Unimproved toilet (pit latrine without slab or none)	570 (65.8)	1.99 (1.23-3.20)	0.005	1.50 (1.03-2.19)	0.037
No faeces observed on floor or w/in 1m of toilet	604 (69.8)	REF		REF	
Faeces observed on floor or w/in 1m of toilet	259 (29.9)	1.29 (0.86-1.92)	0.22	1.17 (0.81-1.70)	0.40
Wiping materials observed at toilet	239 (27.6)	REF		REF	

No wiping materials observed at toilet	624 (72.1)	1.11 (0.77-1.60)	0.59	1.07 (0.72-1.58)	0.73
Does not share toilet facility	754 (87.1)	REF		REF	
Shares toilet facility with 1 or more houses	112 (12.9)	0.90 (0.54-1.50)	0.68	1.19 (0.73-1.92)	0.48
Toilet facility located inside compound	807 (93.2)	REF		REF	
Toilet facility located outside compound	59 (6.8)	1.38 (0.67-2.84)	0.38	1.31 (0.67-2.59)	0.43
Household drinking-water characteristics					
Piped water into yard/plot	40 (4.6)	REF		REF	
Public tap/borehole	239 (27.6)	4.90 (2.18-11.04)	<0.001	3.86 (1.95-7.65)	<0.001
Protected spring/well	362 (41.8)	5.04 (2.47-10.27)	<0.001	3.68 (1.87-7.25)	<0.001
Rainwater/bottled water	57 (6.6)	2.37 (0.89-6.29)	0.083	3.52 (1.37-9.04)	0.010
Unprotected spring	73 (8.4)	3.71 (1.46-9.43)	0.006	3.40 (1.45-7.96)	0.005
Surface water	95 (11.0)	33.98 (10.54-109.55)	<0.001	29.93 (11.69-76.63)	<0.001
Round-trip walking time to water source (minutes)	28.6 (25.0)	1.01 (1.00-1.02)	0.21	1.00 (1.00-1.01)	0.43
Storage container covered (has lid)	238 (27.5)	REF		REF	
Storage container uncovered	625 (72.2)	1.33 (0.84-2.11)	0.22	1.10 (0.72-1.68)	0.67
Small-mouthed storage container	835 (96.4)	REF		REF	
Large-mouthed storage container	29 (3.4)	0.78 (0.25-2.48)	0.68	1.51 (0.48-4.74)	0.48
Household treated water (JMP adequate)	775 (89.5)	REF		REF	
No household treatment	89 (10.3)	2.37 (1.32-4.25)	0.004	1.55 (0.86-2.80)	0.14

Chapter 4. Use, microbiological effectiveness and health impact of a household water filter intervention in rural Rwanda – a matched cohort study

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SECTION A – Student Details

Student	Miles Kirby
Principal Supervisor	Thomas Clasen
Thesis Title	Assessing use, exposure, and health impacts of a water filter and improved cookstove distribution programme in Rwanda

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?			
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	International Journal of Hygiene and Environmental Health
Please list the paper's authors in the intended authorship order:	Miles A. Kirby, Corey L. Nagel, Ghislaine Rosa, Marie Mediatrice Umupfasoni, Laurien Iyakaremye, Evan A. Thomas, Thomas F. Clasen
Stage of publication	**Not yet submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	With input from co-authors, I designed the study. I organized and supervised collection of data and samples, managed daily operations, supervised lab work, and cleaned the data. I analysed the data in collaboration with assistance from Corey Nagel, and I wrote the paper.

Student Signature: _____ **Date:** 11November 2016

Supervisor Signature: _____ **Date:** 11 November 2016

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

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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 13-24 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, 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. The odds of detecting faecal indicator bacteria in drinking water were 78% lower in the intervention arm than the control arm (OR 0.22, 95% CrI 0.10-0.39, $p<0.001$). The intervention arm 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, though potentially exaggerated due to reporting bias, is also suggested by reduced odds of reported diarrhoea-related visits to community health workers or clinics, although these did not reach statistical significance.

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 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 house 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 efficacy studies and use of interventions can change over time (Hunter, 2009) and 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 approximately 2,200 advanced "rocket" cookstoves and water filters to households in 15 villages in 11 of Rwanda's 30 districts. The intervention was accompanied by behaviour change messaging and monitoring conducted by 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 (Rosa et al., 2014b; Thomas et al., 2013a). However, non-exclusive use and consumption of unfiltered drinking water away from the household were identified as challenges. 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 13-24 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 and comprises foothills and mountains of the Congo-Nile Divide, 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 in March, April and May. 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.

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 phone survey was then conducted in July 2013 and administered to one CHW from all intervention and potential control villages. The phone survey contained questions on village-level cooking and drinking water practices, including drinking water sources and household water treatment, which the CHW answered by estimation. Additionally, programmatic DelAgua household survey data from the nine intervention villages, originally collected by village CHWs, were aggregated by village and categorized according to majority

proportion for additional matching to the indicators collected by the phone survey. Finally, a national *ubudehe* (wealth category) database was accessed to derive the proportion of houses according to *ubudehe* category, and estimation of household size according to *ubudehe* category. 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 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. 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. 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 total number of households, children under 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 outcomes.

Enrolment and eligibility

Houses 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). 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 a government-derived village roster. 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-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 Round 1 results from 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 cooking, sanitation, hygiene, and drinking water practices. A socioeconomic status indicator was developed using polychoric principal component analysis based on household materials and durable goods ownership (Supplementary Information 1) (Kolenikov and Angeles, 2009). 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, 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 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 outcomes 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

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. Adherent households were defined as having filled the filter at least once on at least half of the days for which sensor data was available.

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

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

The sample size was based on household drinking water quality, the primary outcome. We assumed a 50% reduction in mean $\log_{10}$-transformed TTC count, which is conservative given results from the previous RCT in this population which reported a 89% reduction in the mean $\log_{10}$ TTC count (Rosa et al., 2014b). We used a sample size calculation for two-sample comparison of means in Stata using sampsi followed by the sampclus package (Garrett, 2001). We assumed mean water quality in the untreated arm to be 1.22 $\log_{10}$ CFU/100mL, with a standard deviation of 0.96 $\log_{10}$ CFU/100mL. With an alpha of 0.05 and power of 0.8, the results indicated a sample size of 39 in each arm. To adjust for the clustered design, we use an intraclass correlation of 0.03 based on data from the previous RCT, an estimated 5 observations per cluster, and 18 clusters. This resulted in a corrected sample size of 44 in each group. To better characterize household water quality and impact of the filter over time, we decided to sample drinking water from all enrolled households.

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 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)

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 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 potential individual, household, and village-level confounders (Figure S1), 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 (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 (Crl) of the true model parameters. The 95% credible interval 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, 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. Propensity score matching resulted in 9 potential control villages that were visited and confirmed during rapid assessment (Figure S2). Median bias on the key

matching variables was 27.8 prior to matching, and reduced to 7.2 after matching (Table S1), indicating improved balance among potential confounders. 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 signs of 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).

Table 1 Intervention and control household characteristics at enrolment.

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
House has electricity	2.7	8.3	-0.251
House has radio	33.6	35.3	-0.034
House 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
Own land	90.3	85.9	0.135
Own house	83.2	90.4	-0.214
Own 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 house 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
Drinking water reportedly treated	74.1	1.3	2.270
	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.

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. Approximately 6 months after enrolment, 144 control houses (92.3%) and 91 intervention households (80.5%) were followed-up and surveyed as part of Round 2. There were no refusals of the household survey, and one child death occurred 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 house 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 houses 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 houses (72.4%) indicated a child's drinking water would come from the filter and had water in it in Round 1, and 63 houses (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 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 houses 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).

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)
House currently has working filter[1]	93 (84.5)	76 (85.4)	169 (84.9)
Observed and reported use	**N=93 houses**	**N=76 houses**	**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	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 houses) [3]	22 (50.0)	14 (36.8)	36 (45.9)
Filter filled on a least one third of days with sensor data (% of houses)	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 unfiltered water while at home[4]	23 (24.7)	25 (33.3)	48 (28.6)
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.

Water quality

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.

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

	Control			**Intervention – all**			**Intervention –directly from filter**			**Intervention –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)	5.5 (3.5-8.5)	106	31.4 (13.0-49.9)	2.7 (2.1-3.5)	75	5.8 (-1.4-13.0)	1.5 (1.2-2.1)	28	103.3 (35.5-171.1)	12.9 (6.2-26.5)
2	138	121.5 (65.5 - 177.6)	10.0 (6.9-14.5	81	19.7 (1.6-37.8)	1.9 (1.4-2.7)	63	3.0 (-2.0-7.9)	1.4 (0.9-2.1)	18	78.3 (21.1-135.6)	6.2 (3.5-11.1)
All	287	85.4 (62.1 - 108.7)	7.3 (5.6-9.5)	187	26.3 (12.1-40.6)	2.3 (1.9-2.9)	138	4.5 (-1.6-10.6)	1.5 (1.1-2.0)	46	93.5 (37.9-149.1)	9.7 (5.7-16.4)
AM=arithmetic mean, WM=Williams mean.												

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 7.3 TTC/100mL (95% CI, 5.6-9.5) compared to 2.3 TTC/100mL (95% CI, 1.9-2.9, p<0.001) in the intervention arm (Table 3). Within the intervention arm, householdss with drinking water from filter storage containers had less TTC contamination (WM 1.5, 95% CI 1.1-2.0) than intervention households that stored their water in another container (WM 9.7, 95% CI 5.7-16.4, 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 houses (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 analysis found there was an OR of 0.17 (95% CrI 0.04-0.35, p<0.001) with source water quality as log TTC. This sensitivity analysis demonstrates the effect of the filters on water quality remained protective despite these factors.

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.

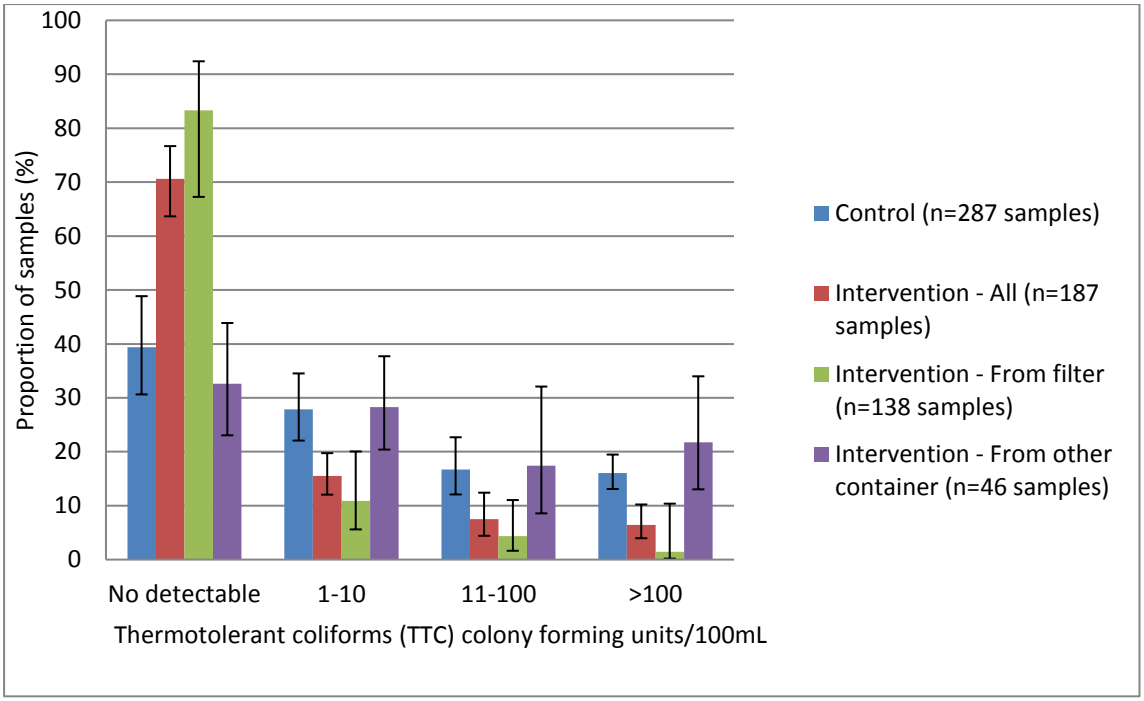

Figure 2 Proportion of drinking water samples by level of faecal contamination with cluster-robust 95% confidence intervals (CFU/100mL) in control and intervention households.

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 (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.

DISCUSSION

This study found high coverage and continued use of a household water filter 13-24 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.

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 houses 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 which sensors were deployed within houses for was largely dependent upon the number of study households within the intervention village and its matched control village, and 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.

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 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. However, this was mainly due to the filter being broken rather than storage in separate containers after filtration.

This study found significant reduced odds of child diarrhoea within the previous week among children in the intervention arm compared to the control arm. Given evidence of filter usage and improved water quality in the intervention arm, reduced diarrhoea could be due in part to the intervention. The magnitude of effect was similar to other filter studies (Clasen et al., 2015), including a study in Zambia examining LifeStraw 1.0, a hanging model (Peletz et al., 2012). Although children within the intervention arm had reduced odds of visiting a CHW or health facility for diarrhoea within the previous 7 days, the finding was not statistically significant, nor was seeking care for diarrhoea at a health facility within the previous 3 months. This is likely due to insufficient sample size. Additionally, the 3-month recall period is likely subject to inaccuracies (Arnold et al., 2013; Boerma et al., 1991). Fewer visits to health facilities would have substantial

public health benefits, including reduced economic burden associated with seeking treatment (Ngabo et al., 2016a).

Evidence of health impacts should be interpreted with caution since the outcomes were self-reported and the intervention was not blinded. 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. Of note is the finding that one-week diarrhoea prevalence was similar between the intervention and control arms in Round 1, yet substantially different in Round 2 (Table S2). The reasons for this are unclear, though are potentially due to unmeasured confounders such as variation in local disease transmission patterns and environmental exposures such as localized seasonal and climatic influences. It is also possible the implementer's health education and behaviour change messaging influenced respondent responses regarding health symptoms and usage behaviour. 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 help determine whether the filter is effective at preventing clinically significant cases of diarrhoea.

This study has several limitations. The study was unblinded, and we cannot exclude the possibility of courtesy bias that can occur with a non-blinded intervention, both for intervention usage and reported health impacts. In some villages, study teams were present in the village for over a month, and 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, particularly among the intervention arm. 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.

Of particular concern is that intervention and control villages were not randomly selected and thus our results are not generalizable beyond the study population. Additionally, we cannot rule out the potential role of unmeasured confounders. For example, we did not measure breastfeeding practices, child nutrition status, or ambient temperature which can impact diarrhoea (Checkley et al., 2000), nor did we assess rotavirus vaccination status, which was introduced in May 2012 and has been associated with both decreased hospitalizations for diarrhoea and rotavirus in Rwanda (Ngabo et al., 2016b; Tate et al., 2016). However, we would not expect these factors to systematically influence the intervention or control arm. Furthermore, the quality of the matching data was low and may not represent true household or village conditions, particularly among neighbouring households which were not eligible to participate in the study yet may influence outcomes of interest in study households. Timely household- or village-level census data could have improved the matching considerably. Despite continued susceptibility to unmeasured confounding, the matched cohort design is a cost-effective approach to estimating intervention effects in populations exposed to non-randomized programmes. It attempts to account for the relationship between treatment and covariates, and is more statistically efficient for estimating difference parameters than post hoc adjustment (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 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 and not solely the filter, 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 scaling up the intervention. The implementers have now delivered filters and stoves to *ubudehe* 1 and 2 households throughout Western Province. A randomized controlled trial to assess the impact of this larger scale roll out is currently underway (Nagel et al., 2016).

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SUPPLEMENTARY INFORMATION

Table S 1 Comparison of unmatched vs. matched village characteristic bias on key matching characteristics.

	UNMATCHED VILLAGES (n=210)			MATCHED VILLAGES (n=18)			
	Intervention	**Control**	**% bias**	**Intervention**	**Control**	**% bias**	**% reduction bias**
Minutes to road	100.56	82.11	18.8	100.56	92.22	8.5	54.8
Percent of households *ubedehe* 1 & 2	32.87	29.99	25.6	32.87	30.27	23.1	9.7
Percent of households using unimproved water supply	11.62	24.72	-52.7	11.62	13.11	-6	88.7
Mean household daily cook times	2.0	1.91	30.5	2.0	1.89	37.9	-24.1
Percent of households treating water	44.02	53.85	-41.5	44.02	42.61	6	85.6
Mean size of *ubedehe* 1 & 2 households	3.42	3.69	-26.7	3.43	3.23	19.5	27
Primary stove (3 stone)	0.44	0.38	13.1	0.44	0.44	0	100
Primary stove (charcoal)	0.44	0.59	-28.9	0.44	0.56	-21.8	24.7
Primary household fuel type (wood)	1	1.23	-32.3	1	1	0	100

Table S 2 Reported diarrhoea, health-care seeking behaviour, and toothache (negative control) among children under 5 years of age.

	Round 1 N=340 children		**Round 2 N=284 children**		**Overall N=624 child observations**	
	Control N (%)	Intervention N (%)	Control N (%)	Intervention N (%)	Control N (%)	Intervention N (%)
Diarrhoea – within previous 7 days	31 (16.1)	25 (17.0)	38 (22.8)	8 (6.8)	69 (19.2)	33 (12.5)
Sought care from CHW or at health facility for diarrhoea within previous 7 days	10 (5.2)	8 (5.4)	17 (10.2)	2 (1.7)	27 (7.5)	10 (3.8)
Sought care at health facility for diarrhoea within last 3 months	25 (13.0)	13 (8.8)	25 (15.0)	7 (6.0)	50 (13.9)	20 (7.6)
Toothache – within previous 7 days	9 (4.7)	6 (4.1)	5 (3.0)	4 (3.4)	14 (3.9)	10 (3.8)
Total child observations	193	147	167	117	360	264

Table S 3 Main household and child health survey enrollment and follow-up for Round 1 (October 2013-May 2014) and Round 2 (May-November 2014).

Intervention villages – Round 1						Control villages – Round 1					
Round 1 start	**Round 1 end**	**Intervention village**	**Enrolled and surveyed houses**	**% of overall round**		**Round 1 start**	**Round 1 end**	**Control village**	**Enrolled and surveyed houses**	**% of overall round**	
29-Oct-13	30-Oct-13	201	8	3.0		01-Nov-13	01-Nov-13	202	15	5.6	
11-Nov-13	12-Nov-13	203	7	2.6		14-Nov-13	20-Nov-13	204	16	5.9	
25-Nov-13	28-Nov-13	205	12	4.5		02-Dec-13	02-Dec-13	206	4	1.5	
10-Dec-13	10-Dec-13	207	3	1.1		14-Dec-13	17-Dec-13	208	15	5.6	
07-Jan-14	08-Jan-14	209	14	5.2		09-Jan-14	09-Jan-14	210	16	5.9	
27-Jan-14	29-Jan-14	211	16	5.9		30-Jan-14	31-Jan-14	212	5	1.9	
11-Feb-14	12-Feb-14	213	27	10.0		21-Feb-14	25-Feb-14	214	13	4.8	
10-Mar-14	17-Mar-14	215	13	4.8		17-Mar-14	27-Mar-14	216	43	16.0	
22-Apr-14	22-Apr-14	217	13	4.8		26-Apr-14	09-May-14	218	29	10.8	
Intervention villages – Round 2						**Control villages – Round 2**					
Round 2 start	**Round 2 end**	**Intervention village**	**Surveyed houses**	**% of overall round**	**% from Round 1 followed up**	**Round 2 start**	**Round 2 end**	**Control village**	**Surveyed houses**	**% of overall round**	**% from Round 1 followed up**
19-May-14	22-May-14	201	8	3.4	100.0	19-May-14	22-May-14	202	15	6.4	100.0
02-Jun-14	03-Jun-14	203	7	3.0	100.0	06-Jun-14	09-Jun-14	204	15	6.4	93.8
16-Jun-14	17-Jun-14	205	10	4.3	83.3	17-Jun-14	17-Jun-14	206	4	1.7	100.0
30-Jun-14	30-Jun-14	207	3	1.3	100.0	01-Jul-14	05-Jul-14	208	12	5.1	80.0
14-Jul-14	15-Jul-14	209	14	6.0	100.0	17-Jul-14	19-Jul-14	210	14	6.0	87.5
29-Jul-14	31-Jul-14	211	11	4.7	68.8	30-Jul-14	31-Jul-14	212	3	1.3	60.0
20-Aug-14	02-Sep-14	213	16	6.8	59.3	18-Aug-14	18-Aug-14	214	11	4.7	84.6
15-Sep-14	16-Sep-14	215	11	4.7	84.6	17-Sep-14	03-Oct-14	216	41	17.4	95.3
21-Oct-14	24-Oct-14	217	11	4.7	84.6	24-Oct-14	11-Nov-14	218	29	12.3	100.0

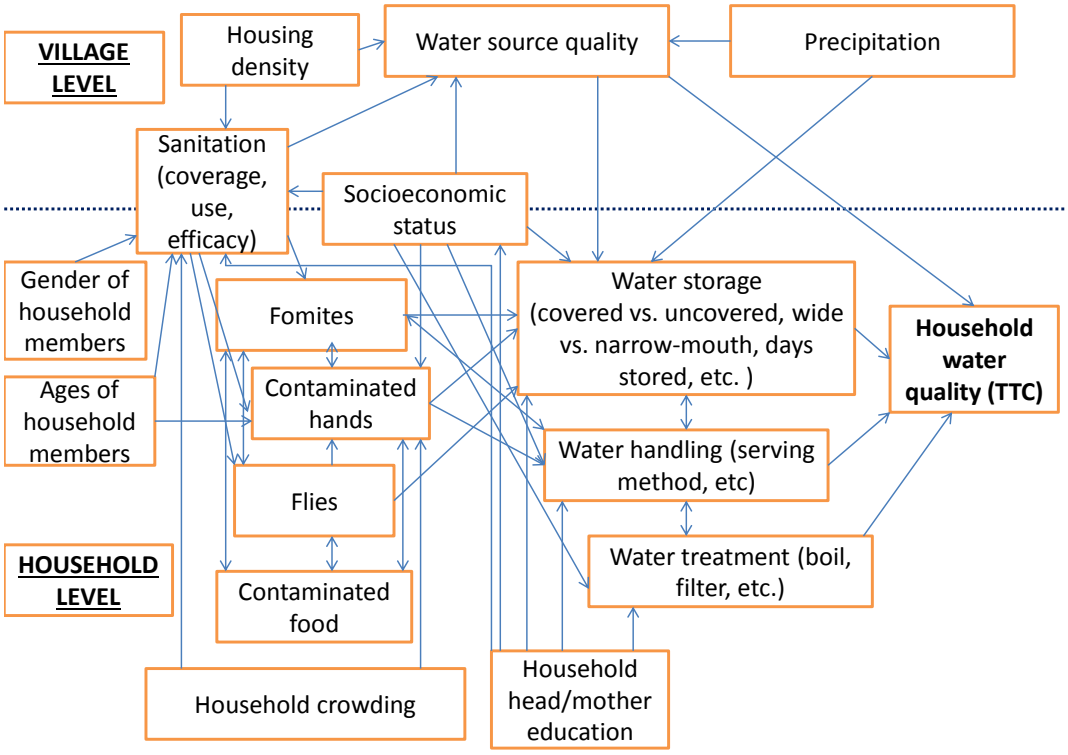

Figure S 1 A theoretical model for the association between determinants and household water quality (thermotolerant coliform, TTC) as an outcome.

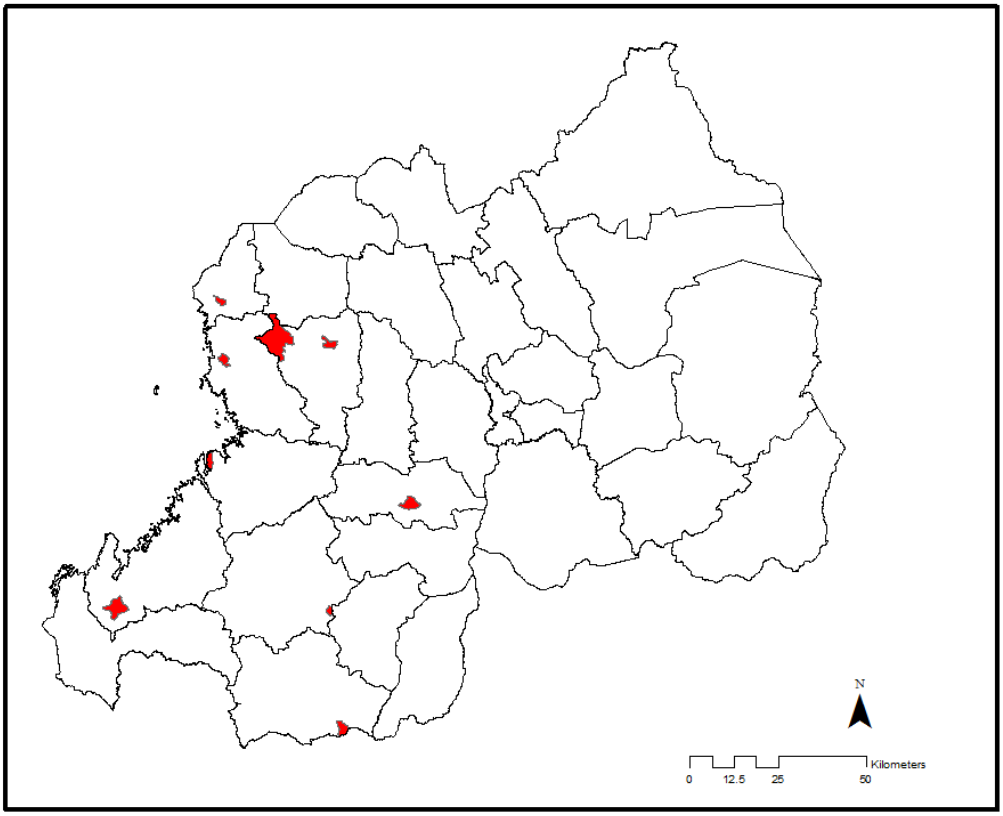

Figure S 2 Map of Rwanda with district boundaries and locations (shaded) of the nine paired intervention and control villages.

Supplementary information 1 – polychoric principal component analysis

The following variables were considered for polychoric principal component analysis:

ubudehe category

respondent ever attended school

respondent highest level of schooling.

head of house ever attended (includes respondent if they are head of house)

head of house highest level of schooling (includes head of house)

highest education, of respondent or head of house

house has electricity

house has radio

house has mobile phone

house has mattress

house has bicycle

house has own land/plot

house has own agricultural land

house has own house

house has own animals

house has cows

house has pigs

house has sheep

house has goats

house has chickens

house has rabbits

house has other animals

house has flooring

type of walls

number of rooms.

number of bedrooms

total people in house

total people in house/# of rooms

total people in house/# of bedrooms

These variables were included in a correlation matrix, and variables were removed when correlations were missing. Components (eigenvectors) with values less than 0.15 were removed. The final model included household durable goods and housing materials:

electricity

radio

mobile phone

bicycle

flooring type

wall type categories

The variance explained by the first principal component was 0.535155.

The continuous PCA variable was then divided into quintiles to construct a categorical socioeconomic status (SES) proxy variable.

Chapter 5. Assessing use, exposure, and health impacts of a portable rocket stove intervention in Rwanda

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Miles Kirby
Principal Supervisor	Thomas Clasen
Thesis Title	Assessing use, exposure, and health impacts of a water filter and improved cookstove distribution programme in Rwanda

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?			
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	Choose an item.

**If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.*

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Indoor Air
Please list the paper's authors in the intended authorship order:	Miles A. Kirby*, Ghislaine Rosa, Corey L. Nagel, Marie Mediatrice Umupfasoni, Michael Johnson, Evan A. Thomas, Jill Baumgartner, Thomas F. Clasen
Stage of publication	**Not yet submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	With input from co-authors, I designed the study. I organized and supervised collection of data and samples, managed daily operations, supervised lab work, and cleaned the data. I analysed the data in collaboration with assistance from Corey Nagel, and I wrote the paper.

Student Signature: _____ **Date:** 11 November 2016

Supervisor Signature: _____ **Date:** 11 November 2016

Assessing use, exposure, and health impacts of a portable rocket stove intervention in Rwanda

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ABSTRACT

Household air pollution (HAP) is a major cause of morbidity and mortality worldwide. Improved cookstoves have been promoted as a way of reducing exposure to fine particulate matter ($PM_{2.5}$) in the absence of clean fuels. In 2012, a public-private program provided a free rocket stove and water filter to households in 15 rural villages. We matched 9 of these pre-existing intervention villages to 9 control villages using propensity score matching to assess medium-term usage, exposure, and child health 13-24 months later. Cooking area $PM_{2.5}$ and personal exposures among cooks and children under 5 to $PM_{2.5}$ and carbon monoxide (CO) was assessed for 48 hours in 455 household visits. Coverage and use of the stove was high, but householders continued to use traditional stoves as well. The geometric mean (GM) concentration of $PM_{2.5}$ in the primary cooking area was 43.4% lower in the intervention arm ($p<0.001$), although accounting for the sum of two different household locations was 32.7% lower ($p=0.017$). Among primary cooks, GM $PM_{2.5}$ concentrations were 192 $\mu g/m^3$ (95% confidence interval (CI) 150-246 $\mu g/m^3$) in the control arm compared to 151 $\mu g/m^3$ (95% CI 134-171 $\mu g/m^3$) in the intervention arm, but not significantly different in adjusted analyses (22.2% lower GM $PM_{2.5}$, $p=0.06$). Child GM $PM_{2.5}$ concentrations were 194 $\mu g/m^3$ (95% CI 138-272 $\mu g/m^3$) in the control arm and 175 $\mu g/m^3$ in the intervention arm (95% CI 135-225 $\mu g/m^3$), but reductions were not statistically significant in adjusted analyses ($p=0.27$). Despite a lack of significant exposure reductions, children in the intervention arm had significantly reduced odds of self-reported acute respiratory infection within the previous 7 days (OR 0.23, $p=0.008$, 95% credible interval (CrI) 0.05-0.57) and self-reported attendance to a health facility for respiratory symptoms within the previous 90 days ($p=0.004$, 95% CrI 0.10-0.64) compared to the control arm. The reported health impacts could be due in part to reporting bias and the impact of the water filter component of the intervention.

INTRODUCTION

An estimated forty percent of the world's population uses solid fuels such as wood, crop residues, charcoal and coal for cooking (Bonjour et al., 2013). Burning of solid fuels on traditional inefficient stoves results in incomplete combustion, resulting in particulate matter (PM) and carbon monoxide (CO), major components of household air pollution (HAP) in addition to more than 250 compounds, many of which are harmful to health (Naeher et al., 2007; Smith et al., 2000).

Household air pollution (HAP) is estimated to have resulted in 2.9 million deaths and 85.6 million disability adjusted life years in 2015(GBD 2015 Risk Factors Collaborators, 2016). Numerous health impacts have been associated with HAP (Bruce et al., 2015b; Fullerton et al., 2008; Smith et al., 2014). There is strong evidence for the adverse impact of HAP on respiratory infections (Gordon et al., 2014), particularly for children who are especially vulnerable to acute lower respiratory infection (ALRI) (Dherani et al., 2008; Gordon et al., 2014; Po et al., 2011). Each year an estimated 1.3 million child deaths are due to pneumonia (Fischer Walker et al., 2013b).

Strong evidence has also been reported for chronic obstructive pulmonary disorder and chronic bronchitis (Assad et al., 2015; Hu et al., 2010; Kurmi et al., 2010; Mortimer et al., 2012). More tentative evidence exists for nasopharyngeal and laryngeal cancer as well as lung cancer and stroke (Bruce et al., 2015a; Gordon et al., 2014; Kurmi et al., 2012a; Raspanti et al., 2016). Exposures early in life may result in increased risk for some of these diseases in adulthood (Kurmi et al., 2012b). Emerging evidence suggests there may be an impact on blinding and other eye conditions (Ravilla et al., 2016; West et al., 2013) as well as tuberculosis (Jafta et al., 2015; Lin et al., 2014; Sumpter and Chandramohan, 2013). Child survival outcomes such as low birth

weight, preterm birth, still birth, and perinatal mortality are also associated with solid fuel use (Amegah et al., 2014; Epstein et al., 2013; Patel et al., 2015; Pope et al., 2010; Wylie et al., 2014). Other non-disease related injuries can occur, such as burns from stoves (Peck et al., 2008) and sexual violence during fuel collection (Patrick, 2007). Much uncertainty exists about exposure-response for these outcomes, and misclassification is possible (Assad et al., 2015; Bruce et al., 2015b; Gordon et al., 2014).

Approaches to reducing HAP include transitioning to cleaner fuel, changing to cleaner cookstoves, increasing ventilation, and other behaviour change techniques (WHO, 2006). Exclusive use of cleaner fuels like liquefied petroleum gas (LPG) is advocated as the best way to reduce HAP exposures (Sagar et al., 2016), however provision of clean fuels in many rural settings is unlikely in the near-term due to high costs and lack of supply (Johnson and Chiang, 2015; Thomas et al., 2015). Improving fuel efficiency and reducing emissions using biomass stoves is therefore an interim option (Johnson and Chiang, 2015; Kshirsagar and Kalamkar, 2014). Improved biomass cookstoves have been found to reduce kitchen concentrations of particulate matter <2.5µm in diameter ($PM_{2.5}$) and carbon monoxide (CO) (Ezzati et al. 2000, Pennise et al. 2009, Clark et al. 2013, Emma Thomas et al. 2015). However, these cookstoves may not reduce kitchen concentrations or personal exposures below WHO guidelines (Bruce et al., 2015b; Clark et al., 2013), and substantial reductions may be necessary to achieve health improvements for acute respiratory infections (Bruce et al., 2015b; Burnett et al., 2014; Ezzati and Kammen, 2001) and cardiovascular disease (Baumgartner et al., 2012; Pope III et al., 2011).

In October 2012, a public-private partnership between the Rwanda Ministry of Health and DelAgua Health Rwanda Ltd., a private company, provided approximately 2,200 improved

combustion cookstoves and water filters at no cost to all households in 15 rural villages in 11 districts. The intervention, described elsewhere (Barstow et al 2014), included one improved portable cookstove and one household water filter, in-home training, instructional materials, repair services, and multiple household visits to measure and encourages behavior change. The intervention stove is a portable rocket stove design known as an Ecozoom Dura stove. The stove's internal chamber allows for improved combustion and channelled air flow resulting in reduced emissions. The stove included a stick support used to increase airflow and a pot skirt to improve thermal efficiency. Households were encouraged to use dry wood when possible, and to cook outdoors.

A 5-month household randomized controlled trial (RCT) of the intervention programme reported a mean 24-hour $PM_{2.5}$ reduction of 46% in cooking area concentrations, though reductions were 73% for the approximately 25% users reportedly cooking outside (Rosa et al., 2014). Although self-reported use was high and sensor-derived use of the stove was confirmed (Rosa et al., 2014; Thomas et al., 2013a), continued use of traditional stoves was observed. Importantly, impacts on personal exposure among cooks and children are unknown. We undertook this study to assess the long-term sustainability of this intervention as delivered programmatically, as well as the long-term effectiveness of these devices on HAP, personal exposures and self-reported health outcomes.

METHODS

Study setting, design and matching.

This study was based in the Western and Southern provinces of Rwanda, as described elsewhere (Barstow et al., 2014; Rosa et al., 2014). The region is predominantly rural and most villagers are

agriculturalists, with two rainy seasons – March to May, and September to December. There is little variation in temperature during the year, and averages 17.5-19°C. Study villages ranged from 1400-2500m in elevation. Most courtyards (66.4%) were open (bordered by 1 wall), while 22% were semi-enclosed (bordered by 3-4 walls). Households typically cook meals in pots over a fire between three stones (three stone fire), or locally-made built-in wood-burning stoves that do not have chimneys (*rondereza*). Additionally, some households cook on portable locally-made charcoal stoves (*imbabura*).

Because this study was designed to assess the longer-term use and impact of the intervention among villages that had received it a year before, an RCT design was not possible. However, since we sought to compare those villages with a contemporaneous control group, we adopted a matched cohort study design (Rubin, 2007). Nine of the original 15 intervention villages were purposely selected for inclusion into the follow-up study, with 3 excluded due to low number of estimated eligible households and 3 excluded due to participation in a previous RCT.

Nine matched control villages were selected using restriction, propensity score matching, and rapid assessment (Arnold et al., 2010). First, intervention villages were matched to potential control villages within the same health centre catchment area as a measure of village similarity.

To create the propensity score model, we first created a dataset for the matching that merged three separate datasets. The covariates used in the matching process were determined by examining items from a baseline survey of intervention households conducted in October 2012 and determining variables most related to the outcomes of interest (HAP and household drinking

water quality). These items were incorporated into a survey of community health workers from potential control villages. More information about each data source is below:

i) DelAgua household survey

This survey was conducted within 48 hours of intervention delivery (October 2012) to all intervention households. The survey was conducted by each intervention village's community health workers (CHWs), and contained questions on stove type, fuel type, and water treatment practices before receipt of the intervention. DelAgua household data were aggregated by village and categorized according to majority proportion.

ii) Community Health Worker phone survey

A phone survey was conducted by LSHTM research team staff in July 2013 and administered to one CHW from all intervention villages and potential control villages. Potential control villages were surveyed if they i) shared same health centre as intervention village and ii) did not share a border with an intervention village. Shared health centres were pre-identified using a national database that lists each village, its CHWs, and its assigned health centre.

If the potential control village CHW reported that the village did not attend the government-listed health centre, or if it shared a border with the intervention village, the survey was not administered and that village was excluded from consideration. The phone survey consisted of 37 questions and lasted approximately 15 minutes. The survey asked the CHW to estimate village-level characteristics including total households, total children under 5, minutes' walk to main road, percent of households using drinking water source types, water treatment practices, and cooking practices

(primary stove type, primary fuel type, number of meals cooked per day). CHW phone surveys resulted in 201 potential control villages.

iii) National *Ubudehe* Database

This government database lists the number of households and number of people in each of six *ubudehe* wealth categories for every village, cell, sector, and district in Rwanda. This database allowed for the proportion of houses according to *ubudehe* category, and estimation of household size according to *ubudehe* category.

Village-level data were combined from the above 3 sources. Characteristics likely to change due to the intervention, such as water treatment and cooking practices, were derived from the DelAgua survey since it assessed these 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.

Control villages were restricted from consideration based on the implementer's original exclusion criteria (Barstow et al., 2014), intended to characterize a rural Rwandan village's energy use and water infrastructure. Namely, if villages were estimated to have more than 20% of households with piped water, more than 60% using water treatment method other than boiling, more than 20% using cooking fuel other than biomass or charcoal or more than 20% using a non-traditional stove, they were excluded.

Propensity score matching using probit regression was then conducted using different combinations of the village-level covariates described above, given their potential relationship to

household air pollution and drinking water quality which were the primary outcomes of interest. The mean bias of each fitted model was examined across the range of potential matching variables in order to obtain optimal covariate balance for all available covariates between arms.

Using the propensity score from the optimal model, each intervention village was 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).

After matching, median bias of key matching variables was reduced from 27.8 to 7.2 (Table S1), suggesting improved balance was achieved reducing likelihood of potential confounders. Village-level bias was reduced in all key matching variables with the exception of mean household daily cook times, although the household differences at enrolment between the intervention and control arms were minimal (Table 1). Lastly, after conducting household surveys in intervention villages, each control village was rapidly assessed by study personnel by conducting a transect through the village, meeting with village chiefs and CHWs to confirm the previously estimated village-level characteristics used in the matching. Following the rapid village assessments, each intervention village was deemed comparable to its matched control village.

Enrolment and eligibility

Eligible households had to have at least one child under 5 years of age and be listed on a government-derived village roster as being in the poorest socioeconomic tertile (*ubudehe* group 1 or 2). Households in intervention villages were enrolled regardless of whether they had received the intervention from the implementer. Study households in control villages received a water filter and stove at the end of the study (2015). From November 2013-May 2014 (Round

1), all consenting eligible houses were enrolled and visited once. Houses were visited a second time between May 2014 and November 2014 (Round 2).

Ethics and consent.

Primary cooks gave written informed consent to participate in the study, and also gave assent for the participation of children within the household. If the respondent could not sign their name, they provided a thumbprint and a literate witness signed on their behalf to confirm comprehension. This study was approved by LSHTM Ethics (6457) and Rwanda National Ethics Committees (494/RNEC/2013), and was registered at ClinicalTrials.gov (NCT01998282).

Household questionnaire

Study enumerators were trained and supervised by the study authors and were not involved in delivery or promotion of the intervention. At each visit, a household survey was administered to the primary cook of the household regarding household demographics, drinking water practices, fuel use, cooking, heating and lighting practices, self-reported child health symptoms and receipt of medical care from a CHW or health facility. Questions were pre-piloted, translated, back-translated and administered verbally in Kinyarwanda, a national language of Rwanda spoken by all study participants. Ownership of household goods were incorporated into a socioeconomic indicator using polychoric principal component analysis (Kolenikov and Angeles, 2009).

Evaluation of cookstove use

Household use of the Ecozoom was assessed using self-reported indicators of frequency of use (e.g., number of times per week, when last used). Staff also visually inspected the stoves for

appearance of use (i.e., accessible, not dusty with cobwebs, etc), and noted if the stove was warm or currently in use. These questions and observations were also administered for each traditional stove in the intervention and control arms.

Primary and secondary outcomes

The primary outcome for this study was 48-hour personal exposure to $PM_{2.5}$ among cooks and children less than 5 years of age since these household members experience the highest exposures and health burden to HAP due to proximity to fires used for cooking. Secondary outcomes included personal exposure to CO among cooks and children under 5, cooking area and outside courtyard $PM_{2.5}$, reported and observed use of the intervention stove, and primary-caregiver reported acute respiratory illness within the previous 7 days for study children. Due to limited time and resources necessary to assess ALRI according to World Health Organization WHO Integrated Management of Childhood Illness (IMCI) protocol (WHO, 2005) or utilize clinical evaluation, acute respiratory infection (ARI) was defined as cough accompanied by "wheeze or rapid or difficulty breathing". Additional information included whether care from a CHW or health facility was sought for ARI within the previous 7 days, and whether care was sought at a health facility for respiratory symptoms within the previous 3 months. Toothache was included as a negative control (Arnold et al., 2016; Lipsitch et al., 2010).

HAP measurement eligibility and enrolment

All households that participated in the main survey were followed up for participation in HAP monitoring in both Round 1 and Round 2 up to one month after the main survey visit. A survey was administered to the primary cook on HAP monitoring deployment and retrieval day (48 hours later), as well as an unannounced check-up visit to evaluate compliance and identify any

problems with the equipment on day two. The survey contained observations and measurements concerning stove lighting events during the monitoring period.

To be eligible for personal exposure monitoring, the primary cook had to be healthy enough to perform normal daily activities, 18 years of age or older, not pregnant, and not a current smoker. For children, HAP monitoring preference was given to any child under 5 who was able to carry either the gravimetric $PM_{2.5}$ and CO monitors in a medium backpack (~ 1kg) (Figure 1) or a smaller backpack (0.25kg) holding only a CO monitor. If more than one child under 5 was able to carry the equipment, 1 child was randomly selected. At Round 2, the HAP cook and HAP child from Round 1 was followed up for monitoring at Round 2 if present if they still met the eligibility criteria and were present; otherwise another cook or child under 5 was selected for exposure monitoring.

Personal exposure to $PM_{2.5}$

Integrated gravimetric exposure to $PM_{2.5}$ was assessed in primary household cooks and children 1.5-5 years of age using a system consisting of a 2.5 µm-diameter BGI-Harvard Personal Environmental Monitor (HPEM) impactor (BGI, Massachusetts, USA) and a Casella TuffPro™ (Casella Measurement, Bedford, UK) low-flow pump set to 1.8 litres per minute at one-minute intervals for 48 hours. The $PM_{2.5}$ particulate matter was collected on pre-weighed 37-mm Teflon filters (Pall, USA) with a drain disk due to anticipated high loading of the filters (Ni et al., 2016). The HPEMs were worn within the breathing zone (between chest-level and mouth) in a diagonal chest strap and connected by tubing to a pump held within a sewn pouch (Figure 1). The equipment weighed approximately 1kg in total. Participants were instructed to wear the equipment at all times for a 48-hour period, except during sleeping, breastfeeding, bathing, or

other activities as necessary, in which case the devices were to be kept within 1 meter of the individual at a similar height (Dionisio et al., 2012). Filter blanks (~15%) were collected throughout the measurement period.

Pump flow was calibrated in the participant's home immediately before and after the 48-hour monitoring period using a Challenger air flow calibrator (BGI, Massachusetts, USA). Samples and blanks were stored at 4°C and then mailed on ice in batches to Berkeley Air Monitoring Group in California, USA for gravimetric analysis. Prior to weighing, the filters were equilibrated for 24 h at 22 ± 3°C and 40 ± 5% relative humidity (Rosa et al., 2014). Filters were weighed in duplicate, unless the two weights differed by more than 5 µg, in which case a third weight was taken and the average of the two closest weights was used. The balance was a 0.1 microgram resolution electro microbalance (XP2U, Mettler, Toledo, USA). Median blank adjustment resulted in a subtraction of 32.30 µg for rainy season deployments (based on 75 blanks), and 23.10 µg in the dry season (based on 37 blanks).

Personal exposure to CO

Personal exposure to CO was assessed using a GasBadge Pro (Industrial Scientific, Pennsylvania, USA) that recorded CO parts per million (PPM) at 60-second intervals using an electrochemical sensor. The measurement range is 0 PPM-1500 PPM, with increments of 1 PPM. The GasBadge Pro was worn within the breathing zone of cooks just below the HPEM andfilter described above. For children with a large backpack holding the PM equipment, the Gasbadge Pro was placed in a side pouch of the backpack. Children with the smaller backpack wore the GasBadge Pro in an open pouch. Child GasBadge Pros were covered with fabric to protect the gas sensor from dirt and water (Figure 1). Before each HAP measurement period, the GasBadge Pros were

zero-calibrated in the study villages but at least 5 m from any household combustion sources. The Gasbadge Pro's responsiveness to 20 PPM and 100 PPM calibration gas was assessed for 17 of 22 used devices after study termination in the United Kingdom due to difficulty obtaining calibration gas. Median difference among the tested devices was 6ppm (range 2 to 7 PPM) for 20 PPM calibration gas and -7ppm (range -3 to -11 PPM) for 100 PPM calibration gas (Table S2).

Figure 1 Personal exposure monitoring equipment set-up for cook and child under 5.
Left : Main cook air monitoring set-up as worn. Top to bottom: HOBO Pendant Temperature and Light Data Logger; HPEM; GasBadge Pro; TuffPro Pump. Centre: Child HAP monitoring backpack with HPEM, tubing, and arrow pointing to fabric-covered GasBadge Pro. Right: Child air monitoring set-up as worn.

Stationary household and courtyard $PM_{2.5}$ measurements

We monitored 48-hour household $PM_{2.5}$ concentrations (simultaneously during personal exposure monitoring) using the University of California, Berkeley Particle and Temperature Sensor (UCB-PATS) (Berkeley Air Monitoring Group, California, USA). The UCB-PATS is a light-scattering nephelometer and it is calibrated to provide semi-continuous, 1-minute averages of $PM_{2.5}$ concentration. This method has been validated in laboratory and field settings

(Chowdhury et al., 2007; Edwards et al., 2006) and has been utilized in a number of recent field studies (Balakrishnan et al., 2013; Clark et al., 2011; Rosa et al., 2014).

In each intervention and control household, field staff placed up to two UCB-PATS monitors, with highest priority to primary and secondary cooking areas. Monitors were placed at a height of 1.5 meters and a distance of 1 meter from the edge of combustion zones according to standard procedures (Berkeley Air Monitoring Group, 2005). If a household had more than two cooking areas, the two most used cooking areas were selected based on self report. If a household had only one reported cooking area, the second UCB-PATS monitor was placed in the household's outdoor courtyard 2 meters from the household door at a height of 1.5 meters. Start and end times of the stationary 48-hour measurement coincided with personal exposure monitoring. Each UCB-PATS record was manually reviewed to identify any irregularities. The limit of detection was set at 0.05 mg/m^3 if the minimum value was greater than 0.075 mg/m^3. However, records with a minimum value of 0.5 mg/m^3 were deemed irregular and discarded.

To calibrate the UCB-PATS response to $PM_{2.5}$, we conducted 48-hour gravimetric co-locations in 51 different cooking areas in a subset of enrolled households. The gravimetric system consisted of HPEMs and TuffPro Pumps, as described above. After excluding incomplete and missing UCB-PATS and gravimetric samples, 21 paired measurements were available for analysis. After confirming a linear relationship, we analysed the pair measurements using linear regression. This resulted in an R^2 value of 0.9152, with an adjustment factor of 0.7963116 (UCB-PATS 48-hr mean)+.0991519 (Figure S1). This adjustment factor is similar to that observed in our previous study in Rwanda (Rosa et al., 2014).

Evaluation of participant compliance

Compliance in wearing the personal exposure monitors was assessed through self-report and observations on the unannounced spot-check visit on day 2 and retrieval on day 3. Additionally, a subsample of adult (89%) and child participants (84%) were also equipped with HOBO Pendant Temperature and Light Data Loggers (Onset HOBO Data Loggers, Massachusetts, USA). These lightweight devices (18 g) record light intensity (International System of Units, lux) and temperature at 1 minute intervals. The device was attached to personal air monitoring equipment on a shoulder strap so that the sensor rested horizontally facing the sky. A lux value of <1000 was considered indoors (Turner and Mainster, 2008), and we excluded the evening hours of 18:00-07:00 from analysis due to ambient light levels below the outdoor threshold. All records indicating less than 20% of time was spent outdoors over the 48-hour period or on the second day of monitoring were manually reviewed visually for signs of non-compliance, indicated by lux levels <500 lux for 6 continuous hours or more.

Intervention stove usage according to sensors

Households were eligible for Ecozoom stove sensor monitoring if the Ecozoom stove they owned was reported to be working properly at the time of the survey. Usage of Ecozoom stoves was objectively quantified using SweetSense instrumentation affixed to Ecozoom stoves (Figure 2) (Thomas et al., 2013a, 2013b). The SweetSense sensor measures temperature of the combustion chamber which can be interpreted as distinct cooking events (Thomas et al., 2013a). Usage events within 60 minutes were grouped together and considered one event (Lozier et al., 2016). Ecozoom stoves equipped with sensors were deployed to households within two weeks of the main household survey. Households were informed that the sensor would collect performance data of their Ecozoom stove, but not told they would detect changes in temperature or frequency of use. Households had the sensored Ecozoom stove for a period of 7-30 days. During

this monitoring period, the household's Ecozoom stove that 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 in order to have whole-day samples.

Figure 2 SweetSense sensor affixed to Ecozoom stove.

Precipitation data

Throughout the HAP exposure assessment periods, an RG3 HOBO Data Logging Rain Gauge (Onset HOBO Data Loggers, Massachusetts, USA) was placed in a central location within each intervention and control period. The rain gauge measured rainfall in 0.01-inch increments, and precipitation total during the three HAP monitoring days was included in HAP area and personal exposure models to adjust for impacts of rainfall on fuel moisture and emission variations. Rain gauges could not be placed in villages in advance of main survey household visits, so precipitation data were downloaded in Network Common Data Form (NetCDF) format for each

village centroid from Climate Hazards Group InfraRed Precipitation with Station data 2.0 (CHIRPS) (Funk et al., 2015). Daily gridded precipitation data derived from satellite and in-situ station data at 0.05 degree spatial resolution (approximately 5.3km) were converted from NetCDF into raster format and joined to village centroid locations using ArcGIS 10.3 (ESRI, Redmond, CA, USA). Total precipitation during the previous 10 days to each household's survey date was included in analyses as a potential confounder for acute respiratory illness to account for seasonal variations and potential imbalance of climatic conditions between arms at the time of household visit.

Sample size and study power

Sample size was based on 48-hour mean primary cook $PM_{2.5}$ exposure, basing assumptions on previously observed reductions in cooking area $PM_{2.5}$. We used kitchen nephelometric $PM_{2.5}$ data from our previous RCT in nearby rural villages that found a mean $PM_{2.5}$ concentration of 0.89 (mg/m^3) with a standard deviation of 0.89 (mg/m^3) in control households (unpublished). Due to anticipated low ambient $PM_{2.5}$ levels outside of household living quarters and the mobility of the primary cook, we estimated that personal $PM_{2.5}$ exposure would be 50% less than kitchen concentrations (Cynthia et al., 2008). We calculated our sample size using an assumption that the Ecozoom stove would reduce personal $PM_{2.5}$ exposure from an estimated 0.45 mg/m^3 to 0.27 mg/m^3 with a standard deviation of 0.5 mg/m3, given previously observed cooking area reductions of 16-75% (Rosa et al., 2014). We anticipated personal air monitoring would occur in 9 intervention villages and 9 control villages with an average of 16 observations per cluster. At 80% power with type 1 error of 0.05, we estimated an unadjusted sample size of 122 households would be needed to observe a 40% reduction in the mean $PM_{2.5}$ levels. In order to account for clustering at the village level, we estimated within village intraclass correlation coefficient at 0.01. Thus, the estimated adjusted sample size was 141 intervention participants

and 141 control participants. In order to account for loss to follow-up (estimated at 15%) and incomplete measurements (estimated at 15%), our sample size enrolment target was 185 households in both the intervention and control arms.

Data analysis

To compare balance between arms, the standardized difference is presented (Table 1), calculated as the mean difference between arms in terms of standard deviations (Arnold et al., 2009; Rosenbaum and Rubin, 1985; Rubin, 2007). A value of 0 indicates equivalent means while a value of 1 indicates a standard deviation of 1 (Austin, 2011). Descriptive statistics, means, and confidence intervals of $PM_{2.5}$ and CO measurements were adjusted for village-level clustering, which was the highest level of clustering in the data (Bottomley et al., 2016). Exposure measurements that were 80% complete based on pump runtime (ran for >=1152 minutes of the 1440 minute runtime) was the main outcome, and we conducted sensitivity analyses for 90% pump runtime samples (>=1296 of 1440 minutes).

Our dependent variables, cooking area $PM_{2.5}$ concentrations and personal exposure to carbon monoxide and $PM_{2.5}$, were highly skewed and natural-log transformed to achieve a normal distribution. A value of 0.0001 PPM was added to all 48-h CO means (below limit of detection) for purposes of regression analysis so as not to exclude mean values of 0.0 mean PPM. The primary outcome for cooking area concentrations was based on the UCB-PATS value placed at the self-reported primary cooking area cooking, or the placement with the higher $PM_{2.5}$ value if used as a cooking area. As a sensitivity analysis, we assessed the sum of both UCB-PATS placements for those houses with two usable measurements that were placed in two distinct areas (either indoors and outdoors, or inside main house and inside separated kitchen).

Multilevel modelling was used to examine differences between the control and intervention groups in reported ARI and measured HAP after controlling for potential individual, household, and village-level confounders (Figure S4). For reported ARI and ARI-related medical care visits, we fitted 4-level, random intercept logistic regression models, with two observations (level 1) per child (level 2), who were clustered within households (level 3) and villages (level 4). Personal CO and $PM_{2.5}$ exposure were modelled separately for primary cooks and children. Because HAP exposure was only measured on one primary cook and one child per household, we constructed 3-level random intercept linear regression models for these outcomes, with observations (level 1) nested within households (level 2) and villages (level 3). Similarly, models of household cooking area $PM_{2.5}$ were 3-level random intercept linear regression models, with multiple cooking area observations (level 1) nested within households (level 2) and villages (level 3).

Models were estimated using Markov Chain Monte Carlo (MCMC) simulation 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 (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 trace plots 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. 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% credible interval can thus be interpreted as the interval within which there is a 95% chance the true population values are included. For $PM_{2.5}$ and CO outcomes which were natural-log transformed, the beta coefficients and credible intervals from the models were exponentiated, which allows the coefficient to be interpreted as the ratio of geometric means associated with a unit change in that variable. All analyses were conducted using MLWin Version 2.1 (Browne, 2009; Rasbash et al., 2009) and Stata 14 (College Station, TX) with the RunMlWin add-on package (Leckie et al., 2013).

RESULTS

Study participants

All eligible households agreed to participate in the study, consisting of 113 intervention households and 156 control households (Figure 3). In Round 2, the second visit approximately 6 months after initial enrolment, 91 intervention households (80.5%) and 144 control households (92.3%) were followed up and surveyed. One child death was reported between Round 1 and Round 2 surveys. Household and child characteristics at enrolment are shown in Table 1 for the overall study population as well as the sub-group that underwent HAP monitoring. Both main survey monitoring and the subset of households in which HAP monitoring occurred showed good balance and were similar to each other on a range of household characteristics and demographics. Differences were observed for characteristics related to fuel use and cooking practices; these are consistent with the provision of the stove among intervention households. The reported travel time to a health facility which a family would use for mild/moderate illness was also lower in the intervention arm (Table 1).

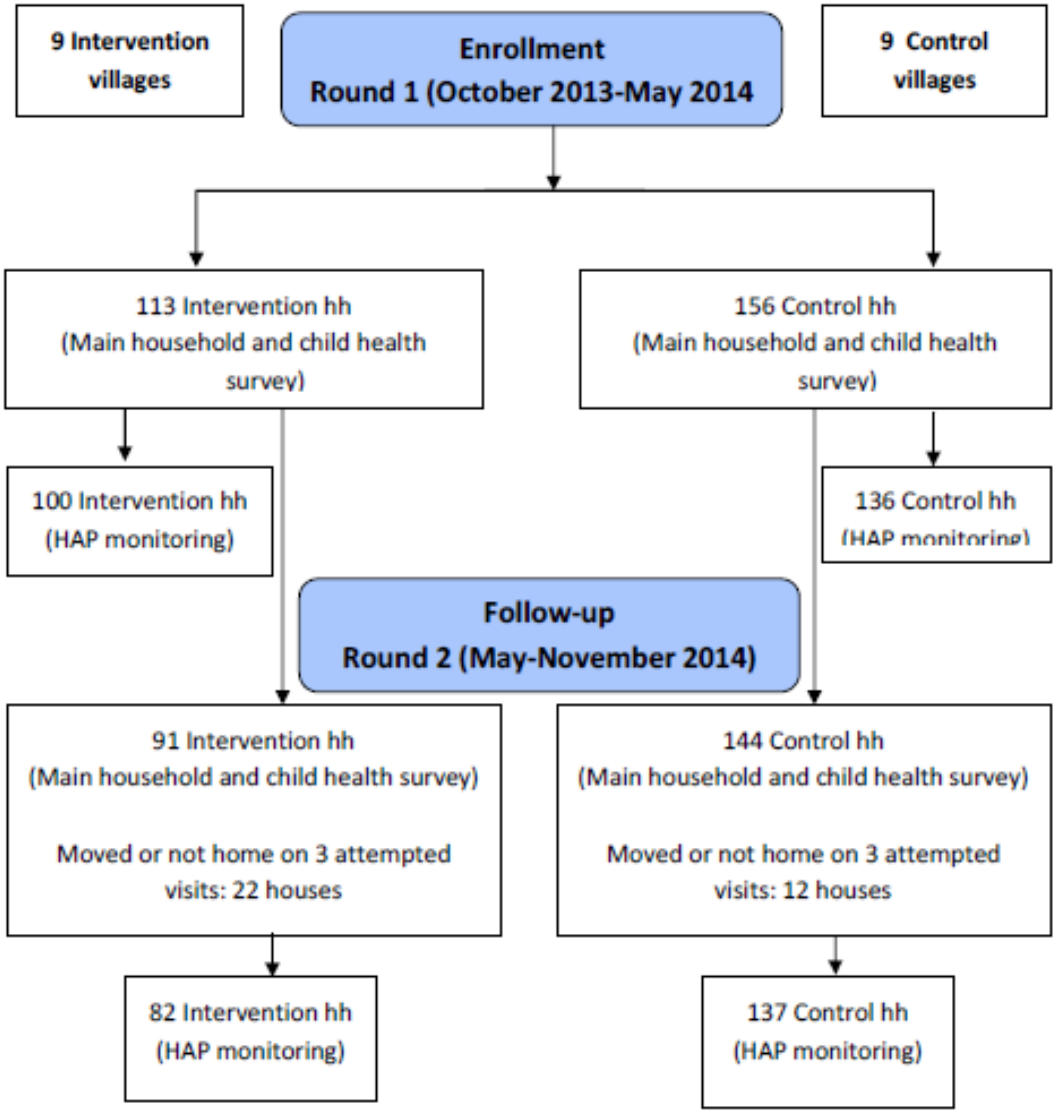

Figure 3 Main household/child health survey and HAP monitoring enrolment and follow-up.

Stove implementation and use

Ninety-eight percent of intervention households reported receiving the Ecozoom stove and, among those, 97% were observed to have an Ecozoom stove reported to be in working order (Table 2). The same 2 stoves were reported broken and not currently in use during both data collection visits. Of the 194 household visits that observed a working Ecozoom, 99% of

households reported currently using it, with 90.7% on day of visit or previous day in Round 1, and 93.0% in Round 2. Overall 26.8% of Ecozoom stoves were warm or in use during the household visit. However, continued use of traditional stoves (stacking) was reported widely. In Round 1, 34.3% of households reported using a traditional stove at least once a week or more, and 40.7% in Round 2; 16.7% reported using traditional stoves everyday in Round 1, and this increased to 27.9% in Round 2. In Round 1, 12.0% of intervention households with a working intervention stove were observed to have a traditional stove in use or warm upon arrival to the household, and 18.6% in Round 2.

Sensor-derived use

Sensors affixed to Ecozoom stoves confirmed consistent usage during the sensor monitoring periods according to a temperature-derived usage algorithm (Thomas et al., 2013a). In Round 1, 93.0% of households used their Ecozoom stoves at least once every day for days with sensor data, decreasing to 84.9% in Round 2. Overall the sensor detected a mean of 1.23 (SD 0.27) stove use events per day per household. Usage of the stove twice per day or more was less common, detected on 23.8% of days with usable sensor data. Overall 9.4% of households used stoves twice per day on at least half of days with sensor data, and 2.1% of households used their stove twice per day on every day with sensor data.

Household $PM_{2.5}$ measurements.

Real-time stationary $PM_{2.5}$ was measured in 455 of the 469 household visits (14 visits did not have stationary $PM_{2.5}$ measurements due to equipment shortage). During these 455 visits, 10 control households (3.6%) and 13 intervention households (7.1%) had only one UCB-PATS placement due to reporting they only cooked outdoors. Thus, a total of 888 stationary $PM_{2.5}$ measurements were conducted inside kitchens and courtyards. Due to missing records and

irregular records due to calibration errors, battery failures, and placement disturbances, 610 UCB-PATS records were deemed complete for data analysis, with 335 indoor placements and 275 outdoor placements (Table 3).

Overall primary cooking area geometric mean (GM) concentrations were 0.668 mg/m^3 in the control arm (0.548-.814 mg/m^3) and 0.385 mg/m^3 (95% CI .306-.484 mg/m^3) in the intervention arm, a 42% reduction (Table 3). Primary cooking locations that were indoors had higher GM concentrations than primary cooking locations outdoors in both the control arm (0.695 vs 0.452 mg/m^3) and intervention arm (0.417 vs 0.292 mg/m^3), although only 18 control placements and 30 intervention placements were usable for this comparison. The majority of primary cooking locations were identified as being indoors, with GM concentrations of 0.417 mg/m^3 in the intervention arm (95% CI 0.335-0.519 mg/m^3) compared to 0.695 (0.573-0.844 mg/m^3) in the control arm (Table 3). The largest percent reduction in GM concentrations was between indoor primary cooking in the control arm compared to outdoor primary cooking in the intervention arm (58%), which had a GM of 0.292 mg/m^3. Outdoor placements overall, with and without stoves present, had lower $PM_{2.5}$ mass concentrations than indoor placements in both control and intervention arms, and were also similar between arms. Since cooking may have occurred in more than one location during the monitoring period, the sum of both placements is used as a proxy for overall household concentrations and only includes placements that were in separate buildings or indoors and outdoors. Geometric mean concentrations were 0.847 mg/m^3 in the control arm (95% CI .685- 1.0485 mg/m^3) compared to .596 mg/m^3 in the intervention arm (95% CI 0.479- 0.741 mg/m^3) (Table 3).

After adjusting for 3-day precipitation, household kerosene use for lighting, and presence of smokers in the home (Table S3), the geometric mean concentration of $PM_{2.5}$ was 43.4% lower in the intervention arm than the control arm (95% CrI 20.8-58.1%, p<0.001). For households with two UCB-PATS placements, geometric mean concentration of $PM_{2.5}$ in the intervention arm was 32.7% lower (95% CrI 5.7-51.3%, p=0.017) (Table S4).

Personal exposure -- cooks

Overall, 410 personal exposures measurements were conducted in primary household cooks, with 397 gravimetric $PM_{2.5}$ and CO, 12 gravimetric $PM_{2.5}$ only, and 1 CO only. Reasons for not meeting eligibility criteria (n=59) included being pregnant (26), current smoker (19), pregnant and current smoker (5), poor health (8), and under the age of 18 (1).

Overall, 359 PM measurements (87.8%) ran 80% of the target 48-hour period (91.8% of control samples, 81.7% of intervention samples); 354 measurements ran for 90% of the target (90.2% control, 80.1% in intervention). Pump battery failure and air-flow restriction due to pinched tubing between the pump and HPEM were the most common causes of stoppage. Of 409 gravimetric deployments for cooks, 402 filter samples were successfully pre- and post-weighed and matched to participant data, although removing anomalous weights indicating potential filter and identification code switches and weighing irregularities resulted in 367 usable weights. Of the 398 CO measurements, 275 measurements were usable and retained for analysis; 123 measurements were deemed unusable due to instrument failure or incorrect field zeroing (95), operating less than 80% of the 48 hours (8), and broken/missing/stolen devices (20). Additionally 35 cooks (8.5%) were deemed noncompliant based on spot-check observations, self-reported compliance/problems with equipment, and light-sensor records and were excluded from

analyses. Thus, 295 $PM_{2.5}$ samples at 80% completeness (292 at 90%) and 254 CO samples were retained for statistical analysis.

Among primary cooks, geometric mean (GM) $PM_{2.5}$ concentrations were 192 μg/m^3 (95% CI 150-246 μg/m^3) in the control arm compared to 151 μg/m^3 (95% CI 134-171 μg/m^3) in the intervention arm (Table 4). The arithmetic mean was 251 μg/m^3 in the control arm and 190 in the intervention arm (Figure 4). Differences in CO between control and intervention cooks were also observed, with a GM of 0.838 PPM (0.592- 1.187 PPM) in the control arm compared to 0.677 PPM (95% CI 0.479-0.958 PPM) in the intervention arm. Our results did not change after limiting our analysis to samples with 90% pump runtimes (Table 4).

After controlling for age, 3-day precipitation, household kerosene use for lighting, and presence of other smokers in the home, the geometric mean personal exposure to $PM_{2.5}$ was 22.2% lower in the intervention arm (95% CrI 40.3% lower to 0.2% higher; p=0.06) (Table S5). Sensitivity analyses for 90% pump runtimes were similar (Table S6). Presence of household smokers that reported smoking inside of the house was associated with a 37% increase in exposure (p=0.003). Although the adjusted model for CO indicated intervention status was associated with lower CO exposure (Table S7), the effect was not statistically significant (p=0.133).

Personal exposure – children

Among children <5 years old, 405 personal exposure measurements were conducted, with 328 gravimetric $PM_{2.5}$ and CO paired measurements, 11 gravimetric $PM_{2.5}$ measurements only, and 66 CO measurements only. Reasons for not meeting eligibility criteria (n=64) included being

above 5 years of age (19), too small (32) or too unwell (8) to support the monitoring equipment, or being away from the household at the time of deployment (5). Of 394 total child CO samples, 271 samples were usable; unusable samples (n=123) were due to drifting/jumping baseline due to incorrect field zeroing and instrument failure (88), incompleteness (11), and broken/missing/stolen devices (24).

Of 339 total child $PM_{2.5}$ samples, 251 (74.0%) had pump runtimes that were 80% complete for the 48-hour period (75.1% incomplete in control, 72.6% incomplete in intervention; 229 (67.6%) had 90% complete pump runtimes (67.9% control, 67.1% intervention). Three hundred thirty-seven filters were successfully post-weighed and merged with deployments, although anomalous weights indicating potential filter ID switches and weighing irregularities resulted in 306 usable weights. Overall 13 children (3.5%) samples were determined to be noncompliant and were not included in final analyses, resulting in 219 $PM_{2.5}$ samples at 80% completeness (199 at 90%) and 263 CO samples for final analysis.

Child GM $PM_{2.5}$ concentrations were 194 $\mu g/m^3$ (95% CI 138-272 $\mu g/m^3$) in the control arm and 175 $\mu g/m^3$ in the intervention arm (135-225 $\mu g/m^3$) (Table 4). Arithmetic mean was 268 $\mu g/m^3$ (95% CI 183-353) in the control arm and 226 $\mu g/m^3$ (95% CI 148-304 $\mu g/m^3$) in the intervention (Figure 4). Exposure to CO was lower among children, and differences between intervention and control were more pronounced than among cooks, with a geometric mean of 0.551 PPM (95% CI 0.346-0.880 PPM) in control compared to 0.355 PPM (95% CI 0.232- 0.542 PPM) in intervention. Concentrations for samples with 80% pump runtime were similar to samples with 90% pump runtime for both cooks and children (Table 4).

Controlling for child age, sex, 3-day precipitation, household kerosene use for lighting, and presence of other smokers in the home (Table S8), exposure to $PM_{2.5}$ was not significantly improved in the intervention arm compared to control (19.5% lower, 95% CrI 45.9% lower to 18.8% higher; p=0.27). Sensitivity analysis including samples that ran for 90% of the 48-hour period were similar (Table S9). Adjusted exposure to CO was also not significantly different between intervention and control (34.8% lower, 95% CrI 62.9% lower to 14.3% higher; p=0.13) (Table S10).

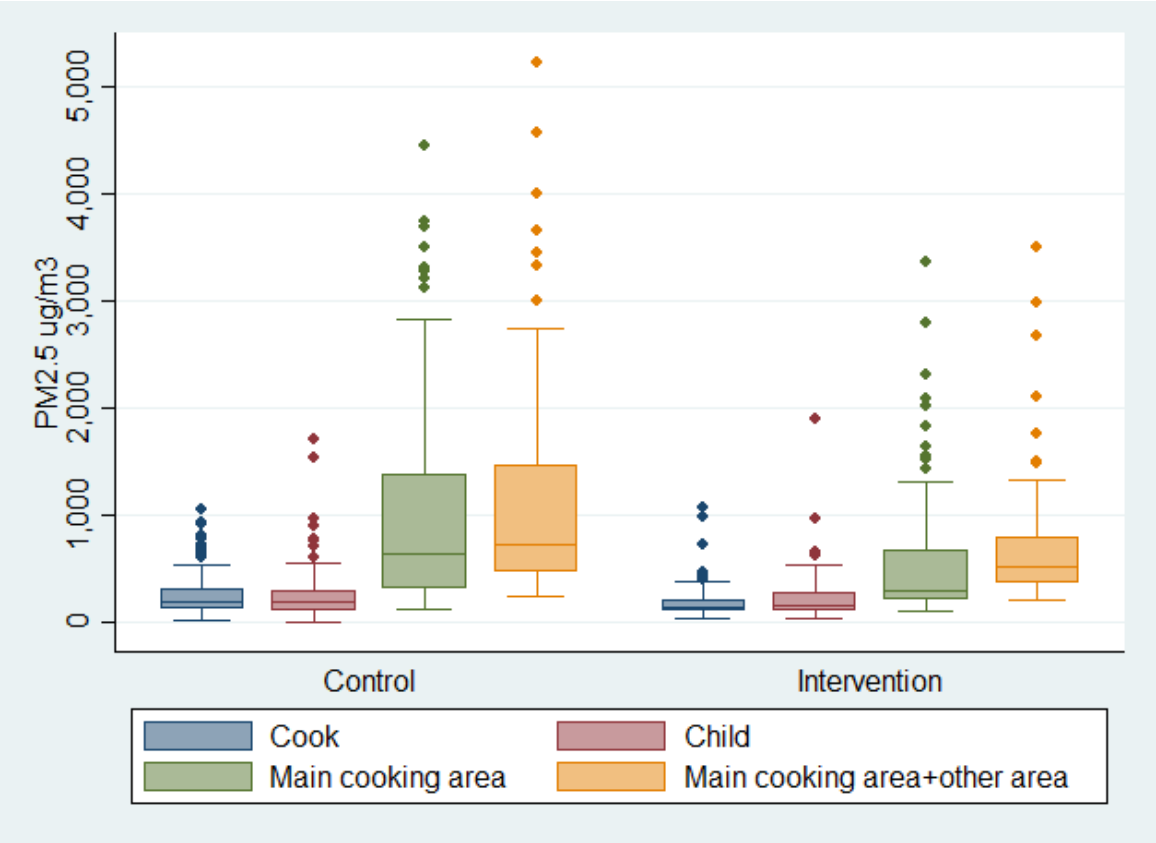

Figure 4 Boxplot of arithmetic mean 48-hour $PM_{2.5}$ concentrations for main cooking area, sum of main cooking area and other household area, cooks, and children under 5 years of age.

<u>Child respiratory health.</u>

One-week prevalence of acute respiratory illness was 9.4% in the control arm and 2.7% in the intervention arm (Table 5). Prevalence of seeking care from a CHW or health facility for ARI within previous 7 days was 3.1% in control and 0.8% in intervention, although in both arms about a third of ARI cases sought care. Within the previous 3 months, care was sought at a health facility for respiratory symptoms by 19.7% among control child observations and 6.8% of intervention child observations.

Controlling for age, SES, sex, and precipitation within the previous 10 days, children in the intervention arm had significantly reduced odds of self-reported acute respiratory infection within the previous 7 days compared to the control arm (OR 0.23, p=0.008, 95% CrI 0.05-0.57). Controlling for age, SES, sex, and precipitation within the previous 10 days, the OR for seeking care for ARI in the previous 7 days was 0.27 among intervention children compared to control children (p=0.131, 95% CrI 0.01-1.06). The OR of attending a health facility for respiratory symptoms within the previous 90 days, controlling for the same covariates as the 7-day care model with the exception of 10-day precipitation, was 0.29 among intervention children compared to control children (p=0.004, 95% CrI 0.10-0.64).

Table 1 Intervention and control household characteristics of main survey and HAP monitoring households at enrolment.

Household characteristics	**Intervention – main survey (n=113 hh) %hh**	**Control -- main survey (n=156 hh) %hh**	**Standardized difference**	**Intervention – HAP households (n=105hh) %hh**	**Control – HAP households (n=150hh) %hh**	**Standardized difference**
Mean number of occupants per household	5.07	5.35	-0.151	5.10	5.35	-0.129
Mean number of females 18+ per household	1.23	1.35	-0.190	1.25	1.35	-0.170
Mean number of males 18+ per household	0.82	0.83	-0.018	0.81	0.83	-0.040
Mean number of children under 5 per household	1.31	1.24	0.126	1.31	1.24	0.141
Female respondent	100.0	100.0	.	100.0	100.0	.
Mean age of respondent	35.34	37.40	-0.160	36.80[1]	38.17[1]	-0.110
Respondent never attended school	36.3	36.5	-0.005	33.3	38.0	-0.098
Respondent completed primary only	14.2	16.0	-0.052	15.2	15.3	-0.003
Respondent completed some secondary or higher	4.4	4.5	-0.003	4.8	4.7	0.004
Floor type -- earth/sand	93.8	90.4	0.127	94.3	90.7	0.138
House has electricity	2.7	8.3	-0.251	1.9	8.0	-0.284
House has radio	33.6	35.3	-0.034	33.3	34.7	-0.028
House has mobile phone	25.7	34.6	-0.196	24.8	33.3	-0.190
Has mattress	27.4	35.9	-0.183	28.6	35.3	-0.145
Has bicycle	1.8	3.8	-0.126	1.9	3.3	-0.090
Own land	90.3	85.9	0.135	91.4	85.3	0.191
Own house	83.2	90.4	-0.214	84.8	90.0	-0.158
Own animals	46.9	44.9	0.041	48.6	45.3	0.065
Mean reported one-way travel time to health facility (min)	45.6	63.6	-0.451	45.11	63.66	-0.461
Method of reaching facility – only on foot	96.5	98.7	-0.148	97.1	98.7	-0.107

Current primary fuel: wood	65.5	51.9	0.278	66.7	51.3	0.316
Current primary fuel: straw/shrubs/grass	29.2	47.4	-0.382	28.6	48.0	-0.408
Current primary fuel: charcoal	5.3	0.6	0.277	4.8	0.7	0.254
Times stove lit per day	2.06	1.83	0.419	2.08	1.83	0.435
Meals cooked per day (mean)	2.08	1.79	0.559	2.10	1.80	0.585
1 meal per day (%)	8.8	25.6	-0.456	7.6	25.3	-0.492
2 meals per day (%)	74.3	69.2	0.114	75.2	69.3	0.132
3 meals per day (%)	16.8	5.1	0.381	17.1	5.3	0.381
Primary cooking location: Inside house – kitchen	30.1	47.4	-0.362	28.6	48.7	-0.422
Primary cooking location: Inside house – other	18.6	14.7	0.103	18.1	15.3	0.074
Primary cooking location: Outside	37.2	5.1	0.853	39.0	5.3	0.888
Primary cooking location: Inside separate kitchen	14.2	32.7	-0.448	14.3	30.7	-0.400
Has secondary cooking location	61.9	13.5	1.155	62.9	14.0	1.162
Has secondary cooking location outdoors	19.5	5.1	0.447	20.0	5.3	0.452
Has traditional three-stone fire and uses more than once per week	15.0	83.3	-1.870	14.3	83.3	-1.910
Has three-stone fire and uses everyday	9.7	82.1	-2.109	10.5	82.0	-2.059
Has traditional rondereza stove[1] and uses more than once per week	6.2	16.0	-0.317	5.7	16.7	-0.353
Has traditional rondereza stove and uses everyday	2.7	15.4	-0.456	2.9	16.0	-0.462
Has traditional charcoal stove and uses more than once per week	8.8	3.2	0.239	7.6	3.3	0.189
Has traditional charcoal stove and uses every day	8.8	0.6	0.393	7.6	0.7	0.354
Has Ecozoom stove and uses more than once per week	88.5	0.0	--	81.4	0.0	--
Has Ecozoom stove and uses every day	81.4	0.0	--	83.8	0.0	--

Use kerosene for lighting more than once per week	18.6	24.4	-0.141	19.0	24.0	-0.121
Use kerosene for lighting every day	17.7	20.5	-0.072	18.1	20.0	-0.049
Ever heat home	24.8	19.2	0.134	23.8	20.0	0.092
Heat home in both rainy and dry seasons	10.8	11.5	-0.023	9.7	12.0	-0.074
Cook beans more than once per week	61.9	52.6	0.191	61.0	52.0	0.181
Use a stove for brewing alcohol	6.2	12.2	-0.208	6.7	12.0	-0.184
Use a stove for business	4.4	1.9	0.143	4.8	2.0	0.153
Use a stove for heating water for bathing	76.1	82.1	-0.147	78.1	81.3	-0.081
Use a stove for roasting	74.3	92.9	-0.520	73.3	94.7	-0.608
	N=147 children	**N=193 children**		**N=99 children**	**N=132 children**	
Mean child age (months)	31.06	30.68	0.023	37.60	37.61	-0.001
Child gender -- female	53.7	52.8	0.018	54.5	55.3	-0.015

[1] Cook that participated in personal exposure monitoring. Age in years at enrolment. 94 intervention cooks, 137 control cooks.
[2] A *rondereza* is a built-in wood stove without a chimney and considered a traditional stove in this study.

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

	Round 1	**Round 2**	**Overall**
Coverage	**N=113 households N (%)**	**N=91 households N (%)**	**N=204 household observations N (%)**
Received stove	111 (98.2)	89 (97.8)	200 (98.0)
Currently has stove[1]	108 (97.3)	88 (98.9)	196 (98.0)
House currently has working stove[1]	108 (97.3)	86 (96.6)	194 (97.0)
Observed and reported use (only if has working Ecozoom)	**N= 108 houses**	**N= 86 houses**	**N= 194 household observations**
Reports currently using stove	107 (99.1)	85 (98.8)	192 (99.0)
Reports using within previous week	104 (96.3)	84 (97.7)	188 (96.9)
Reports stove last used on day of visit or previous day	98 (90.7)	80 (93.0)	178 (91.8)
Stove has the appearance of previous use	106 (98.2)	83 (96.5)	189 (97.4)
Stove warm or in use at time of visit	27 (25.0)	25 (29.1)	52 (26.8)
Reported and observed exclusive use (only if has working Ecozoom)	**N= 108 houses**	**N= 86 houses**	**N= 194 household observations**
Self-reported frequency of traditional stove use –once a week or more	37 (34.3)	35 (40.7)	72 (37.1)
Self-reported frequency of traditional stove use -- every day	18 (16.7)	24 (27.9)	42 (21.6)
Traditional stove observed warm or in use at time of survey day arrival	13 (12.0)	16 (18.6)	29 (14.9)
Control arm or intervention house without working Ecozoom	**N=161 houses[2]**	**N=149 houses[2]**	**N=310 household observations[2]**
Traditional stove observed warm or in use at time of survey day arrival (if control arm or intervention without working Ecozoom)	51 (31.68)	54 (36.2)	105 (33.9)
Sensor-derived use[3]	**N=43 households N (%)**	**N=53 households N (%)**	**N=96 household observations N (%)**
Stove used at least once per day on >=50% of measurement days[4]	42 (97.7)	52 (96.3)	94 (97.9)
Stove used at least once per measurement day (% of houses)	40 (93.0)	45 (84.9)	85 (88.5)
Stove used at least twice per day on >=50% of measurement days	6 (14.0)	5 (9.4)	9 (9.4)
Stove used at least twice per day on each measurement day	1 (2.3)	1 (1.9)	2 (2.1)
Avg proportion of days stove used at least once (SD)	97.7 (10.6)	96.0 (13.5)	96.8 (12.2)

Avg proportion of days stove used at least twice (SD)	26.1 (20.9)	22.0 (21.3)	23.8 (21.1)
Mean (SD) cooking events per day of sensor data per household	1.25 (0.23)	1.22 (0.30)	1.23 (0.27)

[1]Only if household received Ecozoom stove
[2]Only if control arm or intervention without working Ecozoom stove
[3]Only if house had working Ecozoom stove. Ecozoom stove sensors were deployed in 91 hh in Round 1 and 80 hh in Round 2. Due to mobile network challenges, sensor failure, and other technical faults, data was obtained from 44 households in Round 1 and 56 households in Round 2, with a mean of 16.9 deployment days (SD 8.0, range 8-36 days).
[4]Day considered usable with sensor data if the sensor transmitted data to a central server at least once (not including the partial deployment and retrieval days). Forty-three households had usable days in Round 1 and 53 in Round 2 for analysis, with a mean of 9.1 days per deployment (SD 6.8, range 0-30 days)

Table 3 Descriptive statistics for household cooking areas and outdoor courtyard 48-h $PM_{2.5}$ mass concentrations (mg/m^3) by UCB-PATS placement and cooking location, based on usable data.

	Control								Intervention							
	n	Min-max	Med	IQR	Mean (LSE)	95% CI	GM (LSE)	95% CI	n	Min-max	Med	IQR	Mean (LSE)	95% CI	GM (LSE)	95% CI
Primary cooking area[1]	191	.132-4.453	.645	1.069	.967 (.080)	.798-1.137	.668 (.063)	.548-.814	133	.110-3.371	.307	0.462	.540 (.071)	.391-.689	.385 (.042)	.306-.484
Primary cooking – indoors	173	.132-4.453	.699	1.109	.995 (.080)	.826-1.164	.695 (.064)	.573-.844	103	.110-3.371	.351	0.535	.550 (.068)	.417-.703	.417 (.043)	.335-.519
Primary cooking – outdoors	18	.1605-3.277	.381	0.181	.700 (.309)	.048-1.351	.452 (.120)	.258-.791	30	.123-2.792	.2069	0.228	.472 (.161)	.132-.811	.292 (.056)	.195-.436
Indoor placement – stove(s) present	187	.115-4.453	.633	1.092	.943 (.081)	.773-1.113	.632 (.063)	.512-.781	130	.107-3.371	.296	0.363	.489 (.060)	.361-.616	.357 (.038)	.285-.447
Outdoor placement - all	168	.106-3.277	.157	0.079	.234 (.034)	.163-.306	.185 (.010)	.166-.206	107	.109-2.792	.163	0.096	.261 (.046)	.163-.358	.195 (.014)	.168-.227
Outdoor placement – stove(s) present	20	.118-.730	.215	0.181	.262 (.033)	.193-.331	.230 (.025)	.182-.289	76	.109-2.792	.186	0.106	.303 (.067)	.162-.444	.217 (.020)	.178-.264
Outdoor placement – no stove(s) present	148	.106-3.277	.155	0.059	.231 (.040)	.147-.314	.180 (.011)	.159-.204	31	.118-.317	.149	0.033	.156 (.010)	.136-.176	.151 (.008)	.136-.168
Sum of both placements[2]	135	.2493-5.2316	.736	0.996	1.120 (.127)	.852-1.389	.847 (.086)	.685-1.049	80	.218-3.513	.529	0.414	.735 (.087)	.552-.919	.596 (.062)	.479-.741

[1] Self-reported location or location with higher value if both household UCB-PATS placements have complete data or is identified as alternative cooking location.

[2]Only if UCB-PATS data from both placements are usable and only if the placements were in two different locations (e.g. indoors and outdoors, or inside house and inside separated kitchen).

Table 4 Descriptive statistics for 48-h average personal exposure to $PM_{2.5}$ mass µg/m^3 and CO (PPM) among Rwandan women and children under 5 cooking with biomass fuels.

	Control								Intervention							
Pollutant	n	Min-max	Med	IQR	AM (LSE)	95% CI	GM (LSE)	95% CI	n	Min-max	Med	IQR	AM (LSE)	95% CI	GM (LSE)	95% CI
Cook $PM_{2.5}$ (µg/m^3) 80% runtime	186	18-1055	193	195	251 (32)	184-319	192 (23)	150- 246	109	38-1078	148	113	190 (16)	156-224	151 (9)	134-171
Cook $PM_{2.5}$ mass (µg/m^3) 90% runtime	183	18-1055	195	195	250 (31)	185-315	191 (22)	151-243	109	38-1078	148	113	190 (16)	156-224	151 (9)	134-171
Child $PM_{2.5}$ (µg/m^3) 80% runtime	124	5-1707	202	188	268 (40)	183-353	194 (31)	138-272	95	38-1895	167	175	226 (37)	148-304	175 (21)	135-225
Child $PM_{2.5}$ (µg/m^3) 90% runtime	111	5-1707	197	179	252 (42)	164-340	186 (32)	129- 266	88	38-972	175	167	205 (24)	155-256	168 (18)	134-212
Cook CO (PPM)	158	0.000-17.476	.795	1.790	1.790 (.333)	1.088-2.493	.748 (.125)	.526-1.065	96	0.000-7.703	.678	0.967	1.238 (.192)	.832-1.644	.618 (.145)	.376-1.015
Child CO (PPM)	159	0.000-10.590	.503	1.579	1.365 (.437)	.443-2.288	.552 (.122)	.347-.880	104	.001-5.521	.418	0.904	.803 (.086)	.621-.985	.356 (.071)	.233-.543

Min-max, minimum to maximum values; Med, median; IQR, interquartile range; AM, arithmetic mean; LSE, linearized standard error; GM, geometric mean; CI, confidence interval

Table 5 Reported respiratory symptoms, health-care seeking behaviour, and toothache (negative control) among children under 5 years of age.

	Round 1 N=340 children		**Round 2 N=284 children**		**Overall N=624 child observations**	
	Control N (%)	Intervention N (%)	Control N (%)	Intervention N (%)	Control N (%)	Intervention N (%)
ARI[1] within previous 7 days	19 (9.8)	5 (3.4)	15 (9.0)	2 (1.7)	34 (9.4)	7 (2.7)
ARI - Sought care from CHW or at health facility for ARI within previous 7 days	6 (3.11)	1 (0.68)	5 (2.99)	1 (0.85)	11 (3.06)	2 (0.76)
Fever	55 (28.50)	24 (16.33)	40 (23.95)	13 (11.11)	95 (26.39)	37 (14.02)
Fever – sought care	26 (13.47)	6 (4.08)	24 (14.37)	8 (6.84)	50 (13.89)	14 (5.30)
Constant cough	72 (37.31)	37 (25.17)	55 (32.93)	21 (17.95)	127 (35.28)	58 (21.97)
Constant cough – sought care	27 (13.99)	12 (8.16)	17 (10.18)	8 (6.84)	44 (12.22)	20 (7.58)
Congestion/runny nose	91 (47.15)	36 (24.49)	56 (33.53)	23 (19.66)	147 (40.83)	59 (22.35)
Congestion/runny nose – sought care	25 (12.95)	6 (4.08)	13 (7.78)	4 (3.42)	38 (10.56)	10 (3.79)
Panting / wheezing / difficulty breathing	26 (13.47)	8 (5.44)	18 (10.78)	2 (1.71)	44 (12.22)	10 (3.79)
Panting / wheezing / difficulty breathing - sought care	10 (5.18)	1 (0.68)	5 (2.99)	0 (0.00)	15 (4.17)	1 (0.38)
Sought care at health facility for respiratory symptoms within last 3 months[2]	41 (21.2)	13 (8.8)	30 (18.0)	5 (4.3)	71 (19.7)	18 (6.8)

Toothache – within previous 7 days	9 (4.7)	6 (4.1)	5 (3.0)	4 (3.4)	14 (3.9)	10 (3.8)
Total child observations	193	147	167	117	360	264

[1] Acute respiratory illness (ARI) defined as cough accompanied with "wheeze or rapid or difficulty breathing".
[2] Case of cough, congestion/runny nose, difficulty breathing, or rapid breathing

DISCUSSION

Coverage and use; stacking.

This study found high coverage and continued use of an improved biomass stove 13-24 months following intervention delivery. Most stoves were in good working order, and most households reported using the Ecozoom stoves daily. Usage of the cookstove was measured by sensors, and indicated consistent regular usage during the sensor monitoring period. Programmatic engagement, such as technical support, repeated behaviour change messaging, and visits by programmatic staff likely contributed to the high uptake that was observed (Barstow et al., 2016, 2014).

Usage was similar in Round 1 and Round 2, and indicated regular stove usage, although recorded events per day were less than reported typical behaviour, as previously reported in this pilot intervention (Thomas et al., 2013a). This study could have benefited from including stove usage sensors on traditional stoves, as we were unable to objectively quantify the extent to which exclusive use occurred. In this study we were limited by a 7-30 day sensor installation period due to logistical constraints, and it is possible the sensors do not reflect long-term usage, although patterns reflect uptake 13-24 months after receipt. A study in India found that intervention stove usage reduced over time until approximately 200 days after initial receipt (Pillarisetti et al., 2014); also a study in Kenya saw improved stove usage decrease over a period of 12 days of observation (Lozier et al., 2016). In other studies, stove use increased after delivery and then levelled off (Ruiz-Mercado et al., 2008). Within our study it is possible there was some reactivity to our visit and/or knowledge of the sensor's presence or purpose, which can impact usage as well as HAP levels (Lozier et al., 2016; Thomas et al., 2016). Being observed can change behaviour (Arnold et al., 2015; Zwane et al., 2011), and frequent presence of research and

programmatic staff within the village of research could affect the generalizability of these results.

Stove stacking (continued use of traditional stoves) was widespread. Among intervention households with working Ecozoom stoves, over 20% reported using traditional stoves every day, and traditional stoves were observed to be warm or in use on 15% of visits, while the Ecozoom was observed to be warm or in use on 26% of visits. Being warm or in use is an imperfect proxy of usage for all cooking events, and intervention stoves tend to have a lower thermal inertia than traditional stoves and do not stay warm as long after use. The usage of infrared thermometers could increase the observation window and are recommended for other studies assessing stove use. Due to reporting bias, the usage of traditional stoves is likely higher than reported. When traditional stoves continue to be used, there may be minimal impact of the improved stove on HAP (Edwards et al., 2007; Johnson and Chiang, 2015). Even if benefits are initially detected from an improved stove implementation, these can diminish over time in the presence of stove stacking (Pine et al., 2011; Romieu et al., 2009; Ruiz-Mercado and Masera, 2015), even when traditional stoves are used as secondary stoves (Pennise et al., 2009).

Exposure

Despite high and sustained uptake of the intervention stove, both cook and child personal 48-hour exposures to $PM_{2.5}$ in control and intervention arms far exceeded WHO health guidelines of 10 µg/m^3 and interim WHO target of 35 µg/m^3 (WHO, 2014). Slight reductions in geometric mean personal exposure to $PM_{2.5}$ were observed for both cooks and children in the intervention arm, although in adjusted analyses modelling log-transformed $PM_{2.5}$ exposure, the intervention was not associated with a statistically significant difference for cooks ($p=0.059$) or children

(p=0.315). There was no statistically significant impact on CO exposures among cooks and children; mean levels were lower than observed in other studies in The Gambia and Kenya (Dionisio et al., 2008; Ochieng et al., 2013). The lack of a significant reduction in exposure for cooks and children is consistent with other studies of biomass cookstoves that are Tier 2 and 3 for indoor emissions, confirming the need to employ cleaner fuels and address other sources of exposure (Balakrishnan et al., 2015; Rosenthal, 2015; Sambandam et al., 2015; Smith et al., 2011). Other possible reasons for lack of effect include increased time needed to tend the Ecozoom compared to their traditional stove as previously reported for this health programme, resulting in similar exposure levels (Barstow et al., 2014; Rosa et al., 2014). Also, the sharing of cooking tasks among household members may dilute exposure reduction potential (Beltramo and Levine, 2013). Importantly, there could have been behavioural reactivity during HAP monitoring periods resulting in increased use of the intervention stove, so the exposure levels observed might not be representative of typical exposures (Lozier et al., 2016).

CO exposure measurements occurred in children as young as 8 months and $PM_{2.5}$ from 18 months of age. Exposure of infants remains largely unknown, although children are often carried on their mother's back at an early age even during cooking, so exposure is likely similar to levels seen for cooks. In contrast with other studies (Balakrishnan et al., 2004; Dionisio et al., 2008), child $PM_{2.5}$ exposures were very similar to cook $PM_{2.5}$ exposures (Table 3, Figure S3). Reasons for this could include similar time spent close to cooking fires indoors and in outdoor courtyards, and possibly being more sedentary around cooking fires than active cooks who perform multiple tasks while cooking. Even if children are in adjoining rooms to cooking activities, they can be exposed to high $PM_{2.5}$ concentrations, particularly when ventilation is lacking (Patel et al., 2017). High $PM_{2.5}$ concentrations exceeding WHO guidelines were observed in outdoor courtyard areas with and without stoves present, and children often spend time

playing in these areas. It is likely that cooks and children were exposed to additional exposures to varying levels in and outside of the house given different behaviours, such as re-suspended dust during play or walking along roads, or exposure to additional cooking events at neighbouring houses (Accinelli and Gozal, 2015; Secrest et al., 2016). While controlling for rainfall was partly intended to control for potential dust exposures, it is possible this was an inadequate proxy. Moreover, we did not assess cook or child location during the HAP monitoring period. Using person-location tracking in tandem with exposure measurements could help in understanding determinants of exposure.

Another reason why child exposure was similar to adults may have been exposure to second-hand tobacco smoke from the mother or from other household members (Semple and Latif, 2014). We did not measure HAP exposure among cooks who reported they smoked; thus, overall exposure of cooks in our study households is likely underestimated. Presence of a smoker had a statistically significant impact on cook $PM_{2.5}$ exposure in adjusted models (Table S5 and Table S6). Both antenatal and second hand smoke exposure may be important within this population, in addition to impact of cooking with biomass as found in other studies (Gurley et al., 2013; Vanker et al., 2015). Children can also participate in cooking activities which would increase exposures, and smoke from heating may be another exposure pathway, although this was not a wide-spread practice during exposure monitoring periods.

We were unable to conduct ambient air quality monitoring in villages, and this is recommended for future studies. The contribution of biomass cooking to these exposure levels is unknown, and multiple contributing sources are likely (Piedrahita et al., 2017; Secrest et al., 2016). Black carbon analyses are underway for cook and child gravimetric samples, and should help

determining whether exposure to biomass was similar between cooks and children in this setting, although black carbon sources are variable (Soneja et al., 2015). Source apportionment has been recommended as an additional analysis in epidemiological studies looking at the relationship between HAP and health in order to understand more fully the sources of $PM_{2.5}$ contributing to exposure (Huang et al., 2015). Investigating the components of exposure and ambient conditions would also be helpful to understand more fully the reasons for the small to negligible exposure reductions observed among intervention cooks and children.

Reductions in cooking area concentrations were greater than observed for personal exposures. This is consistent with other studies that have measured both personal and cooking area $PM_{2.5}$. For example, a study in Mexico found kitchen reductions of 74% compared with a 35% personal reduction (Cynthia et al., 2008). Even among households exclusively using Ecozoom stoves, kitchen and exposure reductions were likely not as high as could be achieved due to continued indoor cooking behaviour which was observed (Table 1 and Table 2), especially during rainy periods. Relative household concentrations of $PM_{2.5}$ measured in cooking areas among intervention and control were similar to levels as seen in the previous RCT among 3 of the original pilot villages (Rosa et al., 2014). Similar to that study, the greatest difference in cooking area $PM_{2.5}$ was observed for those who cooked outdoors, possibly suggesting the greatest potential for exposure reductions occurs if cooking occurs outdoors. Indeed, carbon monoxide exposure among children has been found lower among households cooking outdoors (Barnes et al., 2006).

However, due to stove stacking and usage in multiple locations, interpretation of cooking area $PM_{2.5}$ as measured at a single location should be interpreted with caution. Given multiple stoves and cooking locations, it is very difficult to accurately place static $PM_{2.5}$ monitors in a way that captures all cooking events and concentrations in all living quarters, particularly in intervention

households using portable stoves. It is possible cooking events were under-measured if the cooking occurred more than 1 meter from our designated UCB-PATS equipment placement. Since intervention households were more likely to report cooking in multiple locations and outdoors given portability of the Ecozoom stove, relying on a single primary cooking area likely underestimates household concentrations. The difference between primary cooking area alone and the sum of primary and other cooking area was greater in the intervention arm, confirming this (Table 3, Figure S2). However, using a sum of two different stationary monitors must also be interpreted with caution since smoke from a cooking event or other sources may have been captured by both UCB-PATS placements leading to double-counting and overestimation. Cooking with grass, leaves, and shrubs was more common in intervention households compared to higher wood-using control households, possibly due to the Ecozoom requiring smaller pieces of fuel or local wood availability. This fuel difference may have contributed to observed differences in cooking area concentrations between arms, although measuring fuel moisture, which can impact CO and $PM_{2.5}$ stove emissions, would help in assessing the importance of this difference between arms (Ochieng et al., 2013).

Courtyard concentrations were similar between intervention and control households regardless of reported cooking behaviour in courtyards. This may indicate intrusion of smoke from indoor cooking areas, smoke from other sources such as garbage burning, charcoal making, agricultural burning, and the burning of biomass by neighbours (Dasgupta et al., 2006; Salje et al., 2014). It is also possible those houses with outdoor placements by a stove tended to use that stove indoors more than outdoors during the HAP monitoring period.

The $PM_{2.5}$ concentrations of control houses with outdoor cooking areas was similar to intervention houses with outdoor cooking areas, and observed reductions could have been mainly attributed to a change in cooking location rather than the stove itself. Further work is needed to assess proportion and type of cooking events by location and impact on kitchen concentrations and personal exposures. The benefits of increased ventilation have been documented elsewhere (Johnson et al., 2011; Ruth et al., 2013). Future interventions involving improved stoves should be coupled with improved kitchen design, particularly in locations experiencing rainy seasons where outdoor cooking is a challenge (Debnath et al., 2016). However, there might be increased risk to other household members by moving cooking into other living areas such as outdoor courtyards where children often play.

Child health outcomes.

Despite the lack of statistically significant personal exposure reduction in the intervention arm among children, both 7-day acute respiratory infection (defined as cough accompanied by "wheeze or rapid or difficulty breathing") and 90-day attendance at a health facility for respiratory symptoms were significantly reduced in the intervention arm. However, these outcomes were self-reported and are subject to reporting bias, although the negative control of toothache was comparable between arms. Importantly, acute respiratory illness should not be interpreted as a proxy for ALRI which is the health outcome of most concern given higher mortality rates (Fischer Walker et al., 2013b). The symptoms we assessed did not allow for characterizing upper versus lower respiratory infection; presence of cough with "wheeze or rapid or difficulty breathing" was assumed to be acute, although this may not have been the case. More objective health outcomes are needed to assess impact and severity, particularly for assessment of ALRI, such as clinic-based diagnostics, the use of portable ultra-sound, or pulse-oximetry in addition to WHO IMCI criteria (Chavez et al., 2015; Ginsburg et al., 2016).

While some reduction in child exposure was observed in unadjusted descriptive analyses, exposure remained well above WHO guidelines; the exposure-response curve from the RESPIRE trial (Smith et al., 2011) and the integrated risk function developed by Burnett et al. (2014) indicates exposure to $PM_{2.5}$ needs to reach much lower levels than those observed to reduce risk to ALRI. Nevertheless, acute respiratory infection is still a burden in low-resource settings and may make one more susceptible to pneumonia and other infections. Additionally, reduced exposure could shorten duration of both upper and lower respiratory illness, as a recent study in Mexico found (Schilmann et al., 2015).

Health facility attendance for respiratory symptoms within the previous 90 days was significantly lower in the intervention arm. The long recall period could lead to misreporting of reason for visit, frequency of visits, and type of care sought , although 3- and 6-month recall periods for health facility attendance are common (Bhandari and Wagner, 2006). A longer recall period likely underestimates health facility attendance , and capturing this burden within intervention studies remains important given the financial burden of seeking care (Ngabo et al., 2016).

Notably, this was a combined intervention with a household water filter. Among the same study households, we observed significant improvements in household drinking water quality and reduced odds of 7-day diarrhoea and visiting a health facility for diarrhoea in the previous 90 days (Chapter 4). This reduction in diarrhoea among children was similar to other water filter trials (Clasen et al., 2015). It is possible the observed impact on self-reported respiratory symptoms was due in part to the health benefits imparted by the water filter, such as reducing immune system vulnerability. Some studies have suggested that reduced diarrhoea risk can also

reduce risk of ALRI (Ashraf et al., 2013; Fischer Walker et al., 2013a; Schmidt et al., 2009). Furthermore, reduced diarrhoea may improve clinical outcomes associated with severe pneumonia (Chisti et al., 2016; Leung et al., 2015), and is also associated with malnutrition, a risk factor for pneumonia (Chisti et al., 2009; Howie et al., 2016; Le Roux et al., 2015).

Limitations

This study has several limitations. First, the intervention villages were purposively selected by the project implementers, and since our study focused on the poorest tertile (*ubudehe* 1 and 2), our results are not generalizable to all pilot intervention households or beyond the study area. However, previous work among these pilot villages reported cookstove adoption was similar between all households and *ubudehe* 1 and 2 households (Barstow et al., 2014). Households with children under 5 years of age may have been more likely to use the intervention and receptive to behaviour change messaging, although impact of the intervention within this high-risk age group was of most importance to the Ministry of Health.

Furthermore, the study was unblinded, so risk of responder bias and observer bias is high. Frequent presence of study staff within villages could have influenced participant behaviour, as well as the presence of sensors on stoves and water filters, and HAP monitoring equipment. In addition, this was a non-randomized study so the potential for unmeasured confounders is high, although the arms showed good balance on most characteristics of interest.

The study could have been strengthened by assessing health insurance status, which has been shown to increase healthcare utilization in Rwanda (Mejía-Guevara et al., 2015). Vaccination

status is another potential confounder that we did not measure, although the pneumococcal conjugate vaccine (PCV3) was introduced into Rwanda in 2009 and reached 98% coverage in 2013 (Gatera et al., 2016). Other factors, such as bedsharing and malnutrition could have impacted prevalence of respiratory infections, and should be examined in future studies (Howie et al., 2016).

Another limitation is that our study did not achieve the sample size target due to higher than anticipated ineligibility, loss to follow-up and sample loss. Differential loss to follow-up between arms was observed, and reasons for higher absence and moving away are unknown. Higher loss to follow-up of intervention households may be due to village visits in the intervention arm coinciding with planting periods; more time was spent in control villages given the higher number of eligible participants, and this could have also increased follow-up success in Round 2. The relatively substantial proportion of HAP monitoring data that was unusable was due in large part to equipment malfunction and theft, and was unlikely to be influenced by treatment status. Households were also not visited at a uniform time, nor were HAP monitoring days standardized, with the exception that monitoring did not occur on Sundays in either arm. However, this is unlikely to have differed systematically by arm.

We did not ask about current heating or kerosene lamp-lighting episodes during the 48-hour monitoring period, and future monitoring should account for these practices more accurately (Carter et al., 2016; Lam et al., 2012). Future work should seek to characterize more fully proximity of study households to neighbours and neighbours' cooking behaviours, dirt and tarmac roads given risks of resuspended dust and traffic –related sources of exposure, and other potential sources of exposure such as garbage burning, commercial cooking, and charcoal

making. Given the time and behaviour-related variability of exposure determinants, repeated and longer-term measures of personal and household $PM_{2.5}$ is recommended, especially for evaluating the potential health impacts of improved cookstoves and clean fuel interventions.

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SUPPLEMENTARY MATERIALS

Table S 1 Comparison of unmatched vs. matched village characteristic bias on key matching characteristics.

	UNMATCHED VILLAGES (n=210)			**MATCHED VILLAGES (n=18)**			
	Interven-tion	**Control**	**% bias**	**Intervention**	**Control**	**% bias**	**% reduction bias**
Minutes to road	100.56	82.114	18.8	100.56	92.222	8.5	54.8
Percent of households Ubedehe 1 & 2	32.87	29.99	25.6	32.87	30.27	23.1	9.7
Percent of households using unimproved water supply	11.62	24.72	-52.7	11.62	13.11	-6	88.7
Mean household daily cook times	2.0	1.91	30.5	2.0	1.89	37.9	-24.1
Percent of households treating water	44.02	53.85	-41.5	44.02	42.61	6	85.6
Mean size of Ubedehe 1 & 2 households	3.42	3.69	-26.7	3.43	3.23	19.5	27
Primary stove (3 stone)	0.44	0.38	13.1	0.44	0.44	0	100
Primary stove (charcoal)	0.44	0.59	-28.9	0.44	0.56	-21.8	24.7
Primary household fuel type (wood)	1	1.23	-32.3	1	1	0	100

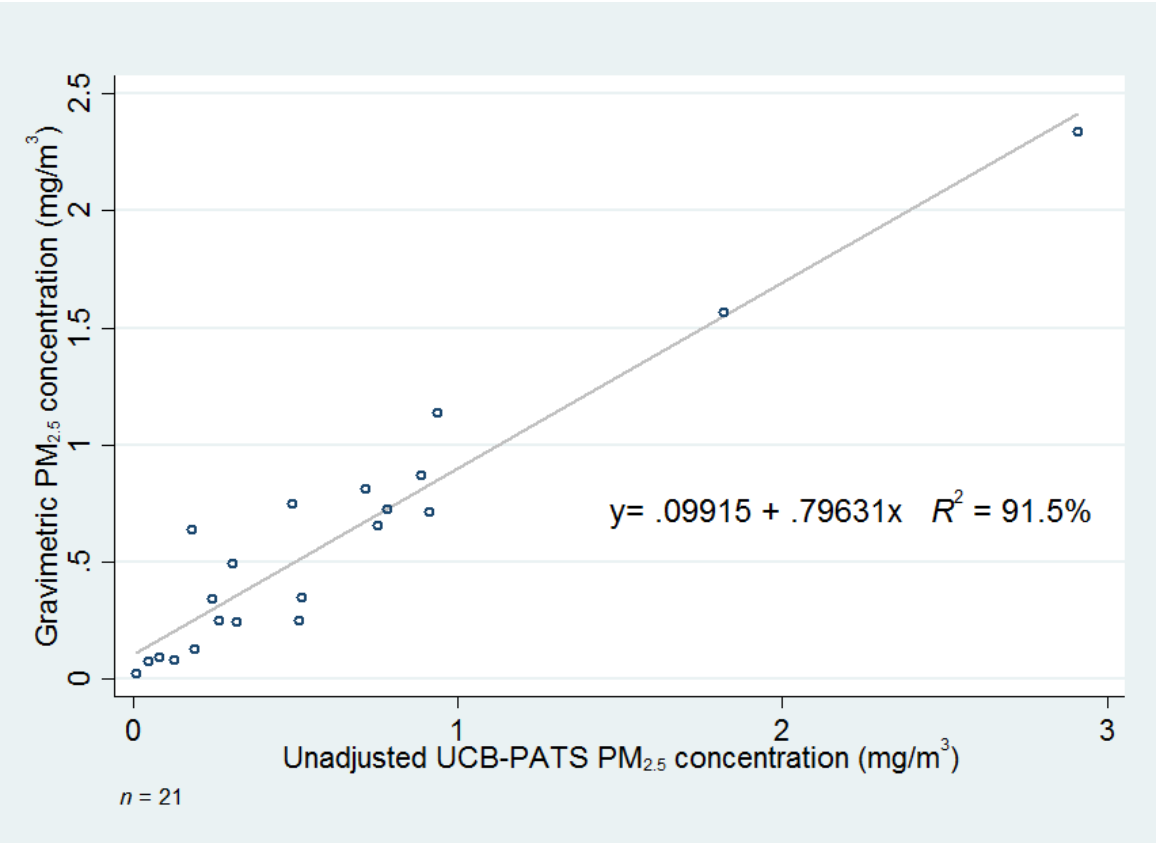

Figure S 1 Mass calibration of UCB-PATS against co-located $PM_{2.5}$ gravimetric samples.

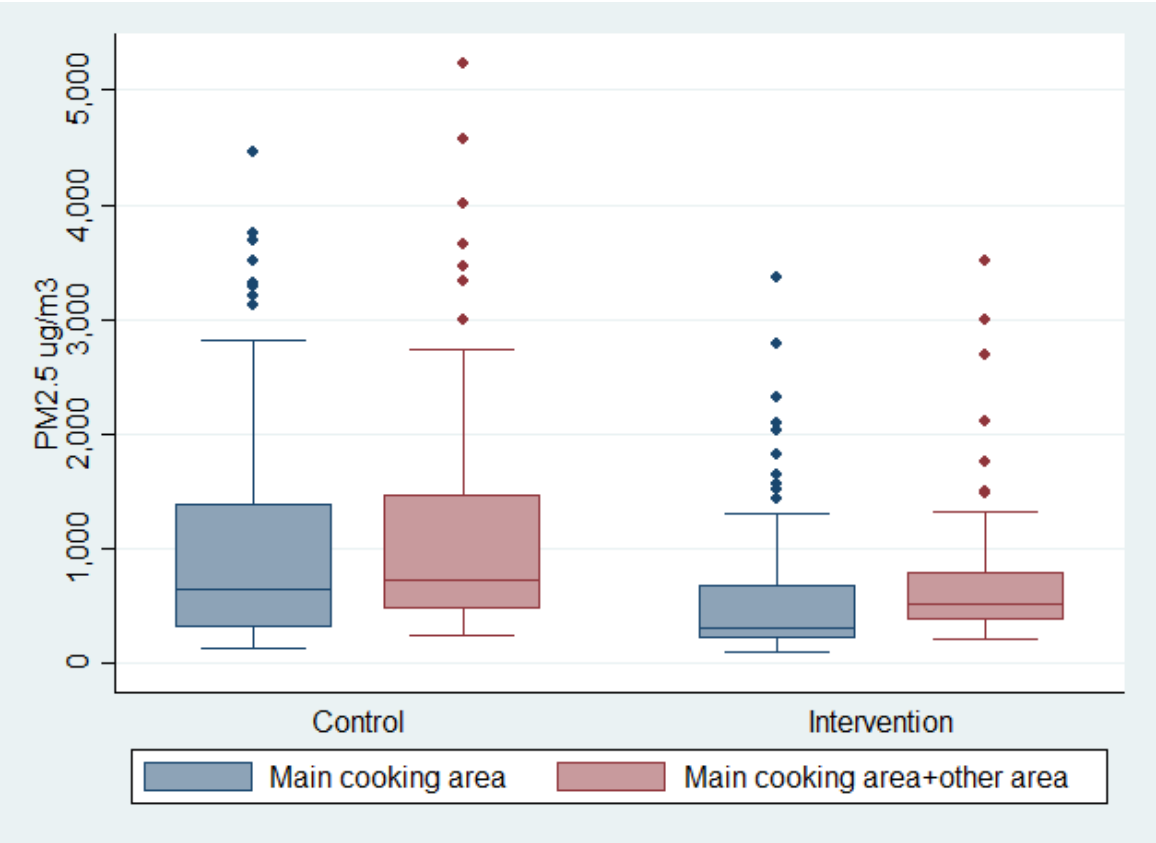

Figure S 2 Boxplot of 48-hour arithmetic mean $PM_{2.5}$ concentrations in main cooking area compared to the sum of main cooking area and other household area (using UCB-PATS nephelometric measurement).

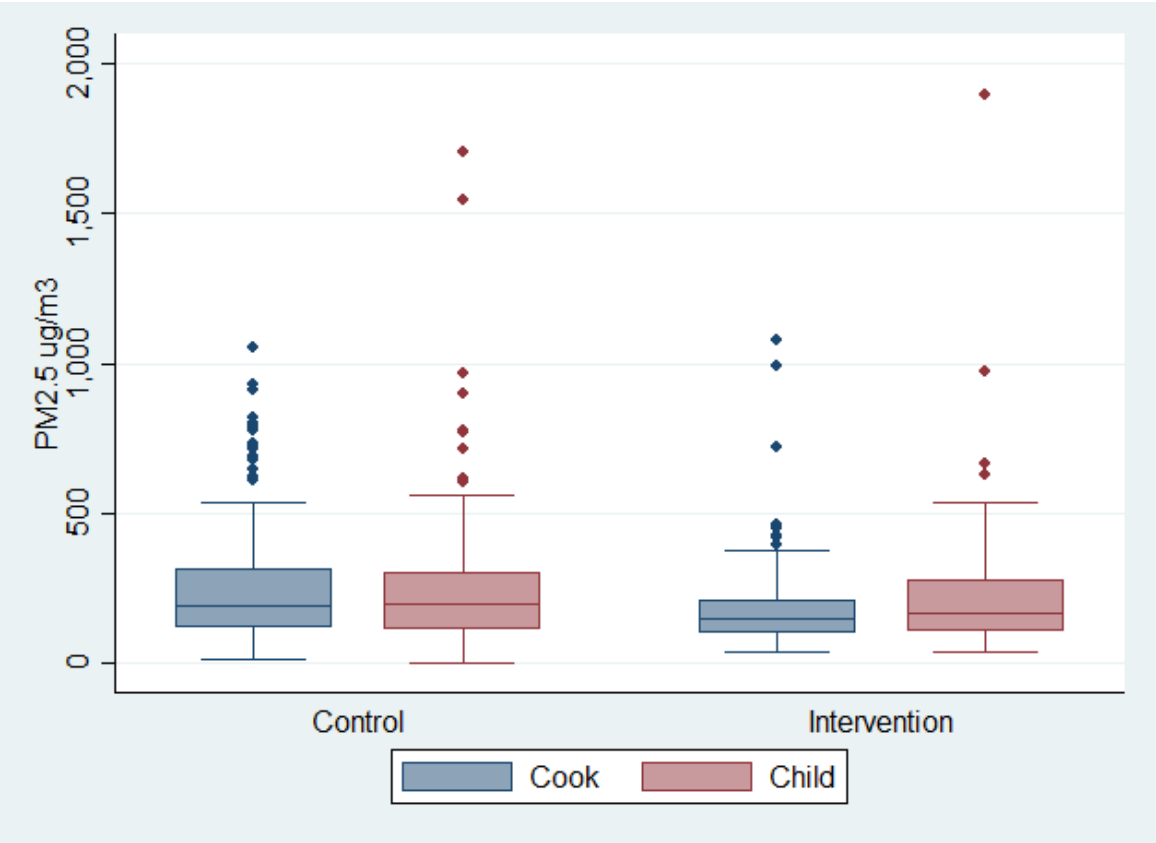

Figure S 3 Boxplot of 48-hour arithmetic mean $PM_{2.5}$ personal exposure concentrations for cooks and children under 5 years of age (using gravimetric measurement).

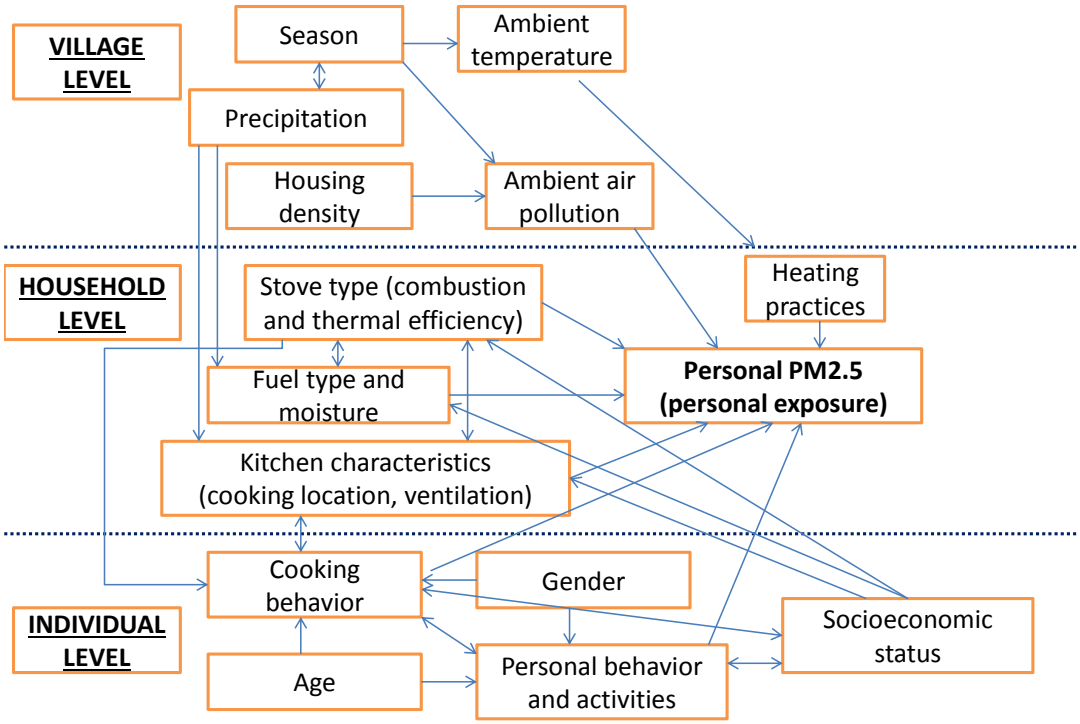

Figure S 4 A theoretical model for the association between determinants (exposures) and personal $PM_{2.5}$ as an outcome.

Table S 2 Response of GasBadge Pro devices to 25 PPM and 100PPM calibration gas (balance nitrogen) following data collection activities.

GasBadge ID	Response to 25 PPM calibration gas (PPM)	Response to 100 PPM calibration gas (PPM)
1	31	92
2	31	92
3	31	94
10	28	89
13	31	97
14	27	93
15	32	95
23	29	91
24	30	93
25	29	91
26	32	93
29	32	96
31	31	92
32	30	92
33	30	95
34	31	93
37	29	91

Table S 3 Primary cooking area $PM_{2.5}$ model

	Beta (exp)	p-value	Lower 95% credible interval	Upper 95% credible interval
Treatment	.566	0.000	.419	.792
3-day rainfall	1.212	0.177	.917	1.603
Smoker who smokes in house	1.202	0.093	.969	1.489
Uses kerosene for lighting	1.235	0.068	.984	1.550

Table S 4 Sum of primary cooking area+ other household area $PM_{2.5}$ model

	Beta (exp)	p-value	Lower 95% credible interval	Upper 95% credible interval
Treatment	.673	0.017	.487	.943
3-day rainfall	1.333	0.058	.990	1.797
Smoker who smokes in house	1.224	0.059	.992	1.510
Uses kerosene for lighting	1.113	0.338	.894	1.386

Table S 5 Cook $PM_{2.5}$ model (80% pump runtime)

	Beta (exp)	p-value	Lower 95% credible interval	Upper 95% credible interval
Treatment	.778	0.056	.597	1.002
3-day rainfall	1.071	0.538	.861	1.335
Smoker who smokes in house	1.373	0.003	1.110	1.696
Uses kerosene for lighting	1.081	0.470	.876	1.334
Age (years)	1.007	0.069	.999	1.014

Table S 6 Cook $PM_{2.5}$ model (90% pump runtime)

	Beta (exp)	p-value	Lower 95% credible interval	Upper 95% credible interval
Treatment	.783	0.058	.603	1.004
3-day rainfall	1.066	0.569	.856	1.329
Smoker who smokes in house	1.382	0.003	1.118	1.708
Uses kerosene for lighting	1.068	0.543	.863	1.323
Age (years)	1.007	0.070	.999	1.014

Table S 7 Cook CO model (PPM)

	Beta (exp)	p-value	Lower 95% credible interval	Upper 95% credible interval
Treatment	.646	0.137	.3589	1.147
3-day rainfall	1.909	0.025	1.082	3.367
Smoker who smokes in house	1.533	0.090	.934	2.513
Uses kerosene for lighting	.809	0.436	.476	1.380
Age (years)	.999	0.861	.982	1.015

Table S 8 Child $PM_{2.5}$ model (80% pump runtime)

	Beta (exp)	p-value	Lower 95% credible interval	Upper 95% credible interval
Treatment	.805	0.273	.541	1.188
3-day rainfall	1.261	0.115	.945	1.684
Smoker who smokes in house	1.111	0.378	.879	1.405
Uses kerosene for lighting	1.009	0.943	.780	1.310
Sex	.986	0.899	.798	1.217
Age (months)	1.001	0.879	.990	1.012

Table S 9 Child $PM_{2.5}$ model (90% pump runtime)

	Beta (exp)	p-value	Lower 95% credible interval	Upper 95% credible interval
Treatment	.827	0.354	.550	1.240
3-day rainfall	1.171	0.305	.866	1.584
Smoker who smokes in house	1.123	0.334	.887	1.421
Uses kerosene for lighting	.935	0.608	.722	1.212
Sex	.953	0.658	.769	1.178
Age (months)	1.005	0.385	.994	1.016

Table S 10 Child CO model (PPM)

	Beta (exp)	p-value	Lower 95% credible interval	Upper 95% credible interval
Treatment	.652	0.133	.371	1.143
3-day rainfall	1.346	0.239	.821	2.215
Smoker who smokes in house	1.438	0.124	.903	2.284
Uses kerosene for lighting	.794	0.369	.481	1.313
Sex	1.060	0.788	.693	1.618
Age (months)	.991	0.273	.975	1.007

Chapter 6. Reflections and Recommendations

Unsafe drinking water and air pollution contribute substantially to the burden of disease, especially among young children in low-income settings. This burden is particularly high among rural populations in Sub-Saharan Africa where safe drinking water is often lacking and where households rely on biomass for cooking. These health risks are exacerbated by poverty, with the poorest populations facing the heaviest disease burden and the most barriers to effective interventions.

The objective of the research described in this thesis was to characterize the health risk presented by drinking water and household air pollution (HAP) in rural Rwanda and to evaluate the potential contribution of a scalable intervention aimed at both of these health risks. 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. A recent evaluation of a large-scale household-based water filter distribution programme in Western Kenya showed little use over the medium term and health impacts were not reported (Pickering et al., 2015).

We sought to assess the medium-term use and impact on exposure and health of the intervention. We also sought to assess these medium-term endpoints for an improved biomass stove, an intervention whose health impacts have also been questioned as a result of recent World Health Organization (WHO) guidelines on household air pollution (WHO, 2014). While

interventions are available, they are often out of reach for the poorest, and long-term adoption and impact is understudied. Evaluations of non-randomized pre-existing interventions are not as rigorous as randomized controlled trials, but still have the strong potential for causal inference (Arnold et al., 2010). Quasi-experimental methods such as matching are helpful for assessing effectiveness of pre-existing interventions as actually delivered.

6.1 Summary of the main findings

Chapter 3 presents a paper summarizing research designed to examine baseline household drinking water quality conditions nationally for Rwanda. The cross-sectional study design allowed for an opportunity to derive a national estimate of household drinking water quality, in addition to sub-national patterns. Since the study sample was nationally representative with a modest sample size, the design additionally afforded the opportunity to examine potential household community-level determinants of drinking water quality. The availability of a robust national sampling frame containing household names was unusual for a national-level study, and increases the ability to generalise the results for Rwanda.

The paper included in Chapter 4 presents research on the coverage, use, and health impact of a water filter among households within the poorest tertile with children under 5 years of age. This population was chosen a priori because the programme implementer planned a large-scale distribution of the intervention to the poorest tertile within Western Province (Barstow et al., 2016), and we were most interested in the impact on children under 5 years given the higher burden of disease in this age group. The main outcome was household drinking water quality. We found high coverage and sustained use according to self-report, observation, and sensors affixed to filters, although non-exclusive use was evident among children and respondents. This

non-exclusive use, particularly away from the household, may have diminished the potential health gains. Nevertheless, we observed statistically significant reductions in child diarrhoea in the intervention arm.

Chapter 5 presents research on the coverage, use, and health impact of the intervention stove within the same households described in Chapter 4. Similar to the filter assessment, we found high coverage and sustained use, as well as reduced concentrations of particulate matter <2.5 µm in aerodynamic diameter ($PM_{2.5}$) in cooking areas. This study adds to the literature suggesting reductions in household cooking area concentrations do not reduce personal exposures by the same levels. Though reductions in personal exposures to $PM_{2.5}$ were observed in cooks and children within the intervention arm, these were not statistically significant in adjusted analyses, and reported and observed regular usage did not translate to the low personal exposures needed to achieve reductions in acute lower respiratory infection (ALRI). Child exposure levels remained similar between arms, and child exposures were similar to cooks, unlike results from other improved cookstove interventions. This may indicate presence of other exposures to particulate matter and carbon monoxide (CO) such as second-hand smoke, cooking smoke from neighbours, and higher than expected ambient levels. The intervention stove, which was promoted to be used outdoors, may have also adversely increased child exposures by introducing cooking smoke into areas where children spend more time.

6.2 Reflections on what could have been done to improve the research presented

This research has certain shortcomings. Some of these limitations have been described in the previous chapters, but will be addressed fully in this section.

6.2.1 Cross-sectional study (Chapter 3)

A larger sample size for the cross-sectional study would have allowed for a more comprehensive analysis of determinants and consequences of drinking water quality contamination, although this was not the main aim of the study. For example, evidence suggests our study was underpowered to adequately assess the relationship between child diarrhoea and faecal contamination given a recent study that only found an effect after combining observations from 26,518 individuals and 8,000 water samples from multiple studies (Hodge et al., 2016). Although growing evidence for a relationship exists, it is likely context-specific and varies depending on underlying determinants related to hygiene, sanitation, nutrition status, communicable disease patterns, and other factors. It would have been helpful to examine the relationship and possible threshold effects within our setting, particularly within the context of household drinking water treatment. Recent studies also suggest it is more important to look at water quality prior to rather than after episodes of child diarrhoea since water quality varies over short periods of time and there is a need to account for the incubation period of the enteric pathogens (Ercumen et al., 2016; Levy et al., 2008; Luby et al., 2015). Testing water quality and then returning to ask about health symptoms would have also been advisable for the matched cohort study (Chapters 4 and 5). However this approach requires two household visits, doubling the cost and potentially aggravating reactivity on self-reported health conditions (Zwane et al., 2011).

Water quality is affected by many factors that are time- and individual -dependent. While I attempted to look at a broad range of community and household-level determinants of water quality, I relied on pre-existing data from the Rwanda Population and Housing Census and publicly available precipitation data. Village-level census data or neighbouring household data would have been much better to include than sector-level, which encompass approximately 35 villages. However, these data were not available to us. This is particularly true with regard to

population density, waste disposal practices and community sanitation levels, which would have benefited from finer geographic resolution than sector-level. A recent study suggests community sanitation coverage may have a greater impact on child diarrhoea and malnutrition than household sanitation practices (Hunter and Prüss-Ustün, 2016). The relative community size and contribution of community-level factors upon diarrhoea and water quality remain understudied and likely varies across different settings.

Given the complexity and time-varying determinants of drinking water quality (Levy et al., 2008), one thing that would have improved the national drinking water quality assessment would have been to take repeated samples at the same house at different times of day, and over the course of multiple days. The issue of time-varying water quality and generalizability has been described previously, and is a known limitation of the planned inclusion of water quality testing into national cross-sectional studies conducted by the WHO Joint Monitoring Programme (JMP) and others (Rosa et al., 2016; WHO/UNICEF, 2015). It would also have also been helpful to examine spatial distribution of risk factors and patterns of contamination within a village in terms of households, sources, and environmental drivers such as groundwater susceptibility, geology, topography, and livestock areas.

The climatic drivers of household drinking water quality are likely quite complex, with interacting influences of short and long-term precipitation trends. Extreme precipitation events may be mediated by preceding precipitation patterns, but our sample size did not allow for extensive analysis of such interactions. One of the challenges is to adequately account for the influence of seasonality. Binary indicators of season, such as rainy vs. dry, may be too broad for some health and exposure studies, especially for non-randomized studies since they are more susceptible to

imbalance between clusters and treatment groups. In addition to impacts on health and exposures, climatic influences can impact follow-up of participants and field work activities. Annual and seasonal variations, extreme weather events, and climate change all contribute to the inadequacy of relying on historical trends to account for these influences on outcomes of interest.

To account for climatic influences, local temperature and precipitation may be better proxies of influence of seasonality and climate on outcomes of interest. However, high quality reliable weather station data is frequently lacking in low/middle-income settings and in rural areas. Studies often lack the resources to set up their own weather stations, although this may become more common as climate increases in variability.

Various global and regional precipitation datasets exist that are derived from various combinations of satellite and ground station data. Reliance on satellite data, particularly for extreme rain events that can be highly localized in this part of Africa, is not ideal. The CHIRPS data and similar datasets could be utilized by other studies concerned with climatic influences, and can be used as a more robust indicator of seasonality and precipitation than relying on crude binary predictors based on historical patterns, which can also have a lot of variability.

It would also have been helpful to have village-level rain gauge (Figure 1) data in the days leading up to household water sampling rather than relying on satellite-derived Climate Hazards Group InfraRed Precipitation with Station (CHIRPS) data (Funk et al., 2015). The time and geographical resolution of CHIRPS is finer than other currently available sources, but

contributing stations are limited in sub-Saharan Africa and data quality is lower than other settings where more weather stations are available to inform the estimates.

Figure 1 HOBO rain gauge used during household air pollution monitoring days.

While we looked at water quality at sources in the water filter evaluation (Chapter 4), this was not done in the national sampling activity due to time constraints. It would also have been helpful to conduct water quality sampling at water sources, particularly in the days prior to household water sampling as water is typically stored for 1-2 days. Source water quality contributes to household water quality, likely varies over time, and may also be subject to climatic events. Perhaps water treatment is most necessary and effective during and after certain precipitation events.

6.2.2 Matched cohort study (Chapter 4 and Chapter 5)

Matching

Village-level matching was done using a combination of restriction, propensity score matching, and rapid assessment (Arnold et al., 2009, 2010). This approach approximates a cluster-randomized design and is consistent with the village-level distribution of the intervention and is necessary due to logistical constraints and data availability. The objective of this matching approach is to minimize potential bias due to systematic differences between intervention and

control villages, which will give optimal covariate balance and overlap between groups than would be accomplished by random selection of control villages (Rubin, 2007; Rubin and Thomas, 1996).

The key to the study design is the quality of the matched control group. Using a combination of restriction, propensity score matching, and rapid assessment, intervention villages were matched to comparison villages on key covariates most likely associated with the outcomes of interest (household air pollution and drinking water quality). Matching improves balance between intervention and control groups on measured confounders at baseline, but the presence of unmeasured confounding is still possible. We additionally matched on shared health centre in order to improve balance on unmeasured confounders that could be related to geographic location. Despite continued susceptibility to unmeasured confounding, the matched cohort design is a cost-effective approach to estimating intervention effects in populations exposed to non-randomized programmes; it attempts to account for the relationship between treatment and covariates, and is more statistically efficient for estimating difference parameters than post hoc adjustment (Arnold et al 2010).

In this study we were limited by the quality of data available for matching. Ideally there would have been household-level data relevant as potential confounders that would have been collected as close as possible prior to the delivery of the intervention being evaluated. When these data are not available, community or regional-level data may be used instead, although the risk of misclassification and unmeasured confounding could increase under these conditions. With additional resources, a representative household survey could have been conducted in all potential control villages, as well as verification of water source types and sanitary inspections of

sources. Additional village characteristics derived from remote sensing data and other pre-existing sources could have been included in matching. These could have included topology, proximity to different types of roadways, altitude, geology, slope, latrine density, proximity and density of livestock, and population density.

We tried to mitigate the risks of unmeasured confounding by constructing a village-level dataset that could be used for matching. However, this dataset had better geographic resolution among intervention households than control households since it included household-level baseline data from intervention households as collected by the implementer.

The ability of community health workers (CHWs) to accurately estimate village-level household drinking water and cooking practices is not completely clear. It is possible that intervention village CHWs were more accurate in their village-level assessments given their programmatic involvement and frequent household visits. Since there are 3 CHWs per village, a better design for studies of this nature would have been to derive a composite village estimate for variables used in matching based on responses from more than one individual. Responses could have included opinions of the village chief or local administrative leader. However, due to resource constraints, this approach was not possible.

Household survey data and potential for bias

Both papers relied heavily on self-reported outcomes. The risk of bias is high when participants and researchers are unblinded to the intervention. The inclusion of care-seeking behaviour could help reduce courtesy bias since it is a more objective and memorable outcome than recall of

specific combinations of symptoms, duration, number of loose stools, etc. The visit to a CHW or health facility may indicate more severe illness, and the visit itself can incur a time and financial burden. While reporting bias is still possible since it is still a self-reported outcome, asking about care-seeking behaviour offers an additional health indicator that should be considered for environmental health evaluations.

Reliability of this outcome could be assessed by verifying CHW and health facility-based records. Frequency of visits by the same individual would also be important to assess recurrent and persistent illness and variations of severity. Objectively capturing care-seeking visits throughout the year, as opposed to relying on self-reported outcomes with long recall periods, is recommended if resources permit. An additional analysis of the paper-based clinic patient registers could verify visits at health facilities based on village of residence and even name of patient. A primary outcome of the large-scale cluster randomized trial is CHW- and health facility-diagnosed severe acute respiratory illness and diarrhoea. Verifying CHW and health facility care for these outcomes will be a main research focus of mine moving forward (Nagel et al., 2016; Weston et al., 2016).

There remains the possibility for systematic bias with regard to care-seeking behaviour. It is possible that CHWs in intervention villages were less available to offer care and make health facility referrals, given their involvement with the intervention program and additional responsibilities. On the other hand, it is possible the frequent programmatic visits made by CHWs to households could have resulted in more opportunities for child health consultations and referrals to health facilities, as well as re-enforcement of health and behaviour change

messaging. This limitation will be present in other studies concerned with care-seeking behaviour related to interventions that involve CHWs in implementation.

Problematic outcome – acute respiratory infection (ARI)

As the primary aim of this research was to measure the sustained use and exposure impacts of the intervention, health outcomes were not a primary focus and were collected mainly as a pilot for the larger Phase 2 trial. We elected to assess specific symptoms of ARI rather than relying on uncertain case definitions. While this increased sensitivity and provided a useful comparison between study arms, it limits ability to compare to other studies and inferences that can be made. We also collected data on reported health seeking behaviours, an outcome that may reduce risk of reporting bias and while providing more policy-relevant data to government authorities. A more comprehensive approach to understanding determinants and barriers of health care-seeking behaviour is recommended, such as inquiring about visits to traditional healers, costs, and purchase or use of medication.

Focus on children's health

Both chapter 4 and chapter 5 focused on health of children under 5 given the higher burden and mortality rate associated with diarrhoea and respiratory infection among this age group. We did not ask about self-reported health symptoms and care-seeking behaviour among other age groups. Diarrhoea, respiratory symptoms, eye discomfort, and headaches among others involved in cooking or who spend time at the house during cooking are outcomes worth exploring.

More objective measurements

The evaluation of the improved stove would have benefited from more objective health outcome measures and additional indicators of exposure such as biomarkers of inflammation, carboxyhemoglobin and expirated CO.

I advocated for the usage of this equipment for a trial I helped launch in fall of 2014. These may provide additional indicators of exposure, although there is still uncertainty about their relationship to health outcomes. Another step would have been to assess child health outcomes according to Integrated Management of Childhood Illness (IMCI) protocol. While quality control is challenging for this protocol, new technologies are being developed to improve the sensitivity and specificity of field-based assessments by non-health professionals. For example, a new mobile device app has been developed based on IMCI protocol that includes breath counting and pulse oximetry (Ginsburg et al., 2016).

Quality control issues

Identification code conflicts and data discrepancies across multiple data types made post data processing very challenging and time consuming. A barcode system would have likely reduced some of these problems. Barcodes could have been placed on household air pollution (HAP) pumps, Harvard Personal Environmental Monitor (HPEMs), air filter Petri dishes, and water sampling bags. Barcodes could have also been installed at households. There were barcodes on stoves and filters, and these were useful for the sensor monitoring given sensored stove and water filter switch-outs. However, many of the most time-consuming issues could not have been fixed by using barcodes, and related more to organizing, cleaning, and clipping real-time CO and $PM_{2.5}$ data to the correct 48-hour periods. It would be helpful to automate some of these

processes, although to ensure data quality, manually reviewing graphical presentations of the real-time data was helpful for identifying problematic records such as drift and battery problems. File name notation errors further complicated the data processing process; it is recommended the field supervisor matches each digital exposure record to each household and individual in a more timely fashion. Taking pictures of equipment IDs during household surveys could also minimize data loss.

It would also have been preferable to get data off of devices more frequently. Some data were lost due to phones or devices being stolen, damaged, or lost. More frequent backup onto secure servers would have also been helpful to prevent data loss. Problematic devices and some abnormal patterns were not discovered until midway or after the study. For example, the Gasbadge Pro (Figure 2) experienced CO baseline drift (Figure 3). The University of California, Berkeley Particle and Temperature Sensor (UCB-PATS) (Figure 4) sometimes experienced download errors, battery failures (Figure 5). Identifying these issues sooner could have mitigated the amount of missing data by training specific staff members or removing problematic devices from rotation. Additionally, GasBadges could have been tested and calibrated more frequently throughout the study period using calibration span gas.

Figure 2 GasBadge Pro for measuring carbon monoxide (CO).

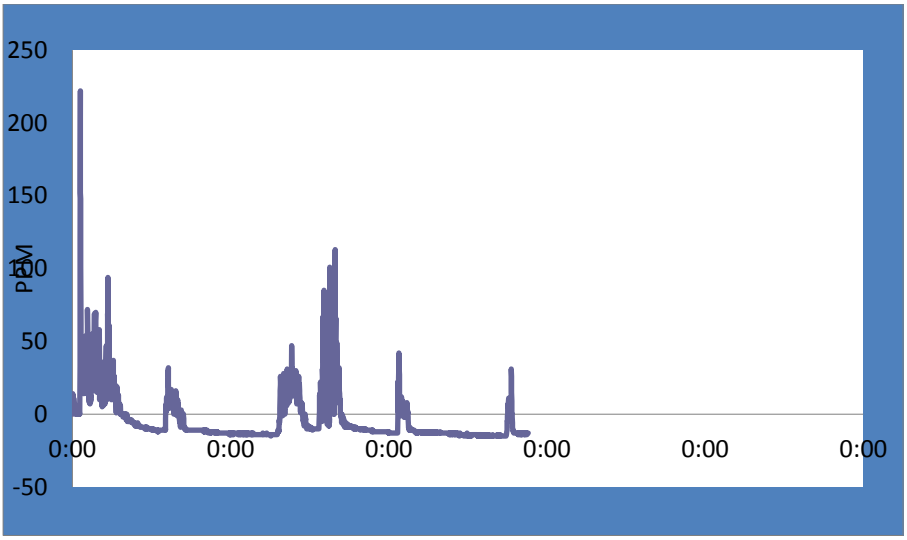

Figure 3 Example of drifting baseline, GasBadge Pro CO record.

Figure 4 Indoor and outdoor UCB-PATS placement during household air pollution monitoring.

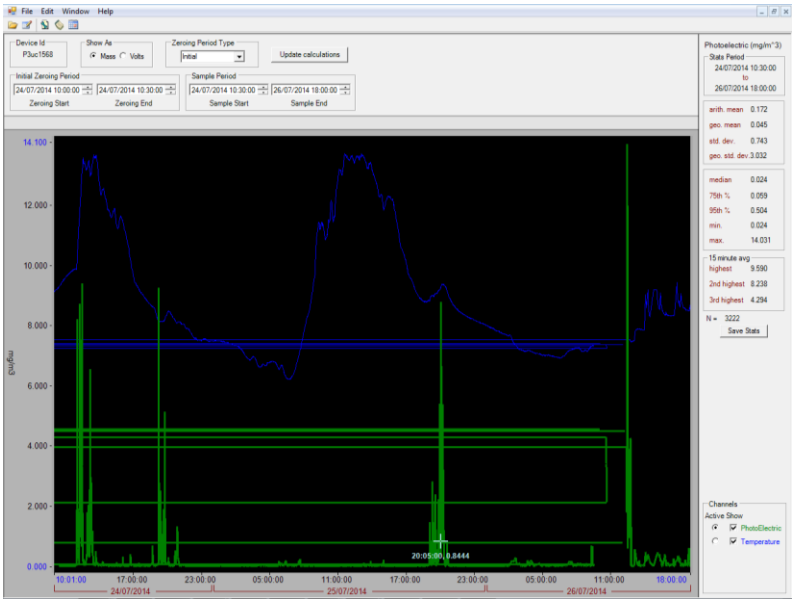

Figure 5 Abnormal UCB-PATS PM2.5 record indicative of battery failure.

Repeated measures

Overall, there were substantially fewer eligible households than anticipated. Accurate lists of *ubudehe* 1&2 households with a child under 5 were not available during the planning stages of the study and sample size calculations were based on rough estimates of village demographics. There was high variability in exposures among households. More frequent repeated measures within the same individuals over time would have been helpful, although this could have led to fatigue among respondents and would have added substantial costs.

Other sources of exposure

Exposure to second hand smoke and kerosene lamps contributed to cooking area concentrations and personal exposures. The degree to which second hand smoke contributed within this setting was unexpected. In retrospect, it would have been helpful to collect more detailed information on specific tobacco smoking events during the monitoring period, including quantity

smoked and location. Similarly, we could have characterized kerosene lamp usage during the monitoring period in more detail.

Assessments of ambient air quality during the monitoring period with more sensitive equipment would have also been helpful. The limit of detection for the UCB-PATS, many of which were placed outside, is only 30-50 µg/m^3; it is expected that ambient levels during non-cooking episodes are lower than this, although this is not well understood in this setting. Contribution to HAP by neighbouring households and non-cooking sources could also be assessed, and would be helpful for understanding how low exposures could be attained with cleaner fuel such as liquefied petroleum gas LPG). Additionally, the influence and frequency of air inversion events and resuspended dust should be investigated and quantified, although source apportionment was beyond the scope of this study.

Reactivity of participants

There could have been reactivity during air quality monitoring (Arnold et al., 2015; Zwane et al., 2011) For example, we observed some households dismantling their three stone fire as we arrived to the household. Drinking water and cooking practices could have been altered during sensor monitoring and HAP monitoring activities. A recent study noted increased improved stove usage during HAP monitoring (Lozier et al., 2016), and it is likely this occurred in our study. HAP monitoring could have resulted in the altering of other behaviour due to added inconvenience or participant fear of damaging equipment, resulting in more time spent at the house, children's ability to play as normal, less time working in fields, etc. To minimize the influence of this reactivity, we recommend placing stove use sensors and static air quality

monitors in households for longer periods of time. Battery life has traditionally been a limiting factor, but is improving with the development of new devices.

Measuring compliance of wearing exposure monitoring equipment remains challenging. The spot-check observation on the second day of monitoring was helpful for switching out batteries and encouraging compliance among cooks and children. The light-sensor (Figure 6) provided a potentially useful indicator of compliance.

Figure 6 HOBO Pendant Temperature and Light Data Logger. (source: http://www.onsetcomp.com/products/data-loggers/ua-002-08)

In reviewing light-sensor records based on records indicating <20% outdoor time, it appeared some cases of non-compliance would have been missed by relying on observation alone. Some people appeared to put the equipment on only for the survey visit (Figure 7). However, it is not possible to adequately assess whether the device was being worn inside. Thus, some compliant cook and child measurements could have been unnecessarily dropped from analysis. Similarly, it is possible compliance is over-estimated; the light-sensors could not detect ambient light after dark, which is when evening cooking episodes often occur (Figure 8). In addition, weather, shade, local object interference, and inconsistent directionality of the sensor itself, could have affected the light sensor readings. Thus, more validation of the utility of these devices is

needed, although alternative location sensors, such as blue-tooth-based sensors worn on participants and affixed to equipment, would be helpful.

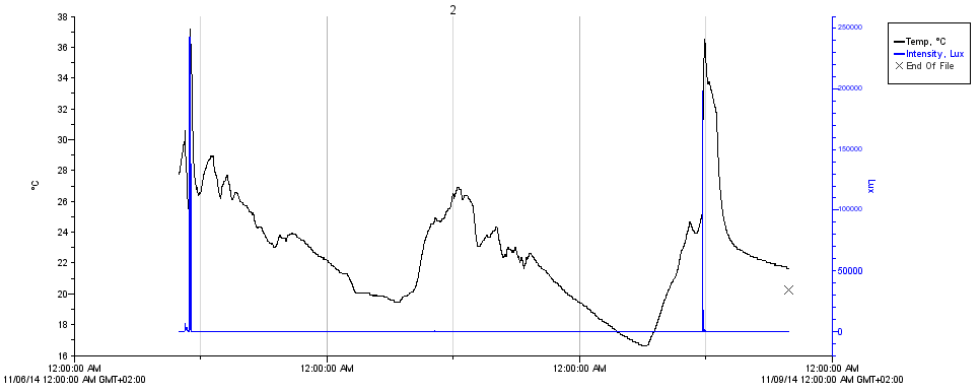

Figure 7 Example of non-compliant exposure record according to light sensor values, with two spikes in lux (light) values indicating survey visits.

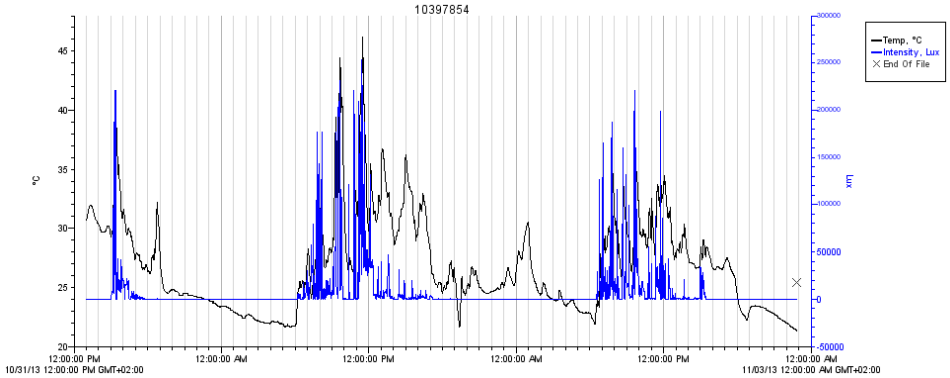

Figure 8 Example of compliant exposure record during daylight hours according to light sensor values, with frequent spikes in lux (light) values.

6.3 Reflections on the intervention programme and similar programmes

Programmatic involvement within the 9 intervention villages was observed 13-24 months after intervention receipt, and regular household surveys and engagement from local community health workers allowed the implementers to respond to breakage or maintenance issues, and reiterate behaviour change messaging (Barstow et al., 2014). The hardware component of the water filter intervention was robust throughout the 13-24 months of observation although

weakened by poor maintenance or attacks by mice. Improvements to filter design have since been developed and deployed (Barstow et al., 2016), and these replacements highlight a strength of the pay for performance model characteristic of carbon financed programs: there is programmatic incentive to keep the intervention in working order (Hodge and Clasen, 2014; Thomas, 2012). The public-private partnership and integration within the Ministry of Health (MOH) system likely encouraged higher adoption and sustained use than would have been achieved through private enterprise alone. The ability of the program to maintain this level of engagement and foster sustained use and impact health at a much larger regional level is the subject of continued research (Nagel et al., 2016).

The water filter demonstrably improved household water quality and appeared in use in most households, yet reported use was non-exclusive. Use of unfiltered water within and outside of the household were identified as challenges, and the intervention only addressed one source of faecal exposure and within one setting – the household. This challenge is not unique to the DelAgua/MOH intervention programme, and is common within household water treatment programmes (Clasen et al., 2015).

Similarly, the cookstove appeared to be in use in most households and reduced household air pollution, yet use was non-exclusive. The observed personal $PM_{2.5}$ exposures among cooks and children within the intervention arm suggest that the cookstove component, as implemented, is likely insufficient to result in substantial respiratory health gains (Bruce et al., 2015; Gordon et al., 2014). Child pneumonia, in particular, is unlikely to be affected by the biomass cookstove given observed exposure levels and existing knowledge about exposure-response curves (Burnett et al., 2014; Ezzati and Kammen, 2001; Ruiz-Mercado et al., 2011). Nevertheless, a

slight reduction in exposure, as was observed for the cook, may translate to small health gains on a population level for very young children as they are often in close proximity to the mother (Johnson and Chiang, 2015a).

The Global Alliance for Cookstoves (http://cleancookstoves.org/), in its effort to promote the distribution and adoption of clean cookstoves and fuels by 100 million households by 2020, has a high visibility within the development sector. Supported by the United Nations Foundation, a key claim by the Alliance and found on its website are the possible health benefits that can be obtained through adoption of clean cookstoves and fuels (Global Alliance for Clean Cookstoves, 2016). Many cookstove NGOs make more overt claims about the health benefits that can be obtained through the use of efficient cookstoves that continue to use biomass, such as reduced child pneumonia. However, while evidence is growing that transitioning exclusively to cleaner fuels like LPG or ethanol can result in health gains such as reduced blood pressure (Alexander et al., 2017), most cookstove programs have so far failed to measurably deliver on the claim of saving lives and reducing illness. Stoves that continue to burn biomass are particularly implicated, even if they are fan assisted and have very low laboratory-measured emissions. The vast majority of real-world cookstove delivery programmes as well as intensive health impact studies have not demonstrated long-term sustainability nor health impacts, and the stoves deployed fail to achieve exposure reductions necessary for measurable health improvements (Hanna et al., 2016; Manibog, 1984; Mortimer et al., 2016; Smith et al., 2011; Tielsch et al., 2016).

Even with exclusive use of an improved cookstove or clean fuel by a particular household, the multiplicity of additional sources of exposure, including local and regional sources, often means

the levels needed to achieve health benefits are not reached (Huang et al., 2015; Piedrahita et al., 2017; Zhou et al., 2014). Just as an "improved" water source does not imply safe water (nor safe water within the household), so too should the term "improved stove" be viewed with caution given the unsafe exposures that persist with such stoves (Clark et al., 2013b). Wide scale dissemination of certain stove types, with the intent for health gains, is premature, and cookstove programs should refrain from proclaiming the health benefits as a main reason for the programme given the lack of objective evidence. A greater emphasis on striving towards clean air rather than simple distribution of clean cookstoves is needed. Many cookstove programmes are likely well-positioned to shift from simply focusing on the delivery of inadequate technologies towards working to address other sources of exposure such as heating, lighting and tobacco use (Carter et al., 2016; Lam et al., 2012), and mitigating local and regional contributors to air pollution. Solutions aimed at reducing exposure within rural and urban settings will likely entail systemic and structural changes to ensure sustainability in addition to technological and behavioural innovations (Amegah and Agyei-Mensah, 2016). These may include regulation, penalties, incentives, and subsidies.

Despite the limitations of household water filter and cookstove intervention programmes, the following recommendations are made to optimize the current and similar programmes:

6.3.1 Water filter recommendations

- Emphasize importance of proper filter usage and maintenance throughout the programme, not just at the beginning. This includes backwashing the filter after use, keeping filtered water in the safe storage container rather than other containers, using clean drinking cups, and consuming filtered water stored in safe water bottles while away from the household.

- Water bottles equipped with water filters, which are commercially available in higher income countries, may be a helpful addition to the tabletop filter, as a bottle is closer to point of consumption and can accompany individuals during activities away from the household.
- To minimize consumption of untreated water, untreated water should be stored out of reach of children.
- Revisit whether filtered water should also be used for handwashing, food preparation, dish cleaning, etc. These activities could result in exposure to faecal matter and more liberal use of filtered water could mitigate these pathways of exposure.
- Emphasize the importance of filtering during and after extreme precipitation events.
- Identify and address other sources of faecal exposure within the household and provide recommendations and assistance to mitigate risk.
- Install Lifestraw community filters at schools so that school-aged children can have access to safe water away from the household. Installing community filters at health facilities and other community gathering areas is also recommended.

6.3.2 Cookstove recommendations

- Emphasize importance of proper filter usage and maintenance throughout the programme, not just at the beginning. This includes using the pot-skirt and stick support, removing ash after use, and using wood that is dry. The implementer could provide instructions and training on ways to dry out and store fuel.
- Encourage all stove use to be located outside, outside, away from doors, windows, children, and other people if possible; identify barriers to outdoor cooking, alleviate safety concerns, and help build protective roofing structures to protect from rainfall, etc. If indoor stove use is essential, assist households in increasing ventilation.

- Acknowledge that some traditional stove use will likely continue, and that any stove use, regardless of whether cooking or for other tasks, should also be done outside away from children and other people.
- Encourage participants to avoid other households while they are cooking. Stress the importance of reducing their own personal exposure in all areas of life, not just at their households.
- Identify and address other sources of smoke exposure within the household and seek to provide replacements if necessary (e.g. solar lamps to replace kerosene lamps). Additionally, provide behavior change programming to reduce the amount of indoor tobacco smoking by all household members, and minimize this exposure to children and pregnant mothers.
- Utilize existing programmatic infrastructure and partnerships to foster transition and adoption of cleaner fuels like LPG, biogas, and ethanol. Programmes should strive to assist households in moving up the energy ladder and not stop with the provision of a single biomass-burning rocket stove.

6.3.3 Overall programme recommendations

- Use sensor monitoring, or sham sensors, as a tool to improve consistent and exclusive use.
- Consider targeting intervention and reinforcement to vulnerable populations, e.g., pregnant mothers, those with chronic illness, houses with young children, children with malnutrition, etc.
- Develop and explore various low-cost, low-effort programmatic “nudges”, potentially through slight modifications to household design, hardware design, repair, promoter materials, competitions, etc. that could positively influence behavior change and appropriate adoption.

- At least every 6 months, schedule focus groups and key-informant interviews in communities with recipients to get feedback on barriers to use, improvements that could be made, etc. Seasonal variability and influence on usage should be factored in to these discussions.
- Develop incentives for exclusive use of both the filter and cookstove. Incentives for improvements in water quality and air quality in cooking areas, perhaps even personal exposure, should be explored.
- Use sensor monitoring, or sham sensors, as a tool to improve consistent and exclusive use.
- Consider targeting intervention and reinforcement to vulnerable populations, e.g., pregnant mothers, those with chronic illness, houses with young children, children with malnutrition, etc.
- Develop and explore various low-cost, low-effort programmatic “nudges”, potentially through slight modifications to household design, hardware design, repair, promoter materials, competitions, etc. that could positively influence behavior change and appropriate adoption.
- At least every 6 months, schedule focus groups and key-informant interviews in communities with recipients to get feedback on barriers to use, improvements that could be made, etc. Seasonal variability and influence on usage should be factored in to these discussions.
- Develop incentives for exclusive use of both the filter and cookstove. Incentives for improvements in water quality and air quality in cooking areas, perhaps even personal exposure, should be explored.

6.4 Comparative challenges of combined intervention study

Nature of the intervention

The nature of the combined Lifestraw water filter and Ecozoom cookstove intervention is a household-based solution to two substantial environmental health concerns. The intervention to improve water and air quality is directed at minimizing the risk of two household-based sources of exposure – household stored drinking water quality, and smoke from stoves predominantly used for cooking. To a certain extent, the particular context of the intervention under evaluation was also community-based in that all households within an "intervention village" received the intervention (Barstow et al., 2014). However, often this is not the case in other household water treatment or cookstove delivery programmes which target certain sub-populations or include some degree of voluntary participation. It remains uncertain to what degree household-based interventions can impact unsafe water and air quality at a community level. For both faecal contamination and household air quality, household levels of contamination can influence community/ambient levels of contamination, and vice versa (Bain et al., 2014; Carter et al., 2016; Chafe et al., 2014; Wright et al., 2004).

Fundamentally the water filter is designed to reduce exposure to faecal contamination, but its impact on other sources of faecal contamination, as highlighted in the F-diagram (fluids, fingers, flies, fields/floors, food), is likely limited (Kawata, 1978). By locating the intervention at the household level, the intention of this component of the intervention is to make water safe at the closest point to water consumption within a household, both physically and temporally.

Similarly, the stove is designed to reduce exposure to high levels of toxic substances created during the combustion process while cooking (in addition to other purported co-benefits such as reduced fuel consumption and shorter cooking time). Cooking may be understood as the main source of exposure to air pollution, although relative contributions to personal exposure from

other sources in different settings is understudied (Huang et al., 2015; Secrest et al., 2016; Zhou et al., 2014). The stove component of the intervention does not address other sources of exposure experienced within a household (e.g. lighting, heating, intrusion of smoke from neighbours ,tobacco smoke, etc.), nor outside of the home (e.g. road traffic, industry, rubbish burning, and other contributors to ambient air pollution).

Exposure assessment at individual and household levels

In this study, exposure to faecal contamination from water quality was assessed by quantifying thermotolerant coliforms (TTC) within a 100mL sample of stored household drinking water at one point in time, at the conclusion of a health survey. If a household did not have any drinking water available at the house at the time of visit, exposure assessment was not possible. Measurement at a single point in time and from a single sample may not reflect average water quality of a container, nor what is actually consumed within the household much less outside of the household (Levy et al., 2008; Luby et al., 2015). Personal measures of exposure to faecal contamination, let alone water quality, are lacking, and perhaps can only be addressed through repeated or continuous sampling of water at sources, within storage containers, and actual consumption devices. Sampling of other sources of faecal exposure, such as food, soil, flies, etc. could also more robustly characterize the extent of faecal contamination an individual is exposed to (Boehm et al., 2016; Pickering et al., 2012; Schriewer et al., 2015; Wolfe et al., 2016).

In contrast, air quality was measured at both an individual and household-level regardless of what was available at the house, making the exposure measure less susceptible to selection bias than water quality. Also in contrast with water quality, measurement of $PM_{2.5}$ and CO, the two indicators of air pollution, was conducted over a 48-hour period, increasing the chance that the measure is more representative of experienced conditions during that time period and during

periods not measured. However, even a 48-hr measure likely fails to adequately characterize normal, much less long-term exposures due to the variability of determinants of air quality, such as climatic conditions and personal behaviours (Dionisio et al., 2012). Measurement is difficult and time-consuming, and worn equipment can be particularly susceptible to breakage, manipulation, and non-compliance (Clark et al., 2013b). Efforts are underway by exposure scientists to measure household-level air pollution over extended time periods, and the advent of low-cost monitors that can be placed throughout a household may improve abilities to characterize micro-environmental exposures (Patel et al., 2017). The development of personal exposure monitors that can be worn for long periods of time and deliver is further off, yet very much needed.

Similar to TTC, PM2.5 and CO are proxy indicators of health relevance, but they may not be the most health-relevant indicators (Secrest et al., 2016). Both water quality and air quality measurement frequently rely on indicator measurements. It is likely particular toxic components of particulate matter, for example, pose a greater risk to health than others, or may have differential impacts on acute vs. chronic health conditions. This challenge is faced in the WASH sector as well – the costs and technical difficulties associated with finer pathogen differentiation make it a rarity in intervention evaluations, thus obscuring potentially important mechanistic relationships and health impacts that could be elucidated. Furthermore, the relative importance of real-time levels vs. cumulative amounts is unknown for both water quality and air quality. The concept of environmental enteropathy (Prendergast and Kelly, 2016)may extend to exposure to air pollution—there is likely a burden from persistent inflammation and oxidative stress that could become systemic . While source apportionment may help illuminate relative contributions of exposure sources and culpable components, attribution to specific behaviours or cookstove types remains a challenge.

Monitoring of sustained exclusive use

Monitoring of sustained exclusive use is another challenge facing both household water treatment and cookstove interventions. Sensors on water treatment devices is a relatively novel application (Thomas et al., 2016, 2013), and is more common in the cookstove sector (Lozier et al., 2016; Mortimer et al., 2016; Pillarisetti et al., 2014; Ruiz-Mercado et al., 2008; Wilson et al., 2016). The limitation of these sensors is often translating usage into meaningful metrics that would indicate sufficient or exclusive use, and data must be interpreted with caution. In this study, beyond limited observation and self-report, objective usage of unsafe water storage containers and consumption by different individuals is unknown, as is the usage of traditional stoves. Duration of monitoring was also limited by battery life and breakage, although sensor durability and longevity is improving. Currently usage is essentially measured at a household level, and thus faces the same weaknesses of using household-level measures to infer personal exposures. To this end, location beacons used in tandem with usage sensors may help clarify the degree of exclusive use. The use of stationary and wearable cameras may also help clarify the extent of exclusive use (Salmon et al., 2016), although reactivity and length of observation are likely to be substantial limitations.

Health impacts for household water vs. air quality interventions

This study relied on self-reported child diarrhoea and respiratory symptoms with a one week recall, as reported by the primary caretaker. While this type of health outcome is often used as a low-cost indicator of impact and is utilized in large-scale surveys such as the DHS, it lacks objectivity and is subject to responder and observer bias (Ercumen et al., 2016; Schmidt and Cairncross, 2009). Respiratory symptoms may be especially prone to misclassification, and assessment of both diarrhoea and respiratory symptoms for infants is particularly challenging. Assessment of child health using WHO IMCI protocol is an improvement for assessing severe

respiratory infections, but only addresses current illness and thus requires larger sample sizes to detect an effect. More objective measures of child enteric and respiratory-related health outcomes exist, although they are often beyond the financial or technical capacity of evaluation efforts. For impacts related to faecal exposure and enteric infection, stool samples can be identified for specific pathogens, and blood samples can be assessed for seroconversion or biomarkers of infection. Rapid assessment techniques, such as saliva tests for biomarkers of recent illness, are in development and could improve objective assessment for diarrhoea. For respiratory illness, multiple methods exist to identify clinical indicators of current acute lower respiratory illness, with more advanced diagnostic capacity through the use of x-ray, ultrasound, lung aspiration, cultures from blood, induced sputum, etc. However, low-cost technologies suitable for use in low-income household settings, the context for many health impact studies, are lacking for enteric and respiratory infections. Moreover, the clinical significance of various objective measures of infection, and categorization according to severity, can be problematic and is a challenge for health impact assessment.

6.5 Future work and recommendations

Several next steps emerge as a result of this research.

Rainfall, source and household water quality, and child diarrhoea and respiratory illness

Chapter 3 highlighted the potential importance of extreme rainfall events and community-level risk factors, and I would like to explore these further. While other studies have begun to investigate these factors in Ecuador and India, relatively little attention has been put on these interrelated determinants in Sub-Saharan African. The study could use highly accurate real-time rain gauges as described in Chapter 5, placed at household water sources and village neighbourhoods. Periodic water quality testing and morbidity surveillance could be conducted. The analysis could be strengthened by examining clinic-confirmed cases of diarrhoea and

respiratory illness. Identification of risk factors and thresholds of effect could help in the development of mitigation strategies for extreme precipitation events. Additional techniques such as time series analysis and spatial analysis could be employed. It is possible that mechanisms involving these factors contributed to the similar prevalence rates in round 1 and substantial differences in round 2 between intervention and control arms.

Blood pressure

As a pilot within the matched cohort study HAP monitoring households, we collected data on blood pressure and potential confounders for all cooks and additional women 18 years of age and older within households if present. These data can be analysed for impacts of the intervention on blood pressure overall between arms as well as for women over 40 years of age, since studies have indicated older women's blood pressure may be more affected by HAP interventions (Baumgartner et al., 2011; Clark et al., 2013a). Exposure relationships between CO and $PM_{2.5}$ could also be investigated.

Personal exposure of other household members

I would like to conduct future exposure assessments on additional members within the household, including men who may have high occupational-related exposures in addition to cooking-related exposures within the household. Future work examining lung function and prevalence of acute and chronic respiratory conditions among adults would also be advisable (Jary et al., 2015). Repeated exposure measurements and treatment success of those with human immunodeficiency virus (HIV) and non-communicable diseases (NCDs) would also be helpful, as treatment success may be mediated by immune system stimulation and systemic inflammation due to high HAP exposures (Meghji et al., 2016).

Recovery of drift samples

Nearly 25% of real-time CO data were not usable due to drifting baseline and negative values. Adjustments to these measurements are possible, although current methods to rapidly adjust are lacking. We are exploring ways of recovering these data and comparing drift to non-drift samples in sensitivity analyses. Current CO records may underestimate overall exposure patterns among participants. Though staff were instructed to zero outside in an environment without any cooking, drift was most often due to field-zeroing the devices within the presence of CO, and may indicate CO levels were high despite absence of cooking activity. Thus, households with higher CO exposures may have disproportionately fewer usable CO measurements since their records were more likely to have experienced drift and have been dropped.

Black carbon and source apportionment

By conducting black carbon measurements, we hope to identify whether exposure to black carbon was similar between cooks and children, and attempt to infer whether sources of exposure were likely to have been similar. Recent research implicates re-suspended dust as a contributor to PM2.5 (Secrest et al., 2016), and children may have been differentially exposed to non-biomass sources given behaviour differences.

Respiratory infection and WASH

The large observed difference in ARI associated with the intervention despite the lack of an observed impact on child exposures suggests some benefit may have occurred due to the water filter. It is possible improved water quality reduced immune system stimulation in turn reducing

community-acquired ARI. HAP exposure may lead to chronic inflammation and immune system stimulation, and this may interact with intestinal pathogens, malnutrition, and environmental enteropathy (Ngure et al., 2014; Prendergast and Kelly, 2016). A future trial with separate and combined drinking water, HAP and sanitation arms would be helpful to disentangle the possible synergistic effects of these household-based interventions designed to improve water quality and air quality. Outcomes could include environmental enteropathy and clinic-diagnosed outcomes. Moreover, future WASH studies should have more rigorous evaluation of respiratory symptoms and ALRI in particular, and future HAP and respiratory studies should include diarrhoea symptoms.

Determinants of kitchen concentrations and personal exposure to $PM_{2.5}$

Along with cooking area and personal exposure data, we collected extensive data on cooking area characteristics such as dimensions and ventilation, along with self-reported cooking locations and stove usage for each meal during the monitoring period. Future analyses could examine determinants of kitchen and personal $PM_{2.5}$ (WHO, 2014), and these could help elucidate typical household exposures in the region since measuring personal exposures is difficult on a large scale (Bruce et al., 2015; Clark et al., 2013b; Northcross et al., 2015). Using these data, we could also examine exposure amongst sometimes, never, and exclusive users, and investigate cooking location as a mediating factor. In a subset of households for which sensor and UCB area measurements are complete, objective indicators of usage and real-time static PM2.5 and personal CO could be modelled. Chapter 5 focused on mean $PM_{2.5}$, but the influence of $PM_{2.5}$ and CO exposure peaks could be equally important for health. A comparison between arms, stove and fuel type, and location would be helpful. Little is known about the influence of exposure peaks, although one study from India suggests black carbon increases results in acute increases in systolic blood pressure (Norris et al., 2016). Additionally, we plan to

assess the relationship between $PM_{2.5}$ and CO using Bland-Altman plots (Klasen et al., 2015; McCracken et al., 2013).

Determine exposure of children less than 2 years of age

A key remaining question is the exposure of children less than 2 years of age since there is increased mortality due to ALRI and diarrhoea in this age group (Fischer Walker et al., 2013). A key strategy may be to conduct gravimetric $PM_{2.5}$ measurements for children by having the mother wear the equipment while the child is on their back, and when the child is not on the back, place the equipment within 1 meter. Future work should assess the feasibility of this approach in order to characterize exposures.

More objective usage and location data

Real-time location info coupled with real-time cooking area and exposure data would help address relative contributions and locations of other sources of exposure. One idea is to affix both usage and location sensors on portable stoves to detect when and where they are being used. This would also provide objective measures on child proximity to cooking fires and other sources of exposure. Respiratory tract infections have been associated with child proximity to cooking fires in Bangladesh (Nasanen-Gilmore et al., 2015). Proximity to cooking may be an easily modifiable risk factor for children, and deserves further exploration.

Behaviour change strategies to increase household ventilation and encourage outdoor cooking, even during the rainy season, similarly merits investigation, although cooking-related behaviour change has demonstrable challenges (Clark et al., 2015; Goodwin et al., 2015; Hanna et al., 2012;

Johnson and Chiang, 2015b). Strategies to reduce exposure to second-hand smoke and kerosene lighting should also be explored in this setting. Such modifiable practices could be incorporated into public health messaging, and especially targeted towards vulnerable populations such as those with HIV or NCDs, or during antenatal and postnatal care and first years of life. Impacts on personal exposure should drive best practice and decision-making in order to minimize unintended consequences, since changes in cooking location may adversely increase exposure of other household members.

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APPENDIX: Co-authored peer-reviewed papers of work undertaken during the research degree period of study

Rosa, G.; Majorin, F.; Boisson, S.; Barstow, C.; Johnson, M.; Kirby, M.; Ngabo, F.; Thomas, E.; Clasen, T. Assessing the impact of water filters and improved cook stoves on drinking water quality and household air pollution: a randomised controlled trial in Rwanda. *PLoS One* **2014**, *9* (3), e91011.

Nagel, C. L.; Kirby, M. A.; Zambrano, L. D.; Rosa, G.; Barstow, C. K.; Thomas, E. A.; Clasen, T. F. Study design of a cluster-randomized controlled trial to evaluate a large-scale distribution of cook stoves and water filters in Western Province, Rwanda. *Contemp. Clin. Trials Commun.* **2016**, *4*, 124–135.

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Assessing the Impact of Water Filters and Improved Cook Stoves on Drinking Water Quality and Household Air Pollution: A Randomised Controlled Trial in Rwanda

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Abstract

Diarrhoea and respiratory infections remain the biggest killers of children under 5 years in developing countries. We conducted a 5-month household randomised controlled trial among 566 households in rural Rwanda to assess uptake, compliance and impact on environmental exposures of a combined intervention delivering high-performance water filters and improved stoves for free. Compliance was measured monthly by self-report and spot-check observations. Semi-continuous 24-h $PM_{2.5}$ monitoring of the cooking area was conducted in a random subsample of 121 households to assess household air pollution, while samples of drinking water from all households were collected monthly to assess the levels of thermotolerant coliforms. Adoption was generally high, with most householders reporting the filters as their primary source of drinking water and the intervention stoves as their primary cooking stove. However, some householders continued to drink untreated water and most continued to cook on traditional stoves. The intervention was associated with a 97.5% reduction in mean faecal indicator bacteria (Williams means 0.5 *vs*. 20.2 TTC/100 mL, $p<0.001$) and a median reduction of 48% of 24-h $PM_{2.5}$ concentrations in the cooking area ($p=0.005$). Further studies to increase compliance should be undertaken to better inform large-scale interventions.

Trial registration: Clinicaltrials.gov; NCT01882777; http://clinicaltrials.gov/ct2/results?term = NCT01882777&Search = Search

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Competing Interests: We have the following interests: This study was funded by DelAgua Health, a for-profit company that implements the program in Rwanda in conjunction with the Rwanda Ministry of Health. Evan Thomas and Christina Barstow, co-authors of this article, are compensated consultants to DelAgua Health, and are in charge of overseeing the implementation of the program in Rwanda. Michael Johnson, co-authors of this article, is employed by the commercial company, Berkeley Air Monitoring Group, which was contracted to provide advice on household air pollution monitoring. This does not alter our adherence to all the PLoS ONE policies on sharing data and materials.

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Introduction

Environmental contamination at the household level is a major cause of death and disease, particularly among rural populations in low-income countries. Unsafe drinking water, together with poor sanitation, account for an estimated 0.9% of the global burden of disease and 0.3 million deaths [1]. Much of this disease burden is associated with diarrhoea, which alone accounts for 10.5% of deaths in children under 5 years in low-income countries [2]. Household air pollution (HAP) from biomass fuel smoke has been linked to increased risk of respiratory tract infections, low birth weight, exacerbations of inflammatory lung conditions, cardiac events, stroke, eye disease, tuberculosis, cancer and nutritional deficiencies [3]. The Global Burden of Disease (GBD) 2010 project found HAP from solid fuels to be responsible for 3.5 million premature deaths globally [1]. In this same assessment, smoke from household cooking fuels was also responsible for another half a million premature deaths due to contributions to outdoor air pollution [1]. These environmental hazards are aggravated among rural inhabitants of sub-Saharan Africa who are more likely to rely on unsafe water supplies and cook using biomass fuels on inefficient stoves [4–6].

Inefficient cookstoves also present substantial economic, developmental and environmental costs. At the household level, poverty is exacerbated and time spent at school is reduced by the burden of collecting more fuel for boiling drinking water and cooking [7]. Individuals, households and governments bear the cost of expenditures for seeking treatment of enteric and respiratory infections. Cookstove emissions also contribute to greenhouse gas and black carbon emissions, and in some cases the fuel harvesting can result in denuding of forests [8,9].

With a population of 10.5 million and a density of 412 persons per sq. km, Rwanda is the most densely populated country in East Africa [10]. Eighty per cent of the population of Rwanda lives in rural areas and is engaged in agriculture [11]. Despite significant progress over the last decade, 57% of the population is living

below the poverty line, 37% of them living in extreme poverty [11]. While a large proportion of the rural population has access to improved water sources (71.2%), mainly through protected springs, only 2.2% of rural areas have water on their premises [12], resulting in an increased risk for drinking water contamination during transport and storage [13]. Almost all of rural Rwanda (99.0%) relies on biomass for their cooking needs [12]. Morbidity and mortality are largely dominated by communicable diseases, including HIV/AIDS, acute respiratory infections, diarrhoeal diseases, intestinal parisitoses, and malaria [14]. Among deaths of children under 5, pneumonia accounts for 20% and diarrhoea for 12% [15].

In an effort to reduce the disease burden in rural Rwanda, decrease poverty associated with expenditures for fuel, and minimize the impact of greenhouse gases from inefficient combustion of biomass in low-efficiency stoves, the Rwanda Ministry of Health (MiniSante) and the Rwanda Environmental Management Authority (REMA) have partnered with DelAgua Health (implementer) to design, deploy and evaluate the impact of a project that will deliver and promote the use of advanced water filters and high efficiency cookstoves to lower-income households in Rwanda. Prior to initiating the full campaign, the implementer with the Ministry of Health undertook a pilot distribution of filters and cookstoves to approximately 2200 households in 15 villages in 11 of the country's 30 districts. We conducted this study in three of those villages in order to assess the uptake of the intervention and its impact on drinking water quality and household air pollution.

Methods

Study setting

The study was conducted from September 2012 to April 2013 in three rural villages, Nyarutovu and Kabuga located in Muhanga district, Southern province; and Rubona, located in Gakenke district, Northern province. These villages were purposely selected from the 15 villages comprising the pilot distribution phase. The sites were changed from the original protocol, Karongi and Ngororero districts in Western province, to accommodate access to better microbiology laboratory facilities in Kigali.

Study design and sample size

The study employed a parallel, household-randomised, control trial design with a 1:1 ratio. This trial followed a non-blinded design because previous attempts to blind an earlier version of the LifeStraw Family filter in the Democratic Republic of Congo were unsuccessful [16]. The objectives of the study were to assess (i) uptake and use of the intervention by the target population when delivered programmatically, and (ii) the impact of the intervention on the microbiological quality of household drinking water and air quality near the self-reported cooking area over the 5-month follow-up period. Our primary outcomes were (i) to assess levels of faecal contamination (measured by thermotolerant coliforms, TTC) in stored water in the home that householders used for drinking, and (ii) to determine average 24-h concentrations of $PM_{2.5}$ in the main cooking area as identified by participants. Our secondary outcome was to assess use of the intervention filters and stoves based on self-report and spot-check observations.

The sample size calculation was based on $PM_{2.5}$ emissions reductions rather than TTC reductions in drinking water as the former was determined to require a larger sample. Assuming a 50% reduction in $PM_{2.5}$ emissions, 80% power, $\alpha = 0.05$ and a coefficient of variation (COV) of 1, we estimated a sample size of 63 households per arm.

The protocol of this trial and CONSORT checklist are available as supporting information; see Text S1 and S2.

Intervention

Each intervention household received one LifeStraw Family 2.0 filter and one EcoZoom Dura improved wood burning stove. The filter is the second-generation of a gravity-based water purifier that uses ultrafiltration in the form of a hollow-fibre cartridge to remove pathogens from drinking water. The first generation device has been shown in field studies to be highly effective in improving water quality and to achieve consistent (though not exclusive) use [16]. The second-generation version used in this study employs a table-top design and an integrated safe storage vessel. Untreated water is poured through a 20-μm pre-filter plastic mesh into a 6.0 L container; over time, gravity forces the water through the cartridge comprised of hollow-fibres with a 20-nm pore size. The water then passes into a 5.5 L storage vessel where it can be dispensed via a plastic tap. The device is cleaned daily by backwashing the cartridge using a squeeze-pump mounted on the back of the storage container. The device is designed to treat 18,000 L of water [17] with a flow rate of approximately 3 L per hour. In the laboratory, the filter cartridge was found to meet the USEPA standards for microbiological water purifiers by reducing bacteria by 6 logs, viruses by 5 logs and protozoa by 4 logs [18]. The filter meets the "highly protective" World Health Organization (WHO) rating for household water treatment technologies [19].

The intervention stove is based on the 'rocket' concept that uses an internal 'chimney' in the stove that directs air through the burning fuel (usually biomass), and encourages the mixing of gases and flame above it. Precise internal stove dimensions are used to achieve high combustion efficiency and transfer heat to the cooking pot. Two additional components are included with the stove, a "stick support" onto which fuel wood is placed to promote airflow and a "pot skirt" which increases fuel efficiency. A study comparing cookstoves in Uganda, Kenya and Tanzania reported that the EcoZoom (aka StoveTec) stove saved 39% to 54% of fuel compared to open fires, cooked meals faster, and was participants' most preferred stove during controlled cooking of local dishes [20–22]. In the intervention group, householders were encouraged to cook outdoors on the EcoZoom stove and to use dry wood only to increase the efficiency of the stove. Further details on the messaging used in the pilot distribution can be found elsewhere [23].

Houses that were allocated to the intervention group also received a poster with illustrations and instructions in *Kinyarwanda*, the local language, on filter and stove use, maintenance, and contact names and phone numbers for the implementer. Most households had easy access to a cellular phone for contacting the implementer. Intervention households received one-to-one training on use and maintenance in their homes by community health workers (CHWs) who were previously trained by trainers who themselves had been trained by the filter and stove manufacturers and implementer. Intervention households were then visited periodically at approximately one-month intervals by CHWs to refresh health messaging and encourage use. Households allocated to the control group were instructed to continue usual practices throughout the study. At the end of the study in April 2013, these control households received their own filters, stoves, posters and training.

Enrolment, baseline survey, randomisation and deployment of devices

Households were eligible to participate in the study if (i) they were registered as being members of the village, (ii) the head of the household was over 18 years, and (iii) no members of the household worked as a CHW. The last criterion was included after the original protocol was drafted as at the time of the design the researchers were not aware that the CHW that would deliver the intervention resided in the villages selected for the study. It was explained that while all participating households would receive filters and stoves, half would receive them at the outset of the study and the balance at the conclusion of the 5-month follow-up period. After obtaining consent from the heads of participating households, a baseline survey was undertaken in September-November 2012 to collect information on demographics, socio-economic characteristics, water, hygiene and sanitation practices as well as fuel and cooking practices. Data collection tools were translated into *Kinyarwanda* and piloted before use.

Following the baseline survey, a public lottery was organised by the implementer and research teams during a village meeting to randomly allocate an approximately equal number of households from each village to intervention or control groups. Local authorities and village chiefs were extensively engaged to assess the suitability of this randomisation approach. After the lottery, members of control households were invited to leave the venue while those of intervention households attended a demonstration on the use and maintenance of the filter and stove, collected their devices, and carried them to their homes.

Outcome assessment

Compliance. Monthly cross-sectional surveys were conducted by trained field investigators (the evaluation team) working independently of the implementation team at unannounced visits among each household. At each visit participants were asked to identify the main drinking water container in the household, whether it was the intervention filter or another container; the surveyor also recorded whether the filter contained water at the time of the visit, a possible objective indicator of filter use. The field investigators also observed the cookstove and if cooking was taking place at the time of the unannounced visit, recorded where and whether such cooking was on the intervention stove or the traditional stove. If no cooking was taking place, field investigators noted the presence of smoke marks on the intervention stove, a possible objective indicator of use. Reported measures of stove use were also collected by asking participants what stove had been used the last time cooking took place in their home.

Independent to our study, the implementers undertook a separate survey, conducted by Environmental Health Officers (EHOs), to assess use and acceptability of the intervention for their own monitoring and evaluation purposes. The details of this assessment have been presented elsewhere [23].

Additionally, to assess use of the intervention in a more objective manner, remotely reporting electronic sensors were mounted onto 23 intervention filters and 27 intervention stoves and deployed in a randomly selected sub-sample of intervention households for a two-week period. The details of the implementation of this nested study, data handling and analysis, and results are presented elsewhere [24].

Water quality. During each of the five monthly visits, field investigators took a sample from the water container identified by the householder as being used mainly for drinking by children under 5 years of age, or adults if no under 5 s resided in the household. If this was other than directly from the intervention filter, a second sample was taken directly from the filter if it contained water. All water samples were collected in sterile Whirl-Pak bags (Nasco, Fort Atkinson, WI) containing a tablet of sodium thiosulphate to neutralize any halogen disinfectant. Samples were placed on ice and processed within 6 h of collection to assess levels of TTC. Microbiological assessment was performed using the membrane filtration technique [25] on membrane lauryl sulphate medium (Oxoid Limited, Basingstoke, Hampshire, UK) using a DelAgua field incubator (Robens Institute, University of Surrey, Guilford, Surrey, UK).

Household air pollution. Monitoring of particulate matter with an aerodynamic diameter <2.5 µm ($PM_{2.5}$) in the main cooking area took place between November 2012 and March 2013. 126 households (63 control and 63 intervention households) were randomly selected for semi-continuous 24-h $PM_{2.5}$ monitoring. Households were numbered and selected by using a computerised random number generator. Upon arrival at the participant's home, the family member mainly responsible for cooking was identified and a short survey was employed to identify the area in the household where cooking primarily took place. "Stacking" of stoves (using different stoves, often in different locations) [26] was a common scenario, both in control and intervention households, though more common in the latter. In cases where the participant reported cooking equally in two locations or with two or more stoves, we sampled from indoor rather than outdoor locations and from traditional rather than intervention stove. UCB-PATS $PM_{2.5}$ monitors (described below) were placed 1.5 m above the ground and 1 m away from the stove and, whenever possible, at least 1.5 m from windows and doors by suspending the monitors from the roof beams. When cooking was reported to take place outdoors, the $PM_{2.5}$ monitor was mounted onto a vertical wooden stand and placed at the same distance and height from the stove. The location of the stand was marked on the floor and participants were advised not to touch or move the equipment.

$PM_{2.5}$ was measured using the University of California, Berkeley Particle and Temperature Sensor (UCB-PATS^{TM}), (Berkeley Air Monitoring Group, USA), a semicontinuous (1-min averages), light-scattering nephelometer [27,28]. Laboratory and field validations of the UCB-PATS have been described previously [27–30]. To take into account that nephelometer sensitivity is a function of an aerosol's specific optical properties such as size, colour, and shape [31], calibration of the UCB response with the target aerosol was undertaken by conducting 24-h $PM_{2.5}$ gravimetric co-location measurements in a sub-sample of homes ($n = 30$). Five field blanks were obtained, resulting in an adjustment of subtracting 5 µg to the final filter masses ($<1\%$ of the mean mass deposition). The UCB-PATS response was then linearly regressed against the gravimetric samples ($n = 27$, $R^2 = 0.86$), with the resulting equation then used to adjust the UCB-PATS response to the gravimetric measures (Figure S1 of supporting information). Three gravimetric samples were omitted due to incomplete sampling durations.

Gravimetric $PM_{2.5}$ samples were collected using standard air sampling pumps (PXR8, SKC Inc., USA) with $PM_{2.5}$ cyclones (SCC 1.062, BGI, USA) using a flow rate of 1.5 L/min. Flow rates were measured before and after installation of the sampling equipment in the home with a rotameter (Matheson Trigas, Montgomeryville, PA, USA) that had been calibrated using a TSI Flow Calibrator 4146 (TSI, Inc., USA). $PM_{2.5}$ was collected on 37-mm Teflon filters (Pall, USA). Filters were stored at 4°C until shipment to Berkeley Air Monitoring Group in California, USA for weighing. Filters were equilibrated for 24 h at 22±3°C and 40±5% relative humidity before being weighed on a 0.1

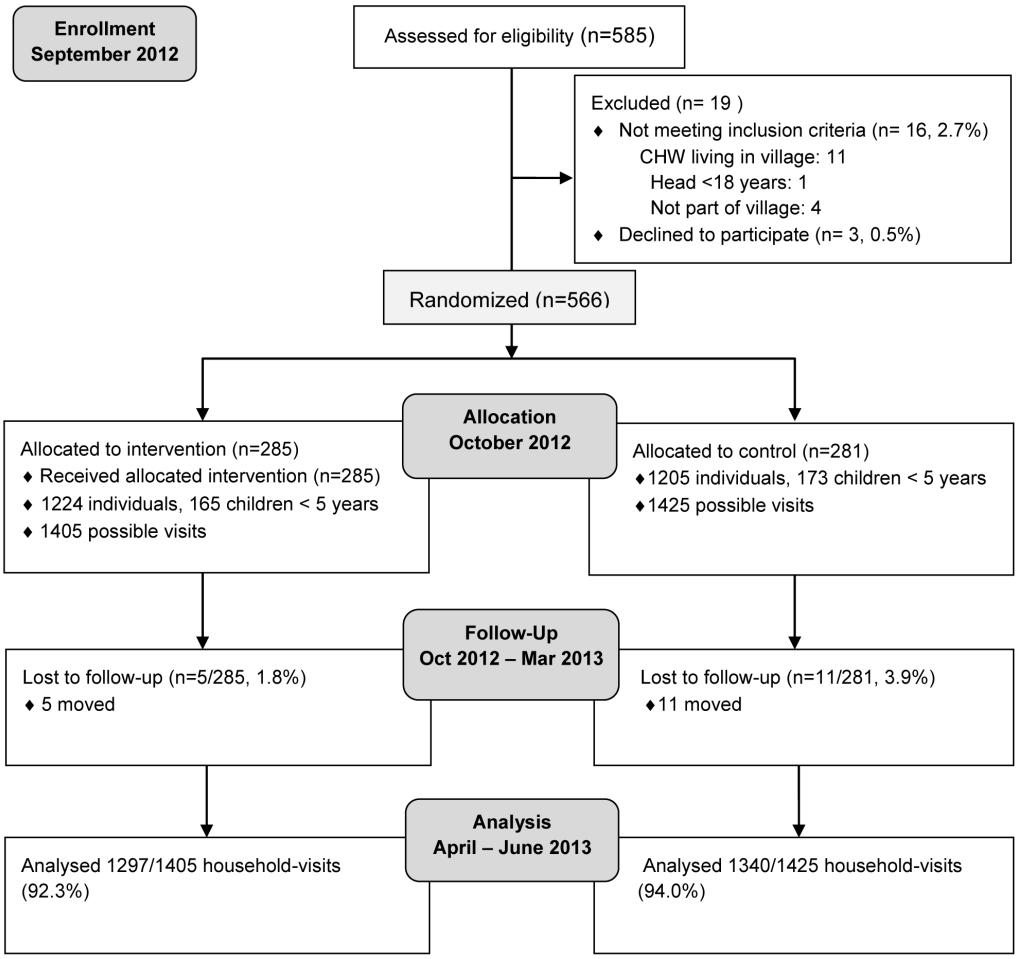

Figure 1. CONSORT diagram showing the flow of participants through the trial.
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microgram resolution electro microbalance (XP2U, Mettler Toledo, USA).

Data analysis

All data were analysed using Stata 12 (Stata Corporation, College Station, TX, USA). Because both $PM_{2.5}$ concentrations and TTC counts in drinking water followed non-normal distributions, medians, geometric means and Williams means are presented together with arithmetic means. The Williams mean is calculated by adding 1 to all the data values, then taking the geometric mean, then subtracting 1 again [32]. Categorical data were compared using a Chi square or a Fisher's exact test where appropriate. The non-parametric Wilcoxon rank sum test was used to compare $PM_{2.5}$ concentrations in the main cooking area between intervention and control groups. To assess the effect of the intervention on water quality, TTC counts during follow-up were compared using random effects negative binomial regression as describe elsewhere [33] to account for (i) repeated observations within households and, (ii) the skewed distribution of the TTC counts. Model comparison was assessed by using the Bayesian information criterion (BIC), which is a well-established measure of goodness of fit that also applies to non-nested models [33,34]. For the purpose of analysis, plates that yielded coliform forming units (CFUs) that were too numerous to count (TNTC) were assigned a value of 300 TTC/100 mL. Data were analysed in an intention-to-treat basis in order to estimate the effect of the intervention regardless of compliance. Only those households with complete follow-up data were analysed.

Ethics

The study was reviewed and approved by the ethics committee at the London School of Hygiene and Tropical Medicine (No. 6239, as amended) and the Rwanda National Ethics Committee (No. 328 RNEC/2012). Written informed consent to participate in the research was obtained from the male or female head or the wife of each participating household.

Results

Study population

The three villages participating in the study comprised 585 households, all of which were screened to participate in the study, 16 (2.7%) were ineligible and 3 (0.5%) refused to participate (Figure 1). A total of 566 households with 2429 individuals were enrolled in the study. Of those 281 (49.7%) were assigned to the control group and 285 (50.4%) were assigned to receive the intervention filter and cookstove. Household loss-to-follow-up was 2.8%, primarily due to participants moving out of the study area. A total of 2737 household-visits were completed during the follow-

Table 1. Filter and stove use among intervention households: Evaluator's survey.

	All visits	
	N	%
Filter use[1]		
Reported drinking container		
Intervention filter	1210	89.2
Other container	146	10.8
Water stored in other container treated	57	39.0
Method of treatment: Intervention filter	56	98.2
No water in intervention filter among households identifying filter as drinking container	12	1.0
No water in intervention filter among households not identifying filter as drinking container	83	56.8
Stove use[2]		
Observation data on use		
Intervention household cooking at time of visit	280	26.9
Stove in current use		
Intervention stove only	152	54.3
Both stoves simultaneously	12	4.3
Traditional stove only	116	41.4
Currently cooking outdoors	59	21.1
Intervention stove users cooking outdoors[3]	49	32.2
Reported data on use		
Reported last stove used[4]		
Intervention stove only	593	78.0
Both stoves simultaneously	15	19.3
Traditional stove only	147	2.0
Reported using intervention stove in last three follow-up visits	130	47.5

[1]Based on households that completed the visits and allowed enumerators to observe the container, 1356/1393 = 97.3%.
[2]Data only available from mid follow-up 2 onwards (1040/1393 = 74.7%).
[3]Among those households cooking only on the intervention stove.
[4]Excludes those households cooking at time of home visit.
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up period (96.7%) and data on one of the primary outcomes (water quality) was collected for 2637 households-visits (93.2%).

Baseline characteristics

Baseline characteristics were distributed evenly between the trial arms, with the exception of availability of soap among households with a designated hand washing area and boiling or chlorination of drinking water (see Table S1 of supporting information). At baseline, drinking water samples were obtained from 551 (97.3%) households. The median and Williams mean of drinking water was 14 and 20.2 TTC/100 mL (95% CI: 15.0–27.0 TTC/100 mL) and 22 and 30.3 TTC/100 mL (95% CI: 22.8–40.2 TTC/100 mL) for control and intervention groups, respectively.

Filter and improved stove use and compliance

Most households used the filter throughout the study period (Table 1). Intervention households identified the filter as the main drinking source in 89.2% of all household visits where drinking water was available. Visual inspection at the time of the unannounced visit was consistent with reported use, with 99% of the filters containing water. Of the 10.8% of intervention households that stored their drinking water elsewhere, overall only 39.0% of them reported that the water had been treated with the intervention filter. Over the course of the study, however, only 62.9% of intervention households identified the filter as the main drinking water storage container in all five follow-up visits with available water (n = 240, 84.2%). Of the remainder, 11.2% reported treating it and storing it elsewhere at least once during the 5-month follow-up, 25.0% reported drinking untreated water at least once during follow-up and 0.8% did not know the status of their water in at least one of the visits. During the last follow-up visit, the major reasons for not having filtered water at the time of the visit were (i) forgetting to fill the filter (48.1%), (ii) drinking mainly locally produced beer instead of water (22.2%), or (iii) having a broken or not properly functioning filter (18.5%).

The intervention stoves were also used throughout the study, though most householders also continued to use their traditional stoves. Field investigators observed actual cooking on about a quarter (26.9%) of their unannounced visits. Of these, 54.3% were cooking only with the intervention stove and 4.3% were using both the intervention and traditional stoves (Table 1). Reported use was higher, with householders claiming they last cooked solely on the intervention stove on 78.0% of visits. Use of the intervention stove was not consistent, with 47.5% of intervention households reporting to have used the intervention stove during the last cooking event at all three home visits (data not collected during initial phases of follow-up). Likewise, of the households that were cooking at all three unannounced visits (n = 8), or at two of the

Table 2. Filter and stove use among intervention households: Implementer's survey.

	N	%
Filter use		
Filter presence confirmed in households[1]	283	99.7
Tap accessible to <5 s	267	94.4
Water present in filter	269	95.1
Stove use		
Observation data on use		
Intervention household cooking at time of visit[2]	78	27.7
Stove in current use		
Intervention stove only	50	64.1
Both stoves simultaneously	4	5.1
Traditional stove only	24	30.8
Currently cooking outdoors	30	38.5
Intervention stove users cooking outdoors[3]	28	17.2
Reported data on use		
Reported last stove used[4]		
Intervention stove only	163	79.9
Both stoves simultaneously	2	1.0
Traditional stove only	39	19.1
Primary stove in current use is intervention stove[4]	253	89.1
Use intervention stove ≥7/week	236	93.3
Use intervention stove ≥14/week	137	54.2
Continue using traditional stove	217	76.4
Use traditional stove ≥7/week	58	26.7
Reported cooking less indoors	175	61.6
Reported main cooking is outdoors	163	57.4
Tend more the fire with the intervention stove[5]	212	83.8

[1]Observation not allowed in one household.
[2]Of those households that allowed the observation (n = 282, 99.3%).
[3]Among those households cooking only on the intervention stove.
[4]Excludes those households cooking at time of home visit.
[5]Among those households identifying intervention stove as main cooking stove.
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three unannounced visits (n = 52), only 50.0% and 34.6% were using the intervention stove at all three or two visits, respectively. During the last follow-up visit, the major reasons for not using the intervention stove during the last cooking event were (i) having no time to tend the fire (34.1%), (ii) not having dry (30.7%) or the right-size wood (10.2%) or, (iii) cooking beans for which a traditional stoves was regarded most appropriate (10.2%).

Data on use of the intervention from the implementer's survey was very similar to our assessment (Table 2). A similar percentage of intervention households (27.7%) were cooking at the time of the visit. Of these, just over two thirds (64.1%) were exclusively cooking on the intervention stove, but only 17.2% of these were cooking outdoors, a figure just slightly lower than the one observed on our independent follow-up. Data from the implementer's more extensive survey confirmed the stacking of stoves in intervention households, with 76.4% of intervention households reporting to continue using their traditional stoves. Of these, 26.7% reported using it ≥7 times per week. Of interest was the fact that 83.8% of intervention households identifying the intervention stove as their primary cookstove reported that the intervention stove required more active tending of the fire as compared to the traditional stove.

In the last round of our follow-up, 5.4% and 5.1% of intervention households reported having problems with their filter or stove at the time of the visit, respectively. Data collected from the implementer's repair team indicates that 24.9% of filters and 6.7% of stoves had to be repaired during the study. No devices had to be fully replaced, though some repairs involved the replacement of individual components. The main reasons for filters being repaired were (i) filters being clogged (48.6%) and, (ii) tubes being damaged by rodents (27.0%). The main reasons for the intervention stoves being repaired included (i) pot skirts melting (65%), and (ii) stick supports breaking (10%).

Overall, only 1.0% of water samples collected from control households were reported to have been treated with a neighbour's intervention filter, showing low levels of cross-contamination between groups.

Water quality

The microbiological quality of the stored drinking water was significantly higher in intervention households than control households (Williams means 0.5 vs. 20.2 TTC/100 mL, respectively, $p<0.001$). Overall, 86.8% (95% CI: 84.9%–88.6%) of drinking water samples from intervention households were free of TTC compared to 22.4% (95% CI: 20.1%–24.6%) of control household samples ($p<0.001$) (Figure 2). The proportion of samples that had >100 TTC/100 mL was 3.6% (95% CI: 2.6%–4.6%) for intervention households and 31.9% (95% CI: 29.4%–34.5%) for control households. Overall, 96.6% of drinking water samples collected directly from filters were free of TTC. In intervention households, water quality was significantly higher in water samples collected directly from the filter (Williams mean 0.14 TTC/100 mL; 95% CI: 0.10–0.18) than water stored in another container (Williams mean 13.8 TTC/100 mL; 95% CI: 9.0–20.7) (see Table S2 of supporting information). The quality of the drinking water stored in other containers did not differ significantly between control and intervention households ($p = 0.07$). However, among intervention households, water that was stored in another container and was reportedly treated with the intervention filter was significantly of higher quality than reportedly non-treated stored water (Williams means 5.4 vs. 23.2 TTC/100 mL, respectively, $p<0.001$). Throughout the duration of the study, only 2.5% of control households had drinking water free of TTC on all follow-up visits as opposed to 56.5% of intervention households. Overall 15.2% of samples from control households and 5.1% of samples from intervention households yielded plates that were TNTC.

Air quality

A total of 121 households (60 intervention and 61 control) completed the 24-h $PM_{2.5}$ monitoring of the main cooking area. 66.7% of intervention households identified the intervention stove as their main cooking stove. However, only 23.3% of intervention households reported that their main cooking area was outdoors as promoted by the intervention. Of these, all households reported cooking with the intervention stove. Among the control households, the three stone fire was identified as the main cooking stove in 65.6% of cases, followed by the locally made *rondereza* stove (24.6%). Only one control household reported cooking outdoors.

Table 3 shows the $PM_{2.5}$ concentrations of the main cooking area for control and intervention households on an aggregate level and stratified by reported main area of cooking. Overall, mean and median 24-h $PM_{2.5}$ concentrations in intervention households were 0.485 mg/m^3 and 0.267 mg/m^3, respectively, compared to

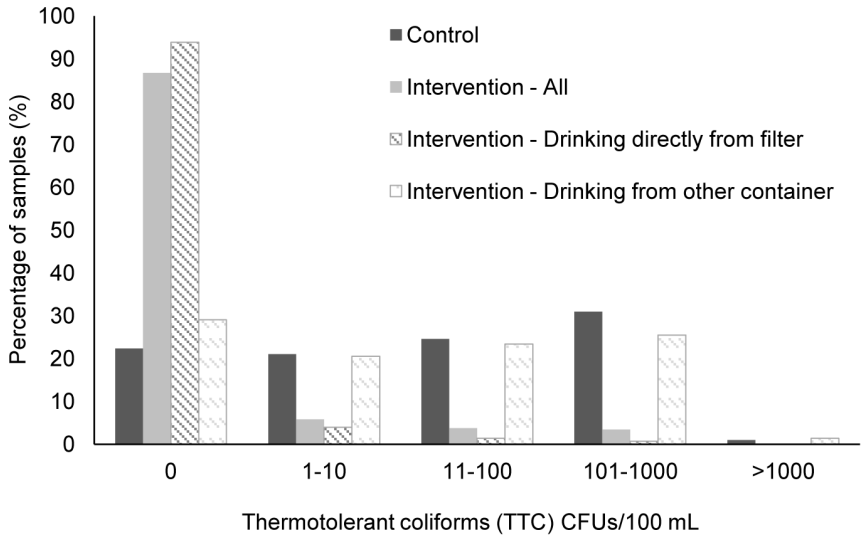

Figure 2. Percentage of water samples by level of contamination (TTC/100 mL).
doi:10.1371/journal.pone.0091011.g002

0.905 mg/m^3 and 0.509 mg/m^3 for control households. This represents a 48% reduction in median 24-h concentrations ($p = 0.005$). Compared to control households that predominantly cooked indoors, intervention homes that reported indoor cooking showed a reduction in median concentrations of 37%, which was only borderline significant, possibly due to the smaller sample size ($p = 0.08$). Outdoor cooking in the intervention was associated with a median reduction of 73% when compared to control households ($p<0.001$) and 57% reduction when compared to indoor-cooking intervention homes ($p = 0.02$).

Discussion

We report on a randomised controlled trial to independently evaluate a pilot implementation program distributing free water filters and improved cooking stoves to rural homes in Rwanda. We found high reported use of the intervention filter, which was associated with significantly higher microbiological quality of drinking water when consumed directly from the filter. Nevertheless, such use was not exclusive; a sizable proportion of householders continued to drink untreated water. We also found improved household air quality among intervention households despite continued use of the traditional stove.

Filter uptake among the intervention population was high, with filters being reportedly used in 89.2% of all household visits. Similar levels of uptake of filter-based interventions have been reported elsewhere [16,35,36]. Nevertheless, we found that 25% of intervention householders were reporting untreated water in at least one of the five follow-up visits. The nested study within this RCT using remotely reporting electronic sensors that collected objective data on use of the intervention devices (mainly times and volumes of water filtered for the intervention filter and times and duration of use for the intervention stove) corroborated our findings, showing that the filters and stoves were not used in a consistent and exclusive manner [24]. Epidemiological modelling based on quantitative microbial risk assessment suggests that even occasional consumption of untreated water can vitiate the health benefits associated with improved water quality interventions [37–39]. However, the intervention did significantly improve the microbiological quality of the drinking water when the filter was used as the main storage container. Since 96.6% of drinking water samples collected directly from filters were free of TTC, the conditions for achieving health gains may be achieved with better messaging.

Exclusive use was more problematic for the intervention stove. Only half of the intervention households reported that the last

Table 3. Summary statistics for 24-h $PM_{2.5}$ concentrations in the reported main cooking area.

$PM_{2.5}$ (mg/m^3)	N	Mean	SD	Min	Median	Max	Geometric mean	% Mean reduction	% Median reduction	Wilcoxon RST[1] *p*-value
Control	61	0.905	1.05	0.06	0.509	4.69	0.51	-	-	
Intervention	60	0.485	0.53	0.04	0.267	2.28	0.28	46%	48%	0.005
Reported cooking location										
Control- Indoor cooking	60	0.910	1.06	0.06	0.506	4.69	0.51	-	-	
Intervention- Indoor cooking	46	0.558	0.56	0.04	0.321	2.28	0.33	39%	37%	0.08
Intervention- Outdoor cooking	14	0.243	0.34	0.05	0.139	1.40	0.16	73%	73%	<0.001
[1]Wilcoxon rank-sum (Mann-Whitney) test										

doi:10.1371/journal.pone.0091011.t003

cooking event was performed with the intervention stove in the last three monthly follow-up visits. Likewise, only a third of those households that were visited twice at times that cooking was taking place were using the intervention stove at both instances, showing that among the intervention arm, households continued to rely on their traditional stove. Results from the implementers' survey showed similar results, with 76.4% of households reporting the continued use of their traditional stove, 26.7% of them using it more than 7 times per week. This is consistent with other studies that have shown that the introduction of a new stove often results in "stacking" rather than an immediate complete substitution [40–43].

Households reported continuing the use of their traditional stove because the intervention stove required more tending, unavailability of the adequate fuel or personal preferences for cooking traditional dishes. Context-specific issues regarding a community's cooking needs and preferences have been commonly cited in the literature as reasons for not achieving higher uptake and/or exclusive sustained use of improved cookstoves [42,44]. Thus re-considerations of the promoted stove or more active messaging addressing each of the main barriers may be required if a switching of the stove as opposed to an addition of the intervention stove to the current cooking system is to be achieved. This is not only going to affect the potential health impact of the intervention but also its environmental impact.

The assessment of HAP among control and intervention households showed an overall reduction of 48% of 24-h $PM_{2.5}$ among intervention households, which was comparable to reductions in household air pollution for rocket stove interventions in Ghana (52%) and Kenya (33%) [22,45]. Indoor cooking with the intervention stoves as opposed to the traditional stove was associated with a 37% reduction in 24-h $PM_{2.5}$, which was of borderline significance. However, we cannot rule out that this association may be due to residual bias by comparing sub-groups. Likewise, cooking outdoors, as recommended by the implementer, doubled the reduction in 24-h $PM_{2.5}$ from 37% to 73% as compared to indoor cooking on traditional stoves. Future studies, randomising participants not only to stove technology but also to cooking location (indoors *vs.* outdoors) would be advisable. More effective messaging may increase the levels of outdoor cooking expected by the intervention, as only 57.4% of households reported that their main cooking area was outdoors. Nevertheless, both the indoor and outdoor concentrations in the cooking area were well over even the initial interim 24-h WHO target for $PM_{2.5}$ (75 $\mu g/m^3$) [46]. At the same time, it will be important to monitor personal exposure directly, as most householders that identified the intervention stove as their primary cooking stove (83.8%) reported that the intervention stove required more tending than their traditional one, which could mitigate some of the impact from the household level reductions in $PM_{2.5}$. Indeed, many studies have found that reductions in personal exposure tend to be lower than reductions of emissions in the cooking area [47,48]. Given that a recent RCT study suggested that personal exposure reductions exceeding 50% may be required to achieve meaningful health impacts [47], further assessments of the intervention stove maybe be needed to determine whether the use of the intervention stove translates into meaningful health benefits.

This study has certain limitations. First, the villages included in the RCT were not selected randomly and should not be viewed as representative of any larger population. Second, we cannot rule out the potential for reactivity due to repeated monthly follow-up visits [49]. Third, while we attempted to collect objective indicators of use, by both undertaking visual observations of the filter and stoves and cooking events, the study relied heavily on reported data, which is susceptible to reporting bias. Furthermore, in this study we failed to collect data on reported supplementation of treated water with untreated water, which would have further implications for the health impact of the study. Previous studies with the earlier version of the LifeStraw Family filter have found quite varied results. A study in the Democratic Republic of Congo showed substantial supplementation despite high levels of filter use [16]. On the other hand, a study among HIV-positive mothers, who may be more aware of their health and their children's health, reported almost no supplementation [36]. However, in the latter storage containers were provided. Fourth, budget constraints allowed only the main cooking area, as identified by the participant, to be monitored for HAP. Given the potential for reporting bias and that stacking was commonly reported among the study population, it is very likely that cooking events may have taken place during the monitoring period in areas other than the one being monitored, thus giving a misleading and probable underestimate of the actual total HAP. Likewise, budget constraints did not permit personal $PM_{2.5}$ assessment, a more reliable metric for exposures associated with health outcomes [50]. Fifth, we did not collect any self-reported or other measures of diarrhoea or respiratory infections in our study communities. Finally, the follow-up period of this evaluation was limited to 5 months. This represents under a fraction of the lifespan of both the filter and stove and provided little opportunity to assess the impact of seasonal variations that are common in water quality and HAP. It also provided no opportunity to assess long-term patterns of use, which have been shown to diminish or vary over time for both water filters and improved cookstoves [35,43]. We are endeavouring to address some of these shortcomings in a longer-term follow-up study, currently underway, that will focus on health outcomes and sustained use.

Notwithstanding these limitations, this study suggests that a combined filter/stove intervention accompanied by consistent follow-up to promote use has the potential to significantly improve drinking water quality and household air pollution among a vulnerable population in Rwanda. If the longer-term follow-up study demonstrates sustained use with more exclusive reliance on the intervention hardware and lower personal exposure to HAP, then a large-scale roll out in Rwanda could significantly reduce exposures linked to much of the country's disease burden.

Supporting Information

Figure S1 Mass calibration of UCB-PATS against co-located $PM_{2.5}$ gravimetric samples.
(TIF)

Table S1 Baseline characteristics of participating.
(XLSX)

Table S2 Summary statistic of TTC/100 mL in household drinking water and filter effluent by study group.
(XLSX)

Text S1 Protocol.
(DOC)

Text S2 CONSORT Checklist.
(DOCX)

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monitoring and acts as lead author for the group, mjohnson@berkeleyair.com.

Author Contributions

Conceived and designed the experiments: GR SB FN TC. Performed the experiments: GR FM MK. Analyzed the data: GR MJ. Contributed reagents/materials/analysis tools: CB ET. Wrote the paper: GR TC.

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Study design of a cluster-randomized controlled trial to evaluate a large-scale distribution of cook stoves and water filters in Western Province, Rwanda

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ABSTRACT

Background: In Rwanda, pneumonia and diarrhea are the first and second leading causes of death, respectively, among children under five. Household air pollution (HAP) resultant from cooking indoors with biomass fuels on traditional stoves is a significant risk factor for pneumonia, while consumption of contaminated drinking water is a primary cause of diarrheal disease. To date, there have been no large-scale effectiveness trials of programmatic efforts to provide either improved cookstoves or household water filters at scale in a low-income country. In this paper we describe the design of a cluster-randomized trial to evaluate the impact of a national-level program to distribute and promote the use of improved cookstoves and advanced water filters to the poorest quarter of households in Rwanda.
Methods/Design: We randomly allocated 72 sectors (administratively defined units) in Western Province to the intervention, with the remaining 24 sectors in the province serving as controls. In the intervention sectors, roughly 100,000 households received improved cookstoves and household water filters through a government-sponsored program targeting the poorest quarter of households nationally. The primary outcome measures are the incidence of acute respiratory infection (ARI) and diarrhea among children under five years of age. Over a one-year surveillance period, all cases of acute respiratory infection (ARI) and diarrhea identified by health workers in the study area will be extracted from records maintained at health facilities and by community health workers (CHW). In addition, we are conducting intensive, longitudinal data collection among a random sample of households in the study area for in-depth assessment of coverage, use, environmental exposures, and additional health measures.
Discussion: Although previous research has examined the impact of providing household water treatment and improved cookstoves on child health, there have been no studies of national-level programs to deliver these interventions at scale in a developing country. The results of this study, the first RCT of a large-scale programmatic cookstove or household water filter intervention, will inform global efforts to reduce childhood morbidity and mortality from diarrheal disease and pneumonia.
Trial registration: This trial is registered at Clinicaltrials.gov (NCT02239250).

1. Introduction

Environmental contamination at the household level is a major cause of death and disease among rural populations in low-income countries. Household air pollution (HAP) contributes to acute lower respiratory infection in children under five, and among adults is a significant risk factor for hypertension, ischemic heart disease,

Abbreviations: ARI, acute respiratory infection; CHW, community health worker; DBSS, dried blood spot samples; HAP, household air pollution; H-PEM, Harvard Personal Exposure Monitor; ICCM, Integrated Community Case Management of Childhood Illness; IMCI, Integrated Management of Childhood Illness; MFI, mean fluorescence intensity; MOH, Rwanda Ministry of Health; MOLG, Rwandan Ministry of Local Government; RCT, randomized controlled trial.

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chronic obstructive pulmonary disease, and lung cancer [14,19,39]. Unsafe drinking water is the leading cause of diarrheal disease [32]. HAP and unsafe drinking water rank 7th and 8th among risk factors for the global burden of disease [18]. Collectively, pneumonia and diarrhea are responsible for an estimated 6.9 million deaths annually [7].

These environmental hazards are common among impoverished rural inhabitants of sub-Saharan Africa, the vast majority of whom cook with biomass fuels on traditional stoves and rely on unsafe water supplies [9]. In Rwanda, where more than half the population is living below the poverty line and more than a third in extreme poverty, 98.1% of rural householders cook with biomass, mainly on open three-stone fires; and only 7.6% have water on their premises [30]. After HIV/AIDS, the leading causes of death in Rwanda are ALRI (20%) and diarrhea (12%) [46].

Despite clear evidence that HAP is an important risk factor for respiratory and cardiovascular disease, evidence for the health impact of improved cookstoves that can be deployed at scale among vulnerable populations is limited [38]. Although trials are currently underway to explore the effectiveness of various improved cookstove types, these are all limited scale efficacy trials [8,17,42]. Further, doubts about the potential of any biomass stove to achieve WHO indoor air quality targets have shifted much of the focus to clean cooking fuels such as LPG, ethanol and electricity, although supply chain limitations currently render these options impractical in most rural settings [51,54,55].

There is strong evidence that household-based water filters are effective in preventing diarrhea [15]. The actual protective effect, however, is likely to vary by setting, season, and the extent to which water is a dominant transmission pathway. As evidence also suggests that even occasional consumption of untreated water vitiates the potential health impact, correct and consistent use is essential [10]. The up-front cost of household filters, together with the need to establish supply chains for consumables, has limited the extent to which they have been scaled up among vulnerable populations, particularly in rural settings. Like improved cookstoves, there has been no large-scale effectiveness trial to assess the impact of household water filters promoted programmatically.

In an effort to reduce the disease burden in rural Rwanda, the Rwanda Ministry of Health (MOH) partnered with the social enterprise DelAgua Health to distribute and promote the use of improved cookstoves and advanced water filters to the poorest 25% of households nationally, beginning in Rwanda's Western Province. The project, know as "*Tubeho Neza*" or "Live Well", earns revenue through carbon credits under the United Nations Clean Development Mechanism (CDM), a program authorized by the Kyoto Protocol that provides credits to the implementer based on a formula that includes population coverage and use [22].

Prior to initiation of the *Tubeho Neza* program, the implementer first undertook a pilot intervention to all 1943 households in 15 rural villages [4]. At this time we conducted a five-month RCT among 566 households in three of these pilot villages to assess the impact of the water filter on fecal indicator bacteria in household drinking water and the impact of the stove on fine particulate mater (PM2.5) in reported cooking areas [56]. Overall, the intervention was associated with a 97.5% reduction in mean fecal indicator bacteria (Williams means 0.5 vs. 20.2 TTC/100 mL, $p < .001$) and a 48% reduction of 24-h $PM_{2.5}$ concentrations in the cooking area (0.485 mg/m3 and 0.267 mg/m3, $p = 0.005$). The reduction was 37% for those cooking indoors ($p = 0.08$) and 73% for those cooking outdoors ($p < 0.001$) [56].

Based on the results from the pilot study, the Rwanda MOH and the implementer elected to proceed with the roll out of the intervention throughout Western Province. However, due to funding constraints, only approximately 100,000 of the 140,000 eligible households in Western Province could be included in the initial implementation. Consequently, it was decided that receipt of the program would initially be limited to households within randomly allocated sectors (groups of villages that generally correspond with catchment areas for primary-care clinics) within Western Province, with the remainder of households scheduled to receive the program the following year. This provided us the unique opportunity to conduct a population-level RCT to assess the impact of the program on health outcomes using records maintained at health facilities and by community health workers (CHW). In addition, we randomly selected a representative sample of households ($n = 1580$) in the control and intervention areas to conduct intensive data collection in order to assess coverage, use, environmental exposures, and additional health outcome measures. This paper provides details on the evaluation of the *Tubeho Neza* program, including the design of the study, the study setting and population, primary and secondary outcomes, and other details concerning the methods to be followed.

2. Methods

2.1. Setting

The study is located in Western Province, Rwanda, a predominantly rural province with a total population of roughly 2.5 million (Fig. 1). The Western Province is 87.8% rural, and the main source of energy for cooking is firewood (88.6%), followed by charcoal (8.3%). Most households in Western Province report their main source of water is from protected sources (26.8% public tap, 39.8% protected spring/well, 4.5% piped water on premises), although 16.3% of households obtain from an unprotected spring/well and 9.4% from surface water [30].

2.2. Study design

The study design is a cluster-randomized trial with sectors (administratively defined areas containing an average of 40 villages) as the unit of randomization. Each of the 96 sectors in Western Province have been randomized to either control or intervention status (Fig. 1). The primary study outcomes are diarrhea and acute respiratory infection (ARI) among children under five residing in households eligible to receive the program. Clinician-diagnosed episodes of diarrhea and ARI among all households in the study area will be assessed from records maintained by health facilities and village-level CHW health records that have been made available for use in this study by the Rwanda MOH.

In conjunction with the assessment of clinical outcomes across the entire population of program recipients (referred to as the "sector-level" study), we are conducting intensive data collection in a random sample of households with children <5 residing in the study area. This nested design permits examination of outcomes in addition to those maintained in health records, such as intervention uptake and use and the effect of the intervention on exposure to HAP and fecally contaminated drinking water. It also permits us to collect self-reported information on respiratory disease and diarrhea (to learn about cases that may not be reported to CHWs and clinics) and to assess a variety of objective measures related to health status (e.g. blood pressure, oximetry, inflammatory biomarkers, enteric pathogen antibodies) among household members. We refer to this intensive data collection in a sample of the larger RCT population as the "village-level" study in sections to follow in order to differentiate these efforts from the primary assessment of outcomes across the entire study population.

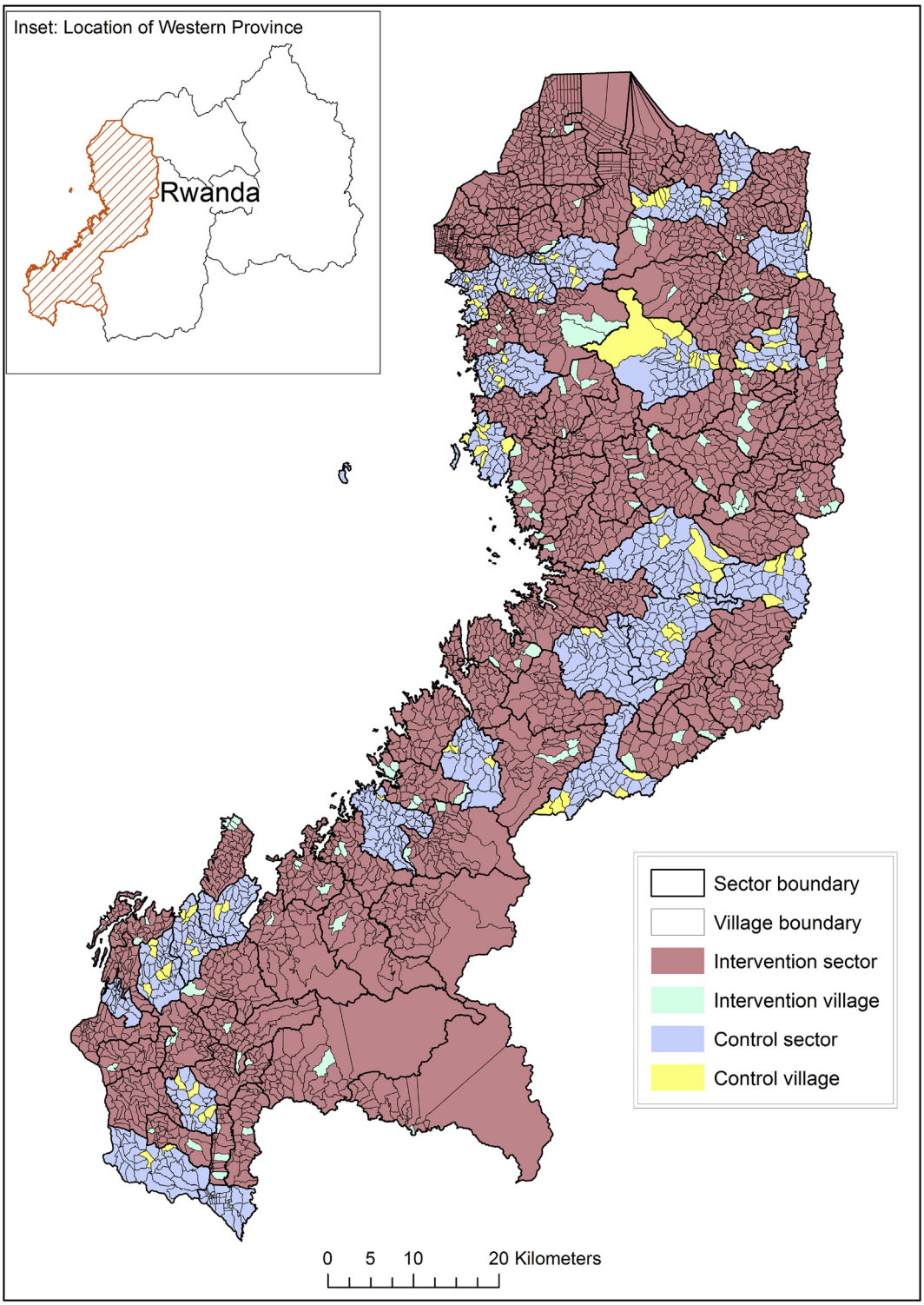

Fig. 1. Map of the study area. Western Province, Rwanda.

2.3. Eligibility criteria

All households in Western Province designated as *Ubudehe* category 1 or 2 were eligible to receive the intervention from the implementer. *Ubudehe* category is a government-defined household economic status classification and *Ubudehe* categories 1 and 2 roughly constitute the poorest 25% of the country. *Ubudehe* category is determined by community members based on classifications outlined by the Rwandan Ministry of Local Government (MOLG), and households categorized as *Ubudehe* 1 and 2 receive free medical and other assistance through government programs [57]. All children <5 in Western Province who reside in households that are categorized as *Ubudehe* 1 and 2 are included in active surveillance of diarrhea and pneumonia cases at local health centers and by village CHW's. These records are collected by research staff, in collaboration with the Rwandan MOH, and no

additional contact with the study population is required for the sector-level study.

2.4. Randomization

The choice of sector as the unit of randomization was made in collaboration with the program implementers and the Rwandan MOH. We used a database maintained by the Rwanda MOLG that contains the *Ubudehe* categorization of all households (subsequently referred to as the '*Ubudehe* database') to generate a count of eligible households in each sector and determined that a 3:1 allocation of intervention to control sectors in Western Province would meet the implementer's programmatic goal of reaching approximately 100,000 households during the initial roll-out of the program. Sectors were randomly assigned to intervention and control arms by the research team using a computer-generated randomization stratified by district to ensure equal distribution of the intervention across the seven districts of Western Province. Neither the implementers nor the Rwanda MOH were involved in the randomization process.

Randomization resulted in 72 designated intervention sectors and 24 designated control sectors, with a total of 97,815 eligible households in the intervention sectors and 36,152 eligible households in the control sectors. Sector-level census data [30] indicate that randomization achieved good balance between the arms in regards to population-level sociodemographic characteristics, water source type, and fuel use (Table 1). It is intended that all eligible households in the 72 sectors randomly assigned to the intervention group received the intervention during the Phase 2 implementation in late 2014, while eligible households in the control sectors will receive the intervention after the 1-year surveillance period (Fig. 2).

2.5. Village-level study

2.5.1. Eligibility criteria for village-level study

All villages within the study area (N = 3617) were eligible for selection as intensive data collection sites, excluding the 10 villages that were previously included in pilot intervention activities. Enrollment in this village-level cohort was limited to *Ubudehe* 1 and 2 households with at least one child 4 years of age or younger residing in the home the majority of the year. We limited enrollment to households with a child $\leq$4 years of age in order to ensure that at least one child per household remained under the age of five for the duration of the study. However, at each visit we collect all outcome data on any additional children present in the household that are currently under the age of five.

2.5.2. Sampling strategy for village-level study

The households selected for intensive data collection were randomly sampled from the study area using a stratified, two-stage design of the type commonly used in nationally-representative surveys in developing countries [45]. Prior to sampling for the village-level study, we estimated the number of eligible households in each village in Western Province using data provided by the Rwandan government and other sources. To ensure that a sufficient number of eligible households were present in each primary sampling unit (PSU), each village in the study area containing fewer than 12 eligible households was randomly paired with a geographically contiguous village in an iterative process using geographic information system software. This yielded 2715 PSUs, of which 2080 consisted of single villages and the remaining 635 were composed of groups of two or more geographically adjacent villages. We then conducted probability proportional to size random sampling of PSUs, stratified by treatment allocation. We oversampled from the control sectors to yield a 1:1 ratio of intervention to control clusters. This resulted in 87 clusters in each arm, with 101 villages in the control group and 98 villages in the intervention group. In stage 2, households were sampled from each PSU in using simple random sampling (Fig. 2). Our target enrollment was 10 households per PSU. The implementer and the Ministry of Health are blinded to the identity and location of villages selected for intensive data collection.

2.5.3. Enrollment in village-level study

Following household selection, trained study staff located the selected households with the assistance of the village CHW. The primary point of household contact was the primary cook. In order for a household to be enrolled into the study, at least one child four years of age or younger had to reside at the house the majority of the year, the primary cook had to be 16 years of age or older, and the primary cook had to give informed written consent. If the primary cook was not present at a first attempted visit of the household, another visit was attempted the same day and a final attempt the following day. If the selected household was not present in the village or if contact was unsuccessful after the repeated attempts, study staff attempted to enroll an alternate household selected by the field supervisor from the list of eligible households in the PSU using simple random sampling. The final sample enrolled in the village-level study consisted of 1582 households. Baseline data collection was conducted in each household immediately following enrollment.

2.6. Intervention

The program implementation under study is branded "*Tubeho Neza*" which means to "Live Well" in Kinyarwanda. The *Tubeho Neza* program includes the free distribution of the Vestergaard Frandsen LifeStraw Family 2.0 household water filter and the EcoZoom Dura high efficiency wood cookstove (Fig. 3) with associated community and household education and behavior change messaging to all households in *Ubudehe* categories 1 and 2 in Western Province. The program was implemented by the UK-based social enterprise DelAgua Health in collaboration with the Rwanda MOH, and is primarily funded through a pay-for-performance model enabled by revenues from the generation and sale of carbon credits under the United Nations Clean Development Mechanism, a program authorized by the Kyoto Protocol. Carbon credits are earned through the reduction of fuel wood from improved stove efficiency and by reduced levels of boiling under a "suppressed demand" construct [22]. To earn credits, the implementer must demonstrate actual use of the intervention hardware through repeated audits one or more times per year.

Large-scale program activities in Western Province began in September 2014, and reached over 101,000 households and nearly 458,000 recipients by December 23, 2014. Approximately 820 DelAgua and MOH trained Community Health Workers conducted community distributions and household education. In community meetings, CHWs and DelAgua supervisors conducted public health focused skits and demonstrations, collected household information, and distributed the cookstoves and water filters. Following distribution, CHWs perform household level education, focusing on correct and consistent adoption of the products. Educational tools are utilized including a picture based flipbook and interactive poster to demonstrate benefits related to health as well as livelihood and environmental benefits. Throughout the lifetime of the project, CHWs visit households approximately bi-yearly to perform further household level education activities with on-going community level engagement. Repair and replacement of products is managed by DelAgua through district level facilities with problems

Table 1
Census-derived sociodemographic characteristics, water source type, and fuel use in intervention and control sectors. Western Province, Rwanda, 2012.

Characteristics	Intervention (n = 72 sectors)		Control (n = 24 sectors)	
	Mean or count	Std dev or %	Mean or count	Std dev or %
Total population	1,854,751	100.0	616,488	100.0
Female	978,973	52.8	323,821	52.5
Children under five	280,442	15.1	94,663	15.4
Rural population	1,625,681	87.6	544,246	88.3
Mean people per square kilometres[a]	691.6	602.5	683.9	392.0
Household socioeconomic characteristics				
Mean size of household	4.5	0.3	4.5	0.2
Own house	350,485	85.8	117,668	87.2
Walls – sundried brick	283,030	69.3	95,933	71.1
Walls – wood/mud	92,864	22.7	29,343	21.7
Roof – iron sheets	193,053	47.3	53,279	39.5
Roof – local tiles	211,544	51.8	80,427	59.6
Owns TV	18,870	4.6	5052	3.7
Owns mobile phone	196065	48.0	62,511	46.3
Owns radio	230,630	56.5	75,937	56.3
Household energy use				
Main cooking source – charcoal	35,971	8.8	9123	6.8
Main cooking source – wood	360,637	88.3	121,274	89.8
Main lighting source – candle	42,629	10.4	15,065	11.2
Main lighting source – kerosene	148,098	36.3	47,274	35.0
Main lighting source – electricity	51,203	12.5	13,088	9.7
Water source type				
Piped to compound	19,315	4.7	5011	3.7
Public tap	111,950	27.4	33,868	25.1
Protected spring/well	157,405	38.5	59,181	43.8
Surface water	39,144	9.6	11,942	8.8
Household sanitation				
Toilet type – Private pit latrine	340,813	83.4	116,054	86.0
Toilet type – Shared pit latrine	43,885	10.7	12,747	9.4
Toilet type – Uses bush	6129	1.5	1337	1.0
Rubbish disposal – bush, farm or river	140,101	34.3	39,817	29.5

Note: Census data includes all households in study sectors-i.e. both eligible (*Ubudehe* 1 & 2) and ineligible (*Ubudehe* 3 to 6 households.
[a] Based on mean values in each sector.
Source: Ref. [30] Fourth Population and Housing Census, Rwanda, 2012, Main Indicators Report, Kigali: National Institute of Statistics of Rwanda

being reported primarily through a dedicated call center phone line and communications with local officials. Further details of the delivery of the interventions and associated program activities are contained in a separate process evaluation paper [5].

2.7. Primary outcomes

The primary outcomes of the sector-level study are the incidence of clinically-reported ARI (all types, severe pneumonia/severe illness and non-severe pneumonia) and diarrhea (including severe persistent diarrhea, persistent diarrhea and bloody diarrhea) among children under five in *Ubudehe* 1 and 2 categories during the 12 months of follow-up, as defined by the Rwandan Integrated Community Case Management of Childhood Illness (ICCM) diagnostic criteria [36], which are based on the World Health Organization Integrated Management of Childhood Illness (IMCI) [52].

Outcomes will be identified from data collected routinely by health authorities including outpatient and inpatient registers maintained at health posts, health centers, and district hospitals, as well as CHW-maintained registers. Together with the Rwandan MOH, health registers in these health facilities as well as CHW registers were modified to include name of the head of household as well as *Mutuelle* insurance number of patient or household member. The Rwanda MOH sent letters to all health facilities in the study area explaining the modification and encouraging compliance, and study staff have visited every health facility in order to explain the changes and assess staff fidelity in recording this information in the clinical registers. To differentiate clinic and CHW-reported cases among *Ubudehe* 1 & 2 households from those in other *Ubudehe* categories, we will use this information to link health records with a MOLG database containing the *Ubudehe* categorization of every household in the study area. Notably, this is the database that is used by the implementer to determine household eligibility to receive the intervention. We will also confirm receipt of the intervention by checking health records in the intervention sectors against a list of recipient households provided by the implementer. While health clinicians at health facilities may not be fully aware of patient *Ubudehe* status nor what sectors in their region have received the intervention and so may be blinded during the health assessment process, CHWs are aware of the allocation of patients during symptom assessment as they are based at the village level. At the end of the follow-up period, non-blinded researchers will screen all health facility and CHW registers and extract data on cases occurring in eligible households.

2.8. Secondary outcomes: intensive data-collection households

We define as secondary outcomes all of those assessed during intensive data collection in the sample of households enrolled in the village-level study. We completed a baseline survey in these households prior to program implementation and are conducting three follow-up visits, at approximately four-month intervals, during the 12-month study period. During these visits, we are assessing the prevalence of caregiver and field staff reported diarrhea and ARI among all children under five in the household (N = 2179), testing household drinking water quality, and evaluating uptake and use of the intervention, as well as collecting extensive survey data on sociodemographic characteristics, cooking practices, water source and treatment practices, and hygiene

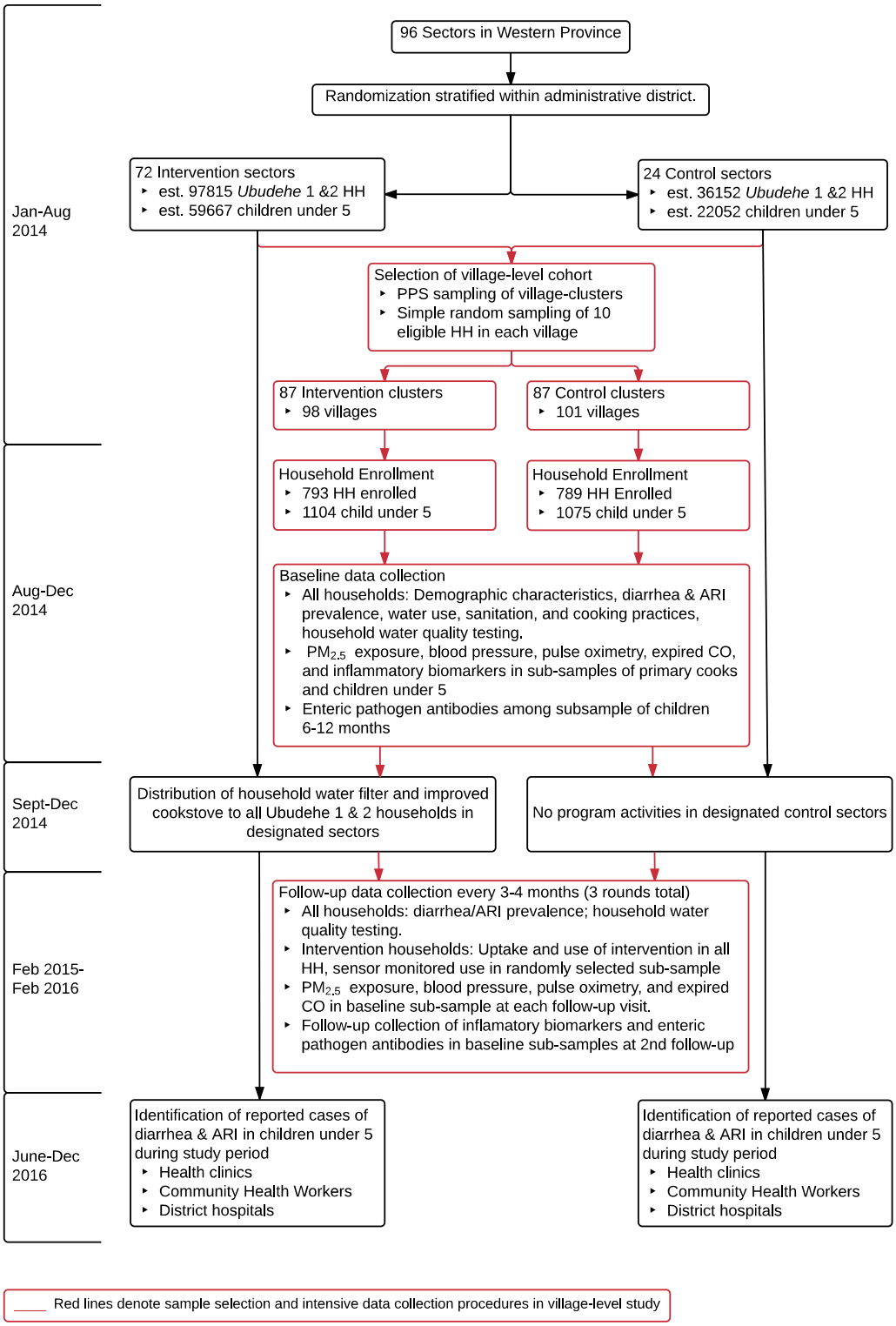

Fig. 2. Flow diagram of the study. *Note*: HH = households; ARI = acute respiratory infection; CO = carbon monoxide.

and sanitation practices among all of the households. In addition, sub-samples of the village-level cohort have been randomly selected for measurement of personal particulate matter (PM2.5) exposure, blood pressure, pulse oximetry, expired carbon monoxide, inflammatory biomarkers, and enteric pathogen antibodies. Details regarding all of these measures are provided in the sections following.

2.8.1. Reported diarrhea and ARI

Among all households enrolled in the village-level study, reported data on diarrhea and respiratory symptoms are collected from the primary caretaker for each child under five at the time of the interview that permanently lived in the household. A 7-day recall period is used for both conditions, with additional follow-up questions to determine length and severity of illness

Fig. 3. LifeStraw Family 2.0 household water filter (left) and EcoZoom Dura high-efficiency wood cookstove (right).

in the event of a positive report and to identify cases for which care was sought at a health facility or from a CWH. Regarding diarrhea, we use the WHO definition of three or more loose or watery stools in 24 h [50]. We define ARI as reported illness with cough accompanied by rapid breathing or difficulty breathing. In addition, caregivers are asked about other symptoms (fever, constant cough, blocked/runny nose, wheezing/stridor) in order to examine the impact of the intervention on specific respiratory symptoms and to construct and test more restrictive definitions of ARI. Lastly, the primary cook is assessed for reported diarrhea and respiratory symptoms at each visit. Toothache, unlikely to be related to either intervention device, was used as a negative control symptom to assess potential reporting bias [26].

2.8.2. Symptom identification using the IMCI methodology

To overcome some of the limitations of the self-reported health data, field staff trained in WHO IMCI methods will assess all children between 2 months and 5 years of age for diarrhea and ARI at baseline and at each follow-up visit. All field staff underwent one-week office and clinic-based IMCI training from a Rwanda MOH community health nurse trainer in diarrhea and ARI sign and symptom recognition including video for fast breathing, chest indrawing and stridor. Field staff were also trained on the classification of illness severity and the identification of children requiring referral to CHW or health centers. Field staff were instructed to remove any clothing covering the chest of the child for the assessment of stridor, chest indrawing and the counting of breaths. Respiratory rate is measured for one minute using a timer in a calm, rested child. Fast breathing is defined as 50 or 40 breaths per minute or more in children 2–12 months and 1–5 years respectively.

These staff-assessed signs and symptoms are combined using IMCI criteria to produce three definitions of ARI (severe pneumonia or very severe disease, pneumonia and no pneumonia (cough or cold) and three definitions for diarrhea (diarrhea with severe dehydration, diarrhea with some dehydration and diarrhea with no dehydration) according to IMCI guidelines.

Additionally, field staff assess objective indicators of nutritional status (mid-upper arm circumference, palmar pallor and edema) in all children undergoing IMCI assessment. While there is no study that directly links to cookstove exposure, these nutritional indicators can be affected by both acute and chronic illnesses [4] and so could be impacted by an intervention targeting diarrheal and respiratory infections, the most common illnesses among children under five in Rwanda.

2.8.3. Cardiovascular function, blood oxygenation and carbon monoxide exposure

A growing body of evidence indicates that exposure to indoor air pollution is a major contributor to cardiovascular disease in low and middle-income countries [6,18,31]. To assess the impact of the intervention on cardiovascular function, we are collecting objective measures of blood pressure among primary cooks in a sub-sample of 348 households. This includes all households randomly selected for personal particulate matter exposure measurement (described below) in 112 total village clusters as well as two additional, randomly selected households in the 62 other village clusters in our study. Diastolic and systolic blood pressure is measured using a validated automated Omron-705CP blood pressure device (Omron Corp, Tokyo, Japan). After five minutes of quiet rest, three seated, consecutive blood pressure measures one-minute apart are taken according to standard recommendations [58] For all participants who undergo blood pressure testing, we are collecting data on previous history and current medication for hypertension, diabetes, heart disease and kidney disease, diet, physical activity, height, weight, and waist circumference.

Carbon monoxide is a key product of incomplete combustion and carboxyhemoglobin (COHb) may therefore be an indicator of recent exposure to household air pollution. COHb levels exceeding 2.5% have been deemed unsafe by the WHO, and excess COHb levels (>5%) are associated with neurobehavioral factors, impaired vision and decreased alertness [43]. To better understand the relationship between COHb level and personal $PM_{2.5}$ exposure and to assess whether the intervention is associated with measurable reductions in COHb, we are measuring COHb saturation among all participants selected for personal particulate matter exposure measurement. Pulse oximetry is used to measure COHb saturation (SpCO), oxygenated hemoglobin (SpO_2), and pulse using a Rainbow-SET Rad-57 Pulse CO-Oximeter (Masimo Inc., Irvine, California, USA). Pulse oximetry is performed by field staff in accordance with manufacturers recommendations for use.

Expired CO may also be an indicator of recent exposure to household air pollution [24,31]. In households selected for personal particulate matter exposure measurement as well as households selected for blood pressure measurements, expired CO (ppm and % COHb) is measured using a MicroCO (CareFusion Corp, San Diego, California, USA). Measurements are conducted outside away from any smoke sources. Primary cooks and the selected child under five are instructed to hold their breaths for as close to 20 s as possible and exhale for up to 5 s. Given variable ability for primary cooks and children to hold their breath, the number of seconds is recorded and may be adjusted for in analyses. In households with personal exposure monitoring, pulse oximetry and expired CO

measurements are taken directly after the 48-hour exposure monitoring.

2.8.4. Inflammatory biomarkers

Recognizing the potential contribution of biomarker data, there are increasing calls for biomarker data to be incorporated into future clean cookstove trials [28,35]. Inflammatory biomarkers related to cooksmoke exposure, ALRI and cardiovascular disease (including interleukin (IL)-1β, IL-6, IL-8, IL-10, tumor necrosis factor-alpha (TNF-α) and C-reactive protein (CRP)) will be assessed among households selected for personal particulate matter exposure, with a target of 2 households per cluster. Enumerators collected capillary blood on Whatman 903 Protein-Saver cards (Sigma-Aldrich, St. Louis, MO). These dried blood spot samples (DBSS) were dried for a minimum of 4 h after collection at room temperature prior to placing them in sealed plastic bags with desiccant. Samples remained at room temperature for a maximum of 7 days before placing them into storage in a −20C freezer [37]. CRP will be measured through ELISA, using paired capture (anti-CRP monoclonal antibody) and detection antibodies. All other cytokines (IL-1β, IL-6, IL-8, IL-10 and TNF-α), in addition to specific cardiovascular disease markers such as sVCAM, sICAM and sCD40L will be measured through multiplex immunoassay with a dual-laser FACSCalibur flow cytometer (BD Biosciences, Franklin Lake, NJ) in Rwanda's National Reference Laboratory. This semi-quantitative method will yield mean fluorescence intensity (MFI) values that correlate with the concentration of the cytokines and disease markers in the blood sample. Analysis of DBSS through flow cytometry is dependent on validation of this particular multiplex assay with DBSS.

2.8.5. Enteric pathogen antibodies

Serological assays that assess antibody production against various enteric pathogens can provide a far more objective measure of exposure to enteric infections than reported diarrhea or diarrhea diagnosed using clinical indices in the field [16,40] characterized the age-specific seroprevalence of antibodies against various enteric pathogens, such as *Escherichia coli*, Norovirus, *Cryptosporidium parvum* and *Helicobacter pylori* and hepatitis A virus (HAV) and found the steepest increase in antibody acquisition against antigens such as *E. coli* heat-labile enterotoxin (ETEC-LT) and norovirus capsid proteins between 6 and 18 months of age. In addition, antibody acquisition against *C. parvum* surface 27kD surface antigen began to increase steadily after 12 months of age, with seroprevalence peaking and leveling out around 18–24 months of age. Together with other studies [11,23,25,44,47] that have demonstrated marked age-specific prevalence of antibodies against these pathogens between 6 and 36 months-old, the appropriate age range to assess seroconversion against WASH improvements likely lies within the 6 to 18 month-old age range.

To avoid the influence of maternal antibodies in our analyses [40], children no younger than 6 month-old were eligible for this study. To capture the time period in which children with waning maternal antibody have not fully weaned, children 6-12 month-old were enrolled at baseline and had capillary blood drawn by heel-stick or fingerstick. After 6–9 months of follow up (between June and September 2015), these children were visited again for a follow-up capillary blood sample. All blood samples will be preserved on TropBio (Sydney, Australia) filter discs. Seroconversion against *G. intestinalis* VSP1-5, *C. parvum* Cry17 and Cry27, HAV, *E. histolytica* lectin adhesion antigen (LecA), enterohemorrhagic *E. coli* heat-labile enterotoxin (ETEC-LT), *Salmonella* lipopolysaccharide (LPS) Group B and D, norovirus, *Campylobacter* spp. and *Vibrio cholerae* will be compared between intervention and control groups using multiplex immunoassay technology on the Luminex xMAP platform, as described by Lammie et al. [59].

2.8.6. Drinking water quality

Drinking water samples are tested for thermo-tolerant coliforms (TTC) at baseline and the first two waves of follow-up among all of the households enrolled in the village-level study. Field staff collect the water sample from the water container identified by the household respondent as being that used mainly for drinking by children under five. If this is other than directly from the intervention filter, a second sample is taken directly from the filter if it contained water. All water samples are collected in sterile Whirl-Pak bags (Nasco, Fort Atkinson, WI) containing a tablet of sodium thiosulphate to neutralize any halogen disinfectant. Samples are placed on ice and processed within 6 h of collection to assess levels of TTC. Microbiological assessment is performed using the membrane filtration technique [1] on membrane lauryl sulphate medium (Oxoid Limited, Basingstoke, Hampshire, UK) using a DelAgua field incubator (Robens Institute, University of Surrey, Guilford, Surrey, UK). For quality assurance, a negative control and two replicates are conducted in each batch of analysis.

2.8.7. Personal particulate matter exposure

Within 56 randomly selected intervention and 56 randomly selected control clusters, two households were randomly selected to undergo personal particulate matter exposure measurements, for a target enrollment of 224 households. Based on data from our pilot studies, we calculate that this sample size is sufficient to detect a 20% reduction in $PM_{2.5}$. To participate, the household had to have a healthy child 1.5–4 years old that could support wearing the exposure monitoring equipment which weighed approximately 1 kg, and the primary cook could not be pregnant or a current smoker.

Personal exposure of the primary cook and child under four to particulate matter less than 2.5 microns in diameter ($PM_{2.5}$) is assessed using integrated gravimetric measurements. The particulate matter is collected on pre-weighed 37-mm diameter PTFE Teflo filters with 0.2-μm pore size and support ring (Teflo, Pall Life Sciences, Port Washington, New York, USA), back supported by Whatman drain disks (Whatman GE Life Sciences, Pittsburgh, Pennsylvania, USA). During the 48-hour exposure measurement period, the sample is collected using a Harvard Personal Exposure Monitor (H-PEM) impactor with a D_{50} cut of 2.5 μm (BGI, Cambridge, Massachusetts, USA) connected by latex rubber tubing to a Casella TuffPro™ (Casella Measurement, Bedford, UK) low-flow pump set to 1.8 litres per-minute flow at one-minute intervals for 48 h. Flow is calibrated in the household immediately before and after the 48-hour monitoring period using a Challenger (BGI, Cambridge, Massachusetts, USA).

For both primary cooks and children, the H-PEM containing the PTFE filter is affixed within the breathing zone (between chest-level and mouth) in a diagonal chest strap with a pouch that held the pump for cooks, and on the shoulder-strap of a small backpack for children (Fig. 4). Participants are instructed to wear the side-pouch or backpack at all times for a 48-hour period, except during breastfeeding, bathing, sleeping or other activities as necessary, in which case the monitoring equipment is to be kept within 1 meter of the individual. To assess compliance of wearing the monitoring equipment, an unannounced spot check approximately 24 h into the monitoring period is conducted. Additionally, a HOBO Pendant® data logger (Onset, Bourne, Massachusetts, USA) set to record light sensor readings at a 1-minute resolution is affixed to the monitoring equipment of cooks and children in order to qualitatively assess compliance during daylight hours. After the 48-hour monitoring period the filters are kept refrigerated at 4 °C or lower until being processed and post-weighed.

Filters are weighed before and after deployment at Emory University. Filters are conditioned inside of their respective petri dishes overnight in a desiccator (BelArt Products, Wayne, NJ) with lithium chloride desiccant inside a safety hood for an optimal temperature of 20–23 °C [and relative humidity between 30 and 40%]. Immediately prior to each measurement, each filter was passed across an electrostatic bar and placed on a microbalance (Cole-Parmer). Measurements are stabilized for a minimum of 15 s and are performed twice for each filter. In the event that two measurements differ by more than 5 μg, a third measurement is taken. The mean of all measurements for any given filter will be used for analysis.

2.8.8. Uptake and use

Household uptake and use of the water filter and improved cookstove is assessed through a combination of self-report, direct observation by trained field staff, and in randomly selected households, sensor-recorded observations. At each visit, participants in the village-level study are asked to identify the main drinking water container in the household and report on usage and maintenance of the water filter. To assess the degree of exclusive use of the water filter, respondents are asked to report the frequency of consumption of non-filtered water in and outside the home. The field staff documents whether the water filter is present in the home and records potential indicators of use, such as whether the filter contained water at the time of the visit, whether the filter looked clean, whether it was placed on a convenient place, or had a cloth on top of it. Similarly, the respondent is asked to identify all cook stoves ever used in the household and report their current frequency of use. Objective indicators of use are collected on each stove, including the current location of the stove, whether it is in use or warm to the touch, or whether there is presence of ash or smoke marks on the stove.

In addition to household surveys and observations, which are known to present risks of reporting bias and cause reactivity [3,53], adoption and frequency of usage is assessed through the use of sensor based monitoring in a randomly selected sub-sample of intervention households for a 30-day period. In the pilot study, we evaluated the correlation of sensors on these filters and stoves against household surveys and found that sensor-collected data estimated use to be lower than conventionally-collected data both for water filters (approximately 36% less water volume per day) and cook stoves (approximately 40% fewer uses per week) [41].

2.9. Sample size calculation

Sample size calculations for the sector-level study were based on the two primary outcomes of health center or CHW reported diarrhea and ARI among children under five. In accord with recently published regional and national estimates [33,48,49]), we assume a baseline diarrhea incidence of 3.1 episodes per child-year and ARI incidence of 0.42 episodes per child-year among the study population. Analysis of data from the 2010 DHS survey in Rwanda suggest that medical care is sought for 32% of diarrhea episodes and 34% of ARI episodes among children in the lowest socioeconomic quintile in Western Province, resulting in an estimated incidence of clinic/CHW reported diarrhea and ARI of 0.99 and 0.14 respectively. The sector-level intra-cluster correlation coefficients were estimated using simulation [12]. The resulting ICC values were quite low for both diarrhea (0.01) and ARI (0.004), which was anticipated given the large average cluster size. With an estimated 59,667 *Ubudehe* 1 & 2 children under five in the intervention sectors and 22,052 *Ubudehe* 1 & 2 children under five in the control sectors, an average of cluster size of 851 *Ubudehe* 1 & 2 children under five per sector, 80% power, a 70% match rate of clinic records to the *Ubudehe* database, a design effect of 9.5 for diarrhea and 4.4 for ARI, and $\alpha = 0.05$ (two-sided test), the sector-level sample size is sufficient to detect a relative risk difference of 15% for clinician-reported diarrhea and 20% for clinician-reported ARI.

The sample size for the village-level study target the primary health outcomes of seven-day period prevalence of caregiver-reported diarrhea and ARI. Based on survey data from 2010 DHS Rwanda (13.98% 14-day prevalence of diarrhea among children under five in the lowest wealth quintile in Western Province) and data from our pilot studies (14.2% 7-day prevalence among Ubudehe 1 and 2 children in Western Province), we estimated the baseline prevalence of diarrhea among children in the control group to be 12%. In regard to respiratory illness among children in Western Province, data from the 2010 DHS Rwanda survey indicate that the baseline prevalence of cough with rapid breathing or difficulty breathing among children under five in Western province was 14.34% in the lowest wealth quintile. We chose this definition

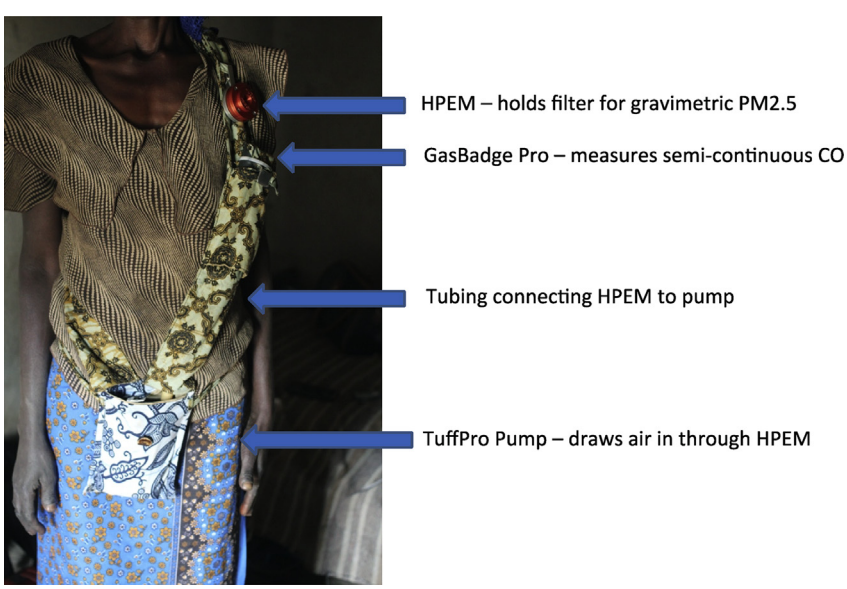

Fig. 4. Personal particulate matter monitoring device worn by primary cooks. *Note*: HPEM=Harvard Personal Environmental Monitor, CO = carbon monoxide.

of ARI (cough with rapid breathing or difficulty breathing) as it is roughly comparable to the clinical definition of pneumonia (reported illness with cough and observed tachypnea) that is the standard for health clinics and CHW's in the study area. Similar to diarrhea, we took a conservative approach relative to the DHS figures and assume a 12% prevalence of ARI in the control group.

The sample size for the village-level study was selected to achieve sufficient power to detect clinically significant differences in the prevalence of caregiver-reported diarrhea and ARI. For both diarrhea and respiratory illness, we calculated the required sample size necessary to detect a 25% reduction in 7-day period prevalence. This effect size is both clinically significant and consistent with previous studies examining the impact of household water treatment on diarrhea [60] and improved cook stoves on respiratory illness [61].

In addition to a baseline prevalence of 12%, our calculation assumes 10 children per village, a total of three post-baseline observations per child, a within-child (repeated measures) ICC of 0.05, a within-village ICC of 0.02, 15% loss to follow-up, 80% power, and a significance level $\alpha = 0.05$ (two-sided test). Estimates of within-child and within-village correlation are derived from our previous studies and simulation modeling. Based on these assumptions, we calculated that we required a minimum of 87 village clusters in each arm to detect a relative difference in prevalence of 25% or greater [20].

2.10. Data management and analysis

Clinic data will be extracted from paper-based IMCI, maternity and outpatient patient registers maintained at public health facilities and entered into a secure digital database. CHW patient-level data will be extracted from paper-based sick child encounter forms. Additionally, individual-level patient identifiers and case histories may be examined in health facility registers and CHW reporting forms in order to identify *Ubudehe* category and more fully characterize health outcomes and care-seeking behavior. A smart phone application is used by field-staff to administer the village-level surveys and data collected in this manner are synced and uploaded to a secure server.

The statistical analysis of all primary health outcomes in the study will be done on an intention-to-treat basis. Baseline data analysis will be conducted to characterize the study population and examine imbalances between treatment arms. The incidence of health center/CHW reported diarrhea and ARI in the control and intervention sectors will be compared using random-effects Poisson regression to account for the sector-level clustering and models will be adjusted for stratified randomization by district [21]. The effect of the intervention on the prevalence of caregiver-reported diarrhea and ARI in the village-level cohort will be assessed with mixed-effects log-binomial regression. Secondary outcomes from the village-level study will analyzed using generalized linear mixed models with the appropriate link function and distribution family (e.g. negative binomial for TTC counts). Analyses of the village-level sample will be adjusted for the multiple levels of clustering resulting from the study design. Analysis of secondary outcomes from the intensive data collection households will be conducted on an intention to treat basis, with per protocol sensitivity analyses.

2.11. Ethics and trial registration

The study has been reviewed by the Ethics Committee of London School of Hygiene and Tropical Medicine, the Institutional Review Board of Emory University, and the Rwanda National Ethics Committee. This trial is registered with Clinical Trials.gov (Registration No. NCT02239250).

3. Discussion

This research seeks to build on prior and existing research in multiple ways. First, previous and ongoing trials of HAP are smaller-scale, research-driven efficacy studies designed to assess the impact of improved cook stoves under controlled conditions. Our study is an effectiveness trial—a health impact evaluation of an intervention as actually delivered at scale. Though our results should be limited to the setting in which it is being delivered, they should be representative of what can be expected when the intervention is delivered programmatically.

Second, because *Tubeho Neza* program is funded through revenue earned through the generation and sale of carbon credits, it creates a mechanism for the free distribution of improved stoves and advanced water filters on a large scale. While both stoves and filters have at least a 3-year useful life, they have a comparatively high up-front cost (estimated $35 for stoves and $40 for filters by the time they reach households) that has limited the potential for governments and others to distribute them without charge to remote populations. High levels of coverage in a given population may increase the protective effect of the intervention by reducing the overall exposure of air pollution and fecal contamination in the community. This may also translate into a protective effect on non-adopters—a type of “herd immunity” that has been postulated but not shown by these environmental interventions.

Third, because carbon credits are awarded on the basis of intervention use and not just coverage, the implementer has a strong incentive to optimize use. Such pay-for-performance programs may address stove “stacking”—the continued use of traditional stoves together with the intervention stove—a well-known problem with improved stove interventions [29,34]. They may also increase adherence of household water treatment that is necessary to achieve health benefits [10,62]. Careful monitoring of actual use in the village-level sub-study, using self-reports as well as remotely monitored sensors, should provide strong evidence of patterns of use over the one-year follow up period.

Fourth, this is the first study evaluating the health effects of a large-scale intervention that combines improved cook stoves and household water treatment. In this way, the intervention is addressing pneumonia and diarrhea, the two major killers of young children both in Rwanda and many other low-income countries.

Fifth, while the LifeStraw 2.0 water filter used in this program meets the WHO's “most protective” standards [50], the EcoZoom stove falls below the Tier 3 performance level recommended by the Global Alliance for Clean Cooking and others. In fact, very few biomass stoves meet this standard; what is required is the use of clean fuels such as LPG or electricity [51,52]. Evidence on the performance level of stoves that is necessary to achieve any health gains is still somewhat limited, however, and modeling does suggest that biomass stoves—especially those that are portable and can be used out-of-doors—are capable of reducing exposure to levels associated with improvements in health [63]. By assessing personal level exposure and health outcomes in the village-level sub-study, we hope to add additional data points on the dose-response curve and help determine whether biomass stoves—the only choice that is available to remote populations that are beyond the supply chain for clean fuels—can not only reduce expenditures for fuel and green house gas emissions, but also prevent disease.

Finally, our study methods combine a large-scale trial at the clinical catchment level with a nested trial at the village level. This allows us to use clinic-based diagnoses of primary and secondary outcomes, avoiding some of the bias associated with self-reported conditions and focusing on the more serious cases that present at clinics. At the same time, the village-level sub-study allows us to carefully document coverage and use of the intervention, as well as

their impact on exposure to HAP and fecally contaminated drinking water.

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Competing interests

We have the following interests: This study was funded by DelAgua Health, a for-profit social enterprise that implements the program in Rwanda in conjunction with the Rwanda Ministry of Health. Evan Thomas and Christina Barstow, co-authors of this article, are compensated consultants to DelAgua Health, and are in charge of overseeing the implementation of the program in Rwanda.

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Behavioral Reactivity Associated With Electronic Monitoring of Environmental Health Interventions—A Cluster Randomized Trial with Water Filters and Cookstoves

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ABSTRACT: Subject reactivity—when research participants change their behavior in response to being observed—has been documented showing the effect of human observers. Electronics sensors are increasingly used to monitor environmental health interventions, but the effect of sensors on behavior has not been assessed. We conducted a cluster randomized controlled trial in Rwanda among 170 households (70 blinded to the presence of the sensor, 100 open) testing whether awareness of an electronic monitor would result in a difference in weekly use of household water filters and improved cookstoves over a four-week surveillance period. A 63% increase in number of uses of the water filter per week between the groups was observed in week 1, an average of 4.4 times in the open group and 2.83 times in the blind group, declining in week 4 to an insignificant 55% difference of 2.82 uses in the open, and 1.93 in the blind. There were no significant differences in the number of stove uses per week between the two groups. For both filters and stoves, use decreased in both groups over four-week installation periods. This study suggests behavioral monitoring should attempt to account for reactivity to awareness of electronic monitors that persists for weeks or more.

INTRODUCTION

Measurement of adoption and compliance with household-level environmental health interventions, such as latrines, water filters, and improved cookstoves, has often relied on surveys and observations. However, surveys and other common methods for assessing behavioral practices are known to have certain methodological shortcomings, including poor correlation between observations and self-reported recall.[1−4] Survey results can also be impacted by errors of interpretation on the part of the informant or the enumerator. Missing data due to participant absences or loss to follow up is another source of systematic bias. Additionally, it is known that the act of surveying can itself impact later behavior, a phenomenon known as reactivity or Hawthorne effect.[5] Structured observation, an alternative to relying on reported behavior in response to surveys, has also been shown to cause reactivity in the target population.[6,7] Finally, the subjectivity of the outcome studied can highly influence reporting bias.[8]

It is unclear whether remote monitoring may also reduce subject reactivity compared to surveys and direct observation. While study participants must be apprised of the presence of the monitor, their discrete operation without the presence of human investigators may be less intrusive and therefore engender less reactivity, especially after some initial period of installation. We undertook this study to assess the reactivity associated electronic sensor-based monitoring of household-based water filters and improved cook stoves based on weekly sensor-recorded stove and filter use between households that were told of the presence of the sensor (open arm) and households that were not (blinded arm) over a four-week installation period.

MATERIALS AND METHODS

Study Design and Implementation. The study was conducted from March to July 2015 in Western Province, Rwanda. The households selected for this study were participating in a broader health impact study of the DelAgua Health and Ministry of Health Tubeho Neza program, wherein over 100 000 households were provided with household water filters, improved cookstoves, and behavioral messaging and monitoring in 2014 and 2015. The program is described elsewhere[9] as is the design of the health impact study.[10]

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The reactivity study was designed as a cluster randomized controlled trial nested within this larger study. Consistent with the sampling design of the health impact study cited above, the unit of randomization was a "village cluster", which consists of 1−3 geographically contiguous villages that together contain a minimum of 12 households eligible to participate in the Tubeho Neza program.[10] A convenience sample of 26 village clusters were included in this trial and randomly assigned to one of two experimental conditions: blinded vs open. In both conditions, filters and stoves that were distributed as part of the Tubeho Neza program were temporarily replaced by nearly identical devices that contained concealed sensors. While households in villages assigned to the blinded condition were not informed that their usage was being recorded by the concealed sensor, households in the open condition were told that the sensor was present and that their filter and stove use was being continuously monitored. A total of 170 households consented to participate and were enrolled into the study, with 70 (41.2%) in the open group and 100 (58.8%) in the blinded group. Receipt of sensor-equipped stoves and filters occurred on average 153.21 (SD 38.48) days after households received their personal stoves and filters in the open group, and 164.99 (SD 27.78) in the closed group. While these differences are statistically significant ($p < 0.04$), there is no practical expectation that a difference of roughly 10 days of use over more than five months would impact our analysis.

The open and closed households were administered identical informed consent statements, translated into English as, "Your house has been chosen to receive this different filter and stove. You may use these in the exact same way you use your own filter and stove. We will leave these with you for 1−3 months. During this time, we will keep your own filter and stove secure, so that you can resume using them when we come back to pick up these devices. Do you agree to participate?"

Households in the closed group were simply informed that this activity related to the overall health impact randomized controlled trial in which they had previously enrolled. Houses in the open group were shown and told the function of the sensor in both the filter and stove. Following a written script, the enumerator was instructed to gather together all household members who were currently home. Those in attendance were then told they had been chosen by chance to have their filter and stove use measured for one month. After revealing the filter and stove sensors and explaining their function, the primary cook was asked to explain back to the enumerator what the filter sensor does in their own words. After the sensors had been in place for at least 28 days, field staff returned to the houses to remove the instrumented stove and filter and replace them with the household's original stove and filter.

Households were surveyed at the time of installation as well as removal of their sensor-equipped stoves and filters. Based on comments entered by enumerators, an estimated three-quarters of households reported preferring their sensor equipped stove (in both open and closed arms) because it was approximately 10 cm taller and therefore perceived to be easier to use.

In the open group, some households asked if the sensor in the cookstove would withstand heat, rain, and mud, and asked questions about theft, out of concern for the instrument. In both arms, some households reported a preference for their own filter, as the sensor-equipped filters were comparatively newer and therefore still had a residual chlorine taste and smell that dissipates after a few days of use.

In the survey that was administered at the time of sensor removal, household respondents were asked to report both the number of times that the water filter was filled and number of times that the stove was used on day of the survey and the day before the survey. Responses to these questions were collapsed into binary variables that indicated household-reported stove and filter use, and these were compared to sensor-recorded use during that time period. This comparison was limited to households with nonmissing, concurrent self-reported use and sensor-recorded water filter ($N = 86$) and stove use ($N = 89$).

Instrumentation. The sensors used in this study are a newer iteration of the technology described in Thomas et. al, 2013.[11] In the case of the water filter, the sensor records water pressure relative to atmospheric within the LifeStraw Family 2.0 safe water storage container. This water pressure corresponds approximately linearly to water volume, from a minimum of 0 L to a maximum of 5.5 L. The sensor system is entirely contained within a watertight enclosure, and includes the pressure transducer, data acquisition board, an SD card, a cellular radio and SIM card, and antenna. A riveted bracket restrains the sensor. When the water filter is fully assembled, the sensor enclosure is hidden from external view. The assembly is shown in in the cover art of this article, with the sensor in hand installed inside safe water storage container (bottom left) and the input container and water filter element shown at right.

The cookstove sensor includes a digital temperature sensor and two K-type thermocouples. The digital temperature sensor is mounted on the electronics board, while one thermocouple lead is installed between the ceramic insulation and the external metal cladding of the stove, and the other is inserted within the ceramic insulation close to the combustion chamber. The stove manufacturer, EcoZoom, specially produced stoves with false bottoms to hide the sensors. These false bottoms increased the height of the cookstove by approximately 10 cm and the weight by less than a kilogram. The stove, false bottom and sensor installation location are shown in Figure 1.

Figure 1. Temperature sensor installed within improved cookstove false-bottom. A metal cover encloses the false-bottom and obscures the sensor from view.

In both cases, the sensors record data on 5 min intervals, and automatically transmit this data over the cellular phone networks directly to the www.sweetdata.org servers daily, at midnight. This data is logged in raw form in MySQL databases, with unique tables for each sensor. Events and usage are then calculated using R (R Foundation for Statistical Computing, Vienna, Austria).

Algorithm Development and Validation—Water Filter. It was observed that daily temperature changes introduced noise to the pressure data therefore, to ameliorate the effect of temperature on pressure readings, a simple linear temperature

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correction is performed. This is accomplished by holding volume, and hence pressure, constant while varying the temperature. After recording temperature and pressure data for many different volumes, the pressure and temperature measurements along with the known pressure can be used to minimize the total pressure error in a least-squares sense. The temperature-corrected pressure is defined as

$$\hat{p}[n] = a \cdot \tilde{p}[n] + b \cdot T[n] + c$$

where $\tilde{p}[n]$ is the raw pressure reading, $T[n]$ is the temperature reading, and a, b, and c are the fitting constants. Note that this approach does not account for hysteresis of the pressure sensor. Incorporating memory into the model could result in more accurate temperature correction.

Water filtration events and corresponding volumes are calculated from the pressure data as time intervals of near-constant, positive slope. These intervals correspond to the linear increase in pressure associated with the accumulation of filtered water in the safe water storage container of the filter, where the sensor is located. To robustly calculate the slope of the raw pressure data, a linear fit is performed on a sliding 30 min window at a 1 min increment. This results in a slope estimate, $s[n]$, with a sampling period of 1 min (in the case of this data, recorded with a 5 min sampling interval, a 5 min sampling period in the algorithm would yield identical results), where n is the time index. In addition to calculating the slope of each window, the normalized residual error of the linear fit, $e_{\mathrm{LF}}[n]$, is also calculated and used as an indication of the noncolinearity of the data for each window.

Filter usage events are detected from $s[n]$ and $e_{\mathrm{LF}}[n]$ using *slope spectrum* techniques.[12] The slope spectrum provides a visual representation of the slope as a function of time similar to the spectrogram for frequency. The range of slopes observed to correspond to filter usage is divided into a number of slope ranges, or bins. A signal is created for each slope bin indicating if the slope at each time index is within the bin. This indicator signal is penalized by the error associated with the slope signal and is defined as

$$b_m[n] = \begin{cases} 1 - e_{LF}[n] & \text{if } s[n] \text{ is in slope bin } m \\ 0 & \text{otherwise} \end{cases}$$

where $s[n]$ is the slope signal, $e_{\mathrm{LF}}[n]$ is the error of the linear fit used to calculate $s[n]$, and m indexes the slope bins. When $b_m[n]$ is one the slope is within the range of slopes corresponding to bin m and the error is zero. As the error increases to a maximum of one, $b_m[n]$ will go to zero. The indicator signals for each bin are convolved with a moving averager, $h_{\mathrm{MA}}[n]$, to build up the slope spectrum. The length of the moving averager is chosen to correspond to the window length used for the linear fit calculation of $s[n]$. This process is mathematically summarized as

$$S[m, n] = h_{\mathrm{MA}}[n] * b_m[n]$$

Events are detected as time intervals when the maximum of $S[m,n]$ over all slope bins is above a specified threshold. This is achieved by first calculating a binary signal indicating when $S[m,n]$ is above the specified threshold. The binary signal is defined as

$$x[n] = \begin{cases} 1 & \max_m S[m, n] \geq 0.4 \\ 0 & \text{otherwise} \end{cases}$$

Intervals when $x[n]$ is high are identified by performing a first difference. To accurately determine the start and stop times of each event, these intervals must be padded by the 30 min window length multiplied by the 0.4 threshold chosen to calculate $x[n]$. This extra step is necessary to accommodate the ramp up and down associated with the moving averager.

After calculating the start and stop times of each filtering event, the volume of a given event is calculated by estimating the filter flow rate during that event then multiplying by the event duration. The flow rate of an event is estimated by performing a linear fit on all pressure data from that event. The event volume is then calculated as the product of the event flow rate and duration. A graphical flowchart describing this data analysis process is shown in Figure 2.

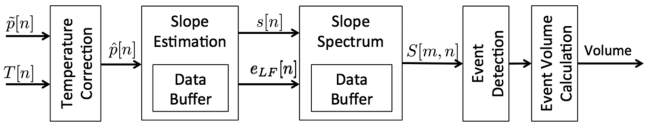

Figure 2. Signal algorithm processing steps.

An example data set from one household-sensor combination from this study, along with the output of the applied algorithm, is shown in Figure 3.

This algorithm was tuned with laboratory-derived data, and validated with a portion of the field-collected data. A simplified sensitivity (true positive rate) and specificity (true negative rate) analysis was conducted with the algorithm applied to independent field-collected data that was not previously used in calibrating the algorithm. Across 80 water filter sensor deployments, 528 events were manually identified.

The algorithm indicated a high sensitivity of 0.98. The specificity analysis assumed the rate of nonevents to be the same as true events. This conservative assumption biases the specificity analysis lower, yielding an approximation of specificity of 0.88, attributable to 70 false positives out of 528 manually identified. A linear regression of algorithm-detected events against manually identified events yielded a R^2 of 0.96 and a mean absolute volume error per detected event of approximately 5%.

Algorithm Development and Validation—Cookstove. The algorithm applied to the cookstove data was considerably more straightforward. For this study, only the manufacturer calibrated digital temperature sensor data was used, and a simple algorithm identified any periods wherein the detected temperature was above 40 °C (104 °F). This threshold was chosen as being unambiguously above the maximum ambient temperature, as verified through manual review of the clear peaks in the temperature data. Events were differentiated by periods where the temperature fell below this threshold. Algorithm validation was conducted through a simple manual review No sensitivity or specificity analysis was conducted for this simplified threshold event detection algorithm.

Statistical Analysis. Enumerators recorded unique household identification numbers, the serial numbers of installed instrumented stoves and filters, and the date and times of installation and removals. After discounting some installation and removal records due to transcription errors and removing household installation periods with no recorded sensor data (indicating sensor or cellular connectivity malfunction), the final sample was 126 households with water filter data (57 open; 69 blind) and 127 households with stove data (49 open,

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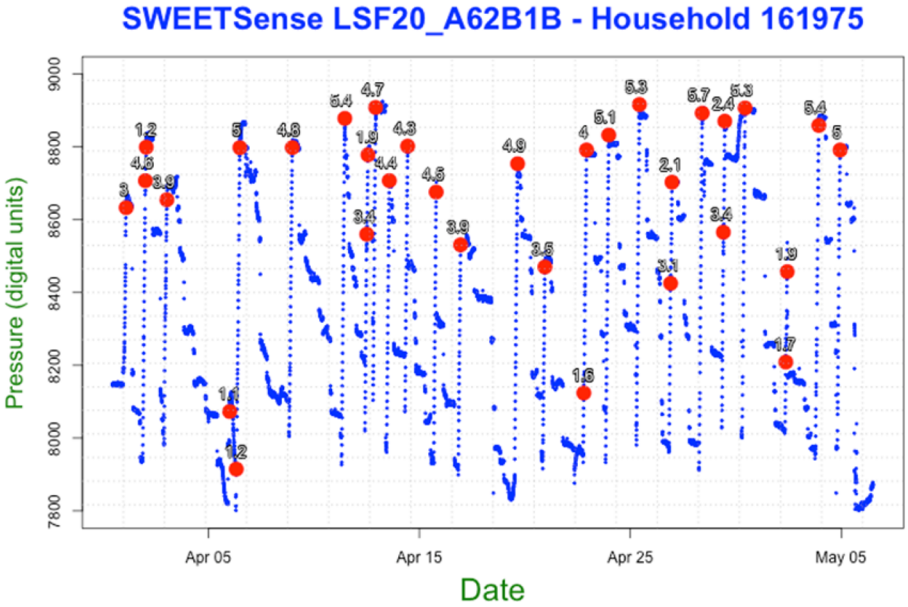

Figure 3. Example raw water pressure data from sensor installed in water filter safe water storage container (small scatter points are digital pressure units); event and volume detection algorithm applied (filled larger circles with water volume detected shown above point).

78 blind). The parsing algorithm identified gaps in the sensor record through hourly and daily data tables that identified sensor functionality separately from event detection. The calculation of household rates of use were based only on observed periods of sensor functionality. As such, the actual samples available per week over 4 weeks ranged between 117 and 126 for water filter sensor, and 106 to 127 for the cookstove sensor.

Data collected during the installation surveys were used to assess for differences in household size and baseline reported stove and filter use between the open and blinded groups. Data collected during the removal surveys were used to compare reported use to sensor recorded use in the 2 days prior to removal.

We used negative binomial regression (mean-dispersion parametrization) to model weekly sensor-recorded stove and filter use and compare the rates of use between households in the open and blinded study groups after controlling for household size. The negative binomial model is a Poisson-gamma mixture model that is robust to overdispersion.[13] The coefficient corresponding to the predicted difference between the groups was exponentiated to yield the ratio of use (RR) in the open group over the blind group. Marginal estimates of weekly use and the average marginal effects (AME) were calculated from the fitted models. Bias-corrected bootstrap 95% confidence intervals were constructed for regression coefficients and model-derived estimates. We employed a stratified bootstrap so that the proportion of open to blinded households in each bootstrap sample (2000 replications) was equivalent to the original sample. Observed significance levels were derived from the coverage of the bootstrap 95% confidence intervals. If the 95% confidence interval for the exponentiated regression coefficient corresponding to the rate ratio between the open and blinded groups failed to include 1, the effect was considered to be statistically significant ($p < 0.05$). A similar approach was taken to compare the volume of water filtered in open and blinded households, with the exception that a covariate for household size was not included in the models, as the metric of use (household volume/number of persons in the household) implicitly accounted for differences in household size.

Poisson regression was used to model the prevalence ratio (PR) of open to blinded households that used the stove and filter during a given observation week. To mitigate potential misclassification bias in households with gaps in the sensor record, this analysis was restricted to households that had recorded sensor data for a minimum of 96 h during the week in question. Lastly, within each household we calculated the average volume per fill event and then used linear regression to assess whether there were differences between the open and blinded groups in the amount of water filtered per use. For both Poisson and linear regression models, bootstrap confidence intervals were constructed for regression coefficients and model-derived estimates as described above.

■ ETHICS AND TRIAL REGISTRATION

This study has been approved by the Institutional Review Boards of Portland State University and Emory University, the Ethics Committee of the London School of Hygiene and Tropical Medicine, and the Rwanda National Ethics Committee. This substudy was part of the larger trial registered with Clinical Trials.gov (Registration No. NCT02239250).

■ RESULTS

Baseline Survey. The average household size in the sample was 5.6 (SD = 2.03, 95%CI = 5.3−6.0). Households contained an average of 1.6 children under the age of 5 (SD = 1.00, 95% CI = 1.4−1.7). There was no significant difference in household size or number of children under the age of 5 between the open and blinded arms. In regards to self-reported use at baseline, 98.0% (95% CI = 93.7−99.6) of households reported using the water filter and 95.1% (95%CI = 89.5−97.8) of households reported using the improved stove during the previous week. However, there was a high reported rate of traditional stove use concurrent with use of the improved stove. 65.3% (95%CI = 56.1−73.4) of households who reported using the EcoZoom in the previous week also reported using a traditional stove during

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Table 1. Key Reactivity Study Results by Week for Open and Blind Groups—Shaded Parameters Identify Groups with Statistically Significant Differences ($p < 0.05$)

	week 1			week 2			week 3			week 4		
	value	SE	95% CI	value	SE	95% CI	value	SE	95% CI	value	SE	95% CI
Filter Water Use—Liters/Person/Week—All Households												
open	2.620	0.290	[2.069, 3.244]	2.002	0.281	[1.511, 2.591]	2.394	0.348	[1.783, 3.150]	1.657	0.356	[1.149, 2.635]
blind	1.603	0.183	[1.254, 1.983]	1.256	0.181	[0.923, 1.631]	0.965	0.150	[0.699, 1.302]	1.068	0.177	[0.765, 1.462]
RR	1.634	0.265	[1.208, 2.240]	1.595	0.336	[1.06, 2.382]	2.480	0.563	[1.641, 3.838]	1.552	0.457	[0.942, 2.807]
Filter Use Events/Week—Controlling for Household Size—All Households												
open	4.399	0.370	[3.693, 5.142]	3.544	0.418	[2.788, 4.443]	3.675	0.448	[2.796, 4.542]	2.825	0.454	[2.046, 3.861]
blind	2.831	0.321	[2.227, 3.480]	2.259	0.344	[1.629, 2.949]	1.909	0.338	[1.328, 2.701]	1.934	0.365	[1.351, 2.820]
RR	1.554	0.214	[1.183, 2.025]	1.569	0.308	[1.082, 2.325]	1.925	0.435	[1.250, 2.905]	1.461	0.387	[0.901, 2.414]
Filter Use Events/Week—Controlling for Household Size—Confirmed Users												
open	4.709	0.342	[4.082, 5.438]	4.226	0.418	[3.450, 5.123]	4.215	0.444	[3.403, 5.122]	3.881	0.534	[2.952, 5.078]
blind	3.698	0.369	[3.007, 4.482]	3.359	0.429	[2.554, 4.239]	3.521	0.494	[2.740, 4.666]	3.465	0.539	[2.574, 4.652]
RR	1.273	0.153	[1.026, 1.633]	1.258	0.206	[0.936, 1.764]	1.197	0.204	[.859, 1.631]	1.120	0.240	[0.748, 1.667]
Proportion of Households Using Water Filter At Least Once/Week												
open	0.947	0.030	[0.876, 0.998]	0.833	0.050	[0.723, 0.922]	0.868	0.046	[0.773, 0.949]	0.736	0.062	[0.609, 0.851]
blind	0.767	0.050	[0.662, 0.860]	0.677	0.058	[0.561, 0.786]	0.542	0.066	[0.422, 0.679]	0.586	0.065	[0.448, 0.708]
PR	1.235	0.093	[1.071, 1.439]	1.231	0.134	[1.006, 1.511]	1.600	0.225	[1.227, 2.111]	1.255	0.180	[0.975, 1.693]
Mean Water Filter Volume/Use—All Households (No Significant Differences Observed for Any Week Period)												
open	2.979	0.120	[2.767, 3.238]	2.988	0.150	[2.710, 3.279]	3.317	0.151	[3.020, 3.608]	3.112	0.199	[2.731, 3.501]
blind	3.031	0.129	[2.791, 3.288]	3.202	0.196	[2.830, 3.602]	3.100	0.227	[2.675, 3.560]	3.008	0.193	[2.628, 3.395]
Improved Stove Uses per Week—All Households												
open	8.120	0.906	[6.526, 9.947]	5.793	0.951	[4.149, 7.905]	5.494	0.891	[3.989, 7.449]	4.899	0.800	[3.411, 6.539]
blind	7.128	0.659	[5.954, 8.478]	5.790	0.608	[4.615, 7.054]	4.812	0.684	[3.613, 6.381]	4.212	0.557	[3.173, 5.360]
RR	1.139	0.169	[0.867, 1.506]	1.001	0.201	[0.685, 1.468]	1.142	0.263	[0.722, 1.736]	1.163	0.266	[0.768, 1.750]
Improved Stove Uses/Week—Confirmed Users												
open	8.654	0.968	[6.839, 10.631]	6.826	0.999	[5.165, 9.073]	6.828	0.995	[5.162, 9.069]	6.071	0.819	[4.548, 7.726]
blind	7.758	0.694	[6.494, 9.274]	6.665	0.634	[5.514, 8.001]	6.782	0.780	[5.337, 8.430]	5.644	0.663	[4.410, 7.027]
RR	1.116	0.165	[0.829, 1.461]	1.024	0.181	[0.722, 1.415]	1.007	0.187	[0.712, 1.432]	1.076	0.200	[0.744, 1.521]
Proportion of Households Using Improved Stove at Least Once/Week												
open	1.000	0.002	[0.998, 1.003]	0.842	0.059	[0.710, 0.946]	0.828	0.062	[0.688, 0.938]	0.813	0.069	[0.661, 0.937]
blind	0.942	0.028	[0.883, 0.986]	0.859	0.045	[0.763, 0.937]	0.703	0.057	[0.584, 0.812]	0.768	0.058	[0.648, 0.876]
PR	1.062	0.033	[1.014, 1.136]	0.980	0.087	[0.811, 1.151]	1.178	0.132	[0.938, 1.460]	1.058	0.124	[0.841, 1.305]

that same time period. 100% of households in both arms reported woody biomass as their primary baseline fuel. There was no significant difference between study arms in the proportion of households who reported water filter use, improved stove use, baseline fuel, or traditional stove use during the previous week.

Sensor-Recorded Water Filter Use. We observed significant differences between the study groups in volume of water filtered per week, number of filter uses per week, and proportion of sensor confirmed users per week (Table 1). During week 1, the average volume of water filtered (Figure 4) in open households was 2.62 L per person (95%CI = 2.07−3.24) compared to an average of 1.60 L per person (95%CI = 1.25−1.98) among blinded households, a 63% difference (RR = 1.63, 95%CI = 1.20−2.24). The volume of water filtered declined in both open households (2.00 L per person, 95%CI = 1.51−2.59) and blinded households (1.26 L per person, 95%CI = 0.92−1.63) during week 2, but remained significantly higher among open households (RR = 1.59, 95%CI = 1.06−2.38). In week 3, the volume of water filtered among blinded households was 0.96 L per person (95%CI = 0.69−1.30), compared to 2.39 L per person (95%CI = 1.78−3.15) in open households, with a resulting increase in the magnitude of the difference between groups (RR = 2.48, 95%CI = 1.64−3.84). This observed trend of increased use in open households persisted in week 4, but the effect was not statistically significant (RR = 1.55, 95%CI = 0.94−2.81).

Households in the open and blinded groups displayed a similar pattern of differences in the number of filter uses per week in all households. During week 1, open households used the filter an average of 4.40 times (95%CI = 3.69−5.14) vs 2.83 times (95%CI = 2.23−3.48) in blinded households, a 55% increase in the rate of use (RR = 1.55, 95%CI = 1.18−2.03). As with water volume, the rate of use continued to be significantly higher in the open group in weeks two (RR = 1.57, 95%CI = 1.08−2.33) and three (RR = 1.93,95%CI = 1.25−2.91), but not in week 4 (RR = 1.46, 95%CI = 0.90−2.41). In the analysis of usage rates among the subgroup of confirmed users, we observed a trend toward increased use among the open households, although this observed difference was of lesser magnitude than that observed when comparing all households and was only statistically significant in week 1 (RR = 1.27, 95% CI = 1.03−1.63).

The proportion of households that used the water filter in a given week in the open group was significantly higher than that in the blinded group during the first 3 weeks of the study period. During week 1, 94.7% (95%CI = 87.6−99.8) of households in the open group used the filter at least once, compared to 76.7% (95% CI = 66.2−86.0) of households in the blinded group (PR = 1.24, 95%CI = 1.07−1.44). The proportion of confirmed users continued to be higher in the

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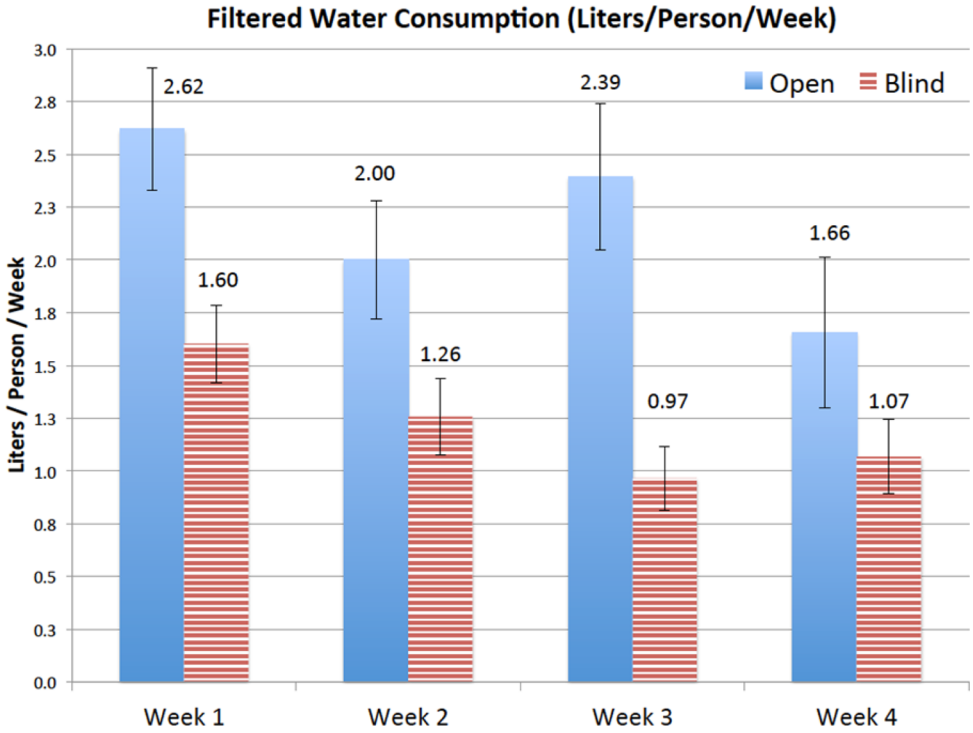

Figure 4. Filtered Water Use per person, per week among all households.

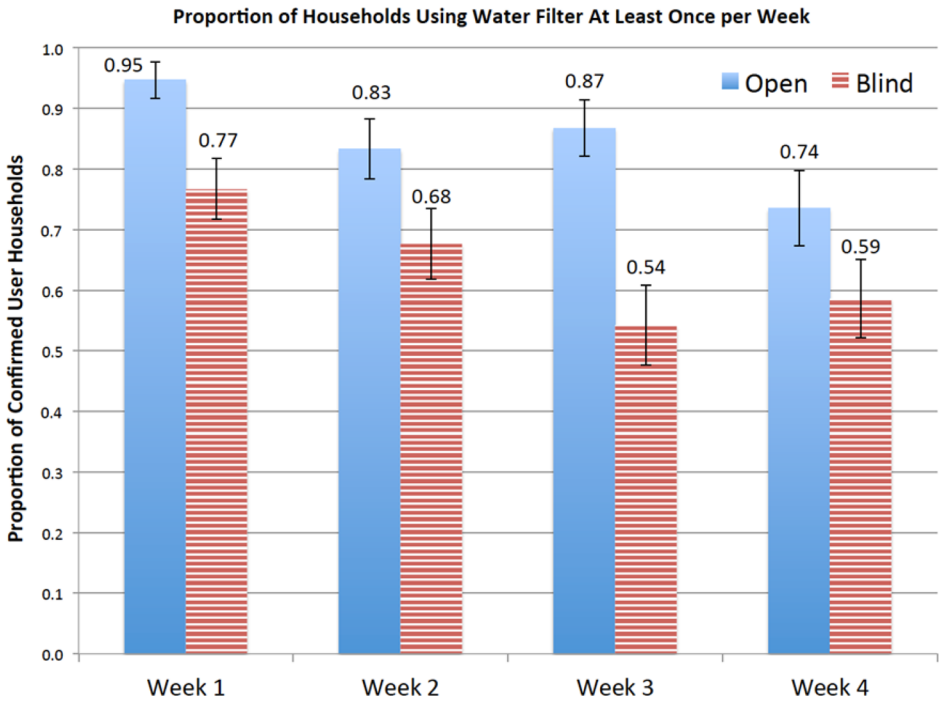

Figure 5. Proportion of households using the water filter at least once in each week.

open group compared to the blinded group in both weeks two (PR = 1.23, 95%CI = 1.01−1.51) and three (PR = 1.60, 95%CI = 1.23−2.11). Notably, the proportion of households that used the filter declined each week in both groups, with only 73.4% (95%CI = 60.9−85.1) of households in the open group and 58.6% (95% CI = 44.8−70.8) of households in the blinded group using the water filter during week 4 (Figure 5).

Lastly, we averaged the volume of water filtered during each filter use within households in order to determine whether observed increases in overall water use were partly attributable to households filtering a larger amount of water when they used the filter in addition to using the filter with greater frequency (Table 1). The average volume of water filtered per use was 3.0 L (95%CI = 2.84−3.16). There were no significant differences in the amount of water filtered per use between groups, and the amount per use did not differ across study weeks.

Sensor-Recorded Stove Use. Similar to water filter use, we observed both the frequency of use and the proportion of

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households with confirmed use in each group to be highest during week 1 and to decrease over time (Table 1). The average number of stove uses among open households was 8.12 (95%CI = 6.53−9.95) during week 1, declining to 4.90 (95%CI = 3.41−6.54) during week 4. Among blinded households, stove use ranged from 7.12 (95%CI = 5.95−8.48) during week 1 to 4.21 (95% CI = 3.17−5.36) during week 4. In contrast to water filter use, there were no statistically significant differences in the number of stove uses per week between the two groups. The proportion of households that used the stove at least once during the week was significantly higher in the open group only during week 1 (PR = 1.06, 95%CI = 1.01−1.14) and the magnitude of the difference was relatively modest (100% vs 94.2%). By week 4, the proportion of households that had at least one use during the week declined to 81.3 (95% CI = 66.1−93.7) in the open group and 76.8% (95%CI = 64.8−87.6) in the blinded group. There were no significant differences between groups in weeks two through four.

Technology Preferences. For households in which we had concurrent stove and filter data, adoption of both the water filter and cookstove in week 1 was 86.05% in the open arm, and 77.05% in the closed arm, with 11.63% of households in the open arm using only the filter, 0% using only the stove, and in the closed arm 4.92% using only the filter and 14.75% using only the stove. In week 3, 78.12% of households used both technologies in the open arm with 9.38% using only the filter and 0% using only the stove; in the closed arm 42.86% of households used both technologies, 12.24% used only the filter and 22.45% used only the stove. In week 4, this trend was not observed. These results indicate that the sensors primarily reinforce water filter use in the open arm while the stove is more consistently adopted in both arms.

Self-Reported Vs Sensor Recorded Use. Overall, 67.4% (95%CI = 56.6−76.6) of households reported using the water filter at least once on the day prior to or the day of sensor removal. The proportion of households with at least one sensor recorded water filter use was 37.2% (95%CI = 27.5−48.1). Among the households that reported water filter use during this time period, 44.2% (95% CI = 32.3−60.0) had no corresponding sensor-recorded use. In contrast, among the 32.6% of households that reported no water filter use, there was perfect correspondence with the sensor record (i.e., no sensor recorded water filter use). In regards to stove use on the day prior to or the day of sensor removal, 84.2% (95% CI = 75.0−90.1) of households reported at least one stove use, while sensors recorded stove use in only 37.1% (95%CI = 27.4−47.7) of households. Of the 84.2% of households with reported stove use, 58.7% (95% CI = 47.0−69.4) had no sensor-recorded events.

DISCUSSION

In this study, we observed significant differences between the open and blind groups for proportion of households using the water filter at least once per week, for the first 3 weeks. Likewise, there are significant differences in the number of uses per week between the groups. The differences in water volume consumed per person between groups is likely primarily attributable to the differences in the number of fill events per week. In contrast to water filter use, there were no significant differences in the number of stove uses per week between the two groups. For both filters and stoves, use decreased in both groups over the four-week installation periods. These results suggest two sources of reactivity. One, to the initial engagement with enumerators, and two, to the known presence of electronic sensors. In another recent study, reactivity to disclosed cookstove sensor installation stabilized after approximately 200 days.[14] Additionally, we observed a considerable fraction of households reporting water filter or stove use that did not correspond to sensor observed use. This lack of agreement between sensors and survey data reinforces existing literature identifying limitations of survey instruments.[15]

The lack of reactivity attributable to sensor monitoring of the cookstoves may plausibly be explained by programmatic insights. The implementer has observed that the cookstoves are more readily adopted by households, as measured through demonstrations and observational indicators of use, in contrast to the water filters that have been more challenging to reinforce consistent use.[9]

Study Limitations. In this study, we did not install sensors on baseline stoves, thereby precluding a direct comparison of "stove-stacking" behavior wherein households continue to use their baseline stove in addition to adopting the improved cookstove.

We also did not evaluate if open households reported remembering the sensor presence at the time of collection, nor if blind households had "discovered" the sensor. We hypothesize that these limitations both bias the results toward the null hypothesis of no difference between groups.

Additionally, while the instrumented water filters were identical to the noninstrumented filters, the cookstoves were aesthetically different in that they were raised above the ground by about 10 cm. While this functionally should not have impacted performance, many households (over 90% of those surveyed) reported they preferred the raised stoves over the programmatic stoves. This indication would not impact the comparison between the open and blind groups, but it cannot be entirely discounted as relevant to comparing sensor-recorded use to the broader program.

FUTURE WORK

In this study, reactivity to known presence of the water filter sensor starts to converge in week 4. However, observed differences remain and we cannot conclusively state the duration of reactivity. These results suggest that instrumented monitoring using disclosed sensors should discount at least the first 3 weeks of data, and should be installed for at least 4 weeks or more. Future work is required to determine the duration of behavior reactivity to sensors, and extend an estimate of this reactivity to other contexts and interventions.

Regardless, these results do suggest an opportunity to use sensors, and even the suggestion of sensors, to reinforce and reward healthy behavior change. For example, while cookstove adoption appears high in this study, encouraging households to cook outdoors instead of indoors (to reduce indoor air pollution and exposure), as well as discontinuing use of their baseline stove ("stove-stacking") has been challenging. A simple instrument with ultraviolet and a temperature sensors can record when cooking occurs indoors or outdoors, remind households to move outside, and reward outdoor cooking with a tally that may correspond to conditional cash transfers. Sensors installed on baseline stoves could be integrated, and households rewarded for exclusive use of their improved cookstove. These payments could be linked to the carbon credit revenue earned by implementers in several programs, including the one under study here. A similar effort is currently underway by others.[16] A similar approach could be taken with water

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filters, latrines and other interventions. The cost of the sensors used in the present study, at least several hundred dollars in production per device, limits applications across an entire household based intervention. However, advancements in technology as well as simplifications in the purpose of the sensors may in some cases reduce costs to the same order of magnitude as a household filter or stove.

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Author Contributions

The manuscript was written through contributions of all authors. All authors have given approval to the final version of the manuscript. E.A.T. was responsible for the sensor design and sensor data analysis. C.N. performed all statistical analysis. T.F.C., M.K., G.A.R., and L.Z. managed the field deployments. S.T,-S, and C.W. developed the water filter analysis algorithm.

Notes

The authors declare the following competing financial interest(s):E.A.T. and Portland State University have an ownership interest in SweetSense Inc., the manufacturer of the sensors used. E.A.T. is a compensated consultant to DelAgua Health, the implementer of the larger program containing this study. T.F.C., C.N., M.K., and L.Z. are compensated under research grants provided by DelAgua Health to their respective universities.

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