

Use of biomass briquettes: its effect on household air pollution and on pneumococcal nasopharyngeal carriage in Gambian women and young children. A Randomized Controlled Trial

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I, Teresa May Litchfield, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I conform that this has been indicated in the thesis.

ABSTRACT

Pneumonia is one of the leading causes of death in children <5 years, accounting for 1 million of the 5.9 million children <5 who died in 2015 [1], of which more than 98% occurred in low-resource countries [2]. Pneumococcal pneumonia, caused by the bacteria *Streptococcus pneumoniae* (pneumococcus), is responsible for 30-50% of pneumonia related deaths [3]. Pneumococcal carriage is a precondition for developing pneumococcal pneumonia. Ten of the most common serotypes are estimated to account for 62% of invasive disease worldwide [4].

Exposure to household air pollution (HAP) from solid fuels has been shown to be a risk factor for developing pneumonia. In 2012, over 4 million people died prematurely from illnesses attributed to HAP exposure from cooking with solid fuels [5], estimated to contribute 2.7% to the global burden of disease and 36% to contributing risk factors for acute respiratory infections globally [6]. In Africa, 94% of rural populations and 73% of urban populations use solid fuels as their primary source of energy [7].

To better understand the relationship between pneumococcal carriage and HAP, including possible interventions to reduce HAP in cookhouses, an intervention study using biomass briquettes and alternative biomass cookstoves was conducted in rural Gambia among women and young children. HAP levels were measured and nasopharyngeal swabs samples were collected to measure the effect that potential reduced HAP pollutant levels had on pneumococcal carriage. This study also assessed the cost of the intervention and whether participants would likely use such an intervention *in lieu* of the 3-stone stove and wood.

No difference in HAP levels between the two cooking methods was found in this study, nor a difference in pneumococcal carriage. Further research needs to be conducted to explore cleaner, more efficient, and less costly methods of cooking in low- and middleincome nations.

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GLOSSARY OF TERMS

- ALRI- Acute Lower Respiratory Infection
- **ARI-** Acute Respiratory Infection
- CCT- Controlled Cooking Test
- CDC- Center for Disease Control and Prevention
- CIA- Central Intelligence Agency
- CO- Carbon Monoxide
- COPD- Chronic Obstructive Pulmonary Disease
- EPA- Environmental Protection Agency
- FAO- Food and Agriculture Organization of the United Nations
- **GDP-** Gross Domestic Product
- **GNI-** Gross National Income
- HAP- Household Air Pollution
- IAP- Indoor Air Pollution
- IEA- International Energy Agency
- LPM- Liters per Minute
- MRC- Medical Research Council
- MRCG- Medical Research Council Unit The Gambia
- NGO- Non-Governmental Organization

OR- Odds Ratio

- PCV- Pneumococcal Conjugate Vaccine
- PCV7-7-Valent Pneumococcal Conjugate Vaccine
- PCV9- 9-Valent Pneumococcal Conjugate Vaccine
- PCV13-13-Valent Pneumococcal Conjugate Vaccine
- PEM- Personal Exposure Monitor
- PIC- Products of Incomplete Combustion
- PM- Particulate Matter
- PM_{2.5}- Particles with a diameter of ≤ 2.5 micrometres (µm)
- PM_{10} Particles with a diameter of 2.5-10 micrometres (µm)
- RCT- Randomized Controlled Trial

SCC- Scientific Coordinating Committee

SDG- Sustainable Development Goals

SOP- Standard Operating Procedures

STD- Sexually Transmitted Disease

UNDP- United Nations Development Program

UNICEF- United Nations Children's Emergency Fund

VT- Vaccine Type

WBT- Water Boiling Test

WHO- World Health Organization

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CHAPTER 1: INTRODUCTION

1.1 Household Air Pollution (HAP) and its Health Burden in Developing Nations

In 2016, over 2.7 billion people (38% of the world population) relied on biomass fuels in the form of wood, dung, crop waste and coal to meet their daily energy needs, especially in the world's poorest regions [8]. 80% of the population in sub-Saharan Africa and 51% in developing Asia use biomass fuels daily, most of whom reside in rural areas where cleaner forms of energy (i.e. electricity, propane) are not available or are unaffordable [8]. The world distribution of biomass fuels in 2010 is shown in Figure 1.





Adapted from INFORSE- International Network for Sustainable Energy- 2010

Biomass fuels are largely burned in open fires or in poorly performing cookstoves, resulting in Household Air Pollution (HAP)¹ in the form of health damaging pollutants [9]. HAP is the result of incomplete combustion, which occurs when the fuel and air are unable to premix fully while burning. Products of incomplete combustion (PIC) are composed of both particulate matter (PM) and gases [10]. PM is made up of solid matter suspended in liquid or gases, composed primarily of organic salts, carbons and hydrocarbons. Particles come in a wide range of sizes. Coarse dust particles (PM₁₀) are 2.5 to 10 micrometres in diameter, and are produced from crushing or grinding operations and dust stirred up by vehicles on roads. Fine particles $(PM_{2.5})$ are 2.5 micrometres in diameter or smaller, and can only be seen with an electron microscope. Fine particles are produced from all types of combustion, including motor vehicles, residential wood burning, and agricultural burning. Extensive studies have shown that exposure to small respirable particles with an aerodynamic diameter of $\leq 2.5 \,\mu m \,(PM_{2.5})$ can cause harmful respiratory effects, as well as serious public health effects [11]. They are considered the PIC most related to adverse health outcomes, and were subsequently measured in this study. The gases found in products of incomplete combustion include carbon monoxide (CO), sulphur oxides, nitrogen oxides, benzene and aldehydes.

The Global Burden of Disease 2010 project (GBD-2010) was a large international effort that was charged in part with conducting Comparative Risk Assessments (CRAs) to help estimate and better understand the portion of the burden attributable to each of the ~60 risk factors in 21 regions [12]. This group gathered only evidence classified as Class 1^2 to be included in the burden-of-disease calculations. Three components of the exposure assessment were used: 1) a global solid fuel use (SFU) model showing the number of households and percentage of population in each country that cook primarily with solid fuels; 2) an Indian model estimating average concentrations of PM_{2.5} for urban and rural

¹ At the start and duration of the study, the researchers used IAP to refer to Indoor Air Pollution. Since then, IAP has been more commonly referred to as HAP (Household Air Pollution), which is how it was referenced in this paper. The documents in the Appendices reference IAP

² "multiple epidemiologic studies of good quality in less-developed-country household settings sufficient for meta-analysis, with consistent results as well as significant and positive summary estimates, and with supporting epidemiologic studies from particle exposures both at higher and at lover exposures (Class 1a) or exposure-response data available from several particle exposure setting (Class 1b)"

households cooking with solid fuels; and 3) a global model estimating the contribution of household combustion of solid fuels to ambient PM_{2.5} levels at the national level. The group found that HAP from cooking with biomass fuel is one of the top ten global health risks [7]. In developing countries, HAP is estimated to account for 3.7% of the total global burden of disease, making it the fourth most serious health risk factor after malnutrition, sexually transmitted diseases (STDs), and inadequate water and sanitation [13]. Not only does HAP disproportionately affect the poor, but it also affects women and children who spend more time near the cooking fires and are therefore most exposed. Acute Respiratory Infection (ARI) in children is an important disease resulting from exposure to HAP [14]. A majority of these ARIs can be attributed to pneumonia, which remains one the leading cause of childhood disease worldwide, and accounts for 14.9% of all deaths of children 5 years and younger [15, 16]. Other diseases associated with HAP include chronic obstructive pulmonary disease (COPD) and lung cancer. It is estimated that 511,000 of the 1.3 million deaths in 2006 from COPD in women worldwide were directly related to exposure to HAP [17]. A summary of the association between HAP and adverse health outcomes is given in Figure 2.

| Health Outcome | Age and Sex | Evidence | Relative |
|--------------------------|-----------------|----------|----------|
| | Group | | Risk |
| Acute Lower Respiratory | Children < 5 | Strong | 2.3 |
| Infection (ALRI) | | | |
| Chronic Obstructive | Women ≥ 30 | Strong | 3.2 |
| Pulmonary Disease (COPD) | | | |
| | $Men \ge 30$ | Moderate | 1.8 |
| Lung Cancer (coal) | Women ≥ 30 | Strong | 1.9 |
| | $Men \geq 30$ | Moderate | 1.5 |

Figure 2: HAP exposure and health outcomes by age group and sex

Smith et al., 2004

1.2 Exposure-Disease Relationship

Many research studies have contributed to identifying HAP from solid fuel as a risk factor for ARI. A review in 2000 of published evidence which analyzed the association of HAP and health effects showed an increased risk of respiratory infections with biomass fuel use in 10 of the 15 studies (OR range, 2.2-2.9) [18]. A recent meta-analysis found that children under 5 years old living in households using biomass fuels had a 78% greater chance of contracting pneumonia than did children in households with cleanerburning fuels [19]. A study from Ecuador found over twice the odds of infant mortality among households using biomass fuels compared to those using liquid petroleum gas [20]. Before this study was conducted in 2011, very few published studies had been able to show evidence of a dose-response relationship [21, 22]. Of the few studies which had, one study in Kenya looked at 93 infants from 55 villages and found that the benefits of reduced exposure to PM_{10} are larger if the average exposure is less than 1000-2000 micrograms per cubic meter ($\mu g/m^3$) [23]. A randomized-controlled trial in Guatemala (commonly referred to as the RESPIRE study) randomly assigned 534 households with a pregnant woman or young infant to receive a woodstove with chimney or to remain as controls using open wood fires [24]. Personal sampling of PM_{10} and CO in over 500 children was collected over 18 months. Personal sampling of PM₁₀ calculates the particulate matter that individuals are exposed to by using battery-powered pumps worn by the participants. This study found that a 50% reduction in personal exposure to CO led to a 25% reduction in physician-defined pneumonia and a 33% reduction in severe hypoxemia pneumonia [24, 25].

Because of the difficulty in measuring exposure, most observational studies use proxies as a way of measuring exposure to HAP. These proxies include the type of fuel used, amount of time spent near the cooking fires, or whether the child is carried on the mother's back during cooking. However, because variations in personal exposure depend on a variety of factors (e.g. fuel, cookstove, housing, and behavioral factors), using proxy indicators can be an insufficient method to effectively capture variations in exposure [22]. These challenges limit our understanding and appreciation of the potential health

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gains that might result from reducing exposure to HAP. Determining this exposuredisease relationship is crucial to understanding the possible impacts that interventions may have on improving health [26]. The large disease burden associated with HAP exposure requires extensive research of these HAP pollutants [27].

1.3 HAP and Sustainable Development Goals

Addressing HAP from cooking fires can potentially make an important contribution to achieving several of the Sustainable Development Goals (SDG). Foremost, reducing Acute Lower Respiratory Infections (ALRI), COPD and Lung Cancer (among women) will help to ensure healthy lives and promote well-being for all at all ages (Goal 3). This includes improving child and maternal health and other diseases. It may also help to ensure access to affordable, reliable, sustainable and modern energy for all (Goal 7) by identifying alternative fuels for developing nations. Lastly, this study will address Goal 15, which aims to sustainably manage forests, combat desertification, reverse land degradation, and halt biodiversity loss.

1.4 Cookstove and Fuel Interventions

There are multiple factors that influence the ambient concentrations of pollutants found in the cooking area. The first factor is cooking with biomass fuels, such as coal, wood, crop waste, charcoal and dung. In 2004, a data compilation was done of studies that had measured pollutants in developing countries. Concentrations of PM₁₀ averaged over 24 hours were found to be in the range of 300-3,000 μ g/m³ [28]. This is in contrast to the Environmental Protection Agency's (EPA) annual air pollution standard of <50 μ g/m³, which is 1-10% the amount that is found in developing countries [29]. Other forms of fuel, such as electricity, natural gas, liquefied petroleum gas, and biogases are considered cleaner fuels [25]. See Figure 3 for a visual of the PM₁₀ and CO levels off different fuels.



Figure 3: PM₁₀ and CO levels of various fuels (per meal)

EarthTrends, 2007 (sources: Smith et al., 2000)

The second factor influencing pollutant levels in the cooking area is the use of inefficient cookstoves. Typically traditional biomass cookstoves achieve a combustion efficiency of less than 60-90%, meaning that between 10 and 40% of the energy in the fuel is not converted to heat, but retained in a large range of PIC. Alternative biomass cookstoves aim to increase thermal efficiency, which is essentially how much energy in the fuel the pot absorbs. Although a majority of these cookstoves concurrently reduce pollutant levels, it is not always the case.

The third main influence is ventilation and removal of smoke from the cookhouses. This can be in the form of flues, chimneys, windows, and other means of accessing outside air. Better ventilation entails diverting the smoke outside, resulting in less concentration of pollutants in the cooking area. One such intervention in Mexico is the Patsari cookstove, which is an alternative wood-burning cookstove with a built-in flue to help direct the smoke outdoors [30]. A study was conducted in Central Mexico to assess the impact of the introduction of Patsari cookstoves on the respiratory health of young children in highlands Michoacán. Use of the Patsari cookstove (as reported by the mother) was found to have a protective effect on the upper and lower respiratory infection duration of the children, compared to households that used traditional open fire cookstoves [31].

When alternative biomass cookstoves were first introduced over 30 years ago, their main objective was to use less fuel, thereby addressing the increasing deforestation problems in many countries [32]. It was generally assumed that the alternative biomass cookstoves would reduce exposure to HAP, yet experience has shown that this was, and still is, often not true. More efficient cookstoves that save fuel have been found to emit more PIC emissions than the traditional 3-stone cookstove [33, 34]. Today, there are currently several hundred cookstove projects and studies worldwide (alternative biomass cookstoves with or without a chimney/flue), most of which aim to reduce both fuel use and pollutant emissions [35]. A majority of the cookstove studies measure impact through quantifying the reduction in PM and CO levels, and most have seen reduction of emissions by 35-85% [23, 36]. However, reductions in local intervention studies do not necessarily translate into real everyday reductions at full scale.

Evidence indicates that water-boiling tests (WBT) performed in a controlled laboratory, and controlled cooking tests (CCT) performed in a simulated cookhouse are not representative of cookstove performance during daily cooking activities. These tests are based on the assumption that performing a simple cooking task produces estimates that can be used when evaluating technology for developing populations [37]. Often, alternative biomass cookstoves perform well in a lab setting (efficiency), but perform

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poorly in real day-to-day life (effectiveness). This can result from a number of factors, including house structure and ventilation, fuel factors (size, moisture content), cooking behaviours, family factors (food cooked and for number of people), weather factors, and source factors (other cookstoves, tobacco) [38].

Another reason why a cookstove might perform better in the laboratory is that cookstoves made in developed countries for testing might differ greatly from cookstoves that are reproduced in the developing countries and disseminated to the populations. Typically, organisations that promote cookstove projects prefer to have cookstoves reproduced in the country using local artisans to promote sustainability and keep costs down. But these cookstoves are often replicated using less rigorous materials and with altered specifications, often resulting in cookstoves that emit the same or more HAP emissions than the traditional 3-stone cookstove. Quality control is important with the introduction of any intervention, especially when the intervention can be more detrimental to the health of the user than the original cookstove.

A third reason why alternative biomass cookstoves might not perform as well in the field is because local women in a village will employ the cookstove differently than trained technicians in a controlled laboratory. The women might not use the cookstoves as efficiently as possible nor maintain and clean the cookstoves properly. Also, as women are often juggling numerous household tasks simultaneously, they might not be tending to the cookstove as closely as the cookstove technicians, thereby resulting in adverse performance of the cookstove. This includes not stoking the cookstove at the optimal time or adding wood when needed. A study entitled "Up in Smoke: The Influence of Household Behaviour on the Long-run Impact of Improved Cookstoves" showed that the alternative biomass cookstoves tested generally reduced smoke exposure for the cook during the 1st year, but after normal use they had no effect on exposure [39]. The decline results from cookstove breakage, insufficient cookstove maintenance, fewer meals being cooked with the alternative biomass cookstoves, and inappropriate use.

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Though alternative biomass cookstoves have been shown to reduce pollutant emissions, the points cited above demonstrate why they are often unsuccessful in reducing pollutant levels in real cookhouses in developing countries. Other interventions to reduce pollutant levels need to be explored, such as the use of alternative biomass fuel *in lieu* of wood. A study in 2003 in rural Kenya looked at modelling potential reductions in disease following interventions including fuel, cookstove type and cooking location. This study showed that the biggest reduction resulted from switching fuels and not cookstoves [7]. Though charcoal is known to be a cleaner fuel, it has been estimated that 1kg of unconverted wood is equivalent, in terms of energy content, to 2.5kg of charcoal, meaning charcoal consumes more resources per energy content than wood [40]. There are many studies currently studying crop waste as an alternative fuel. A Bio-Energy Modernization Demonstration Project in China is developing combined heat, electricity and cooking fuel production from corn stalks [10]. Crop waste varies greatly with locality and therefore techniques for processing different forms of crop waste need to be explored.

1.5 Nasopharyngeal Carriage of Streptococcus pneumoniae

Pneumonia accounts for 14.9% of deaths of children under the age of 5 in developing countries, most resulting from *Streptococcus pneumoniae* (pneumococcus) [15, 16]. *S. pneumoniae* is part of the normal upper respiratory tract flora and can become pathogenic under certain conditions (e.g., if the immune system of the host is suppressed). Pneumococci colonize the nasopharynx in many people, but identifiable disease occurs in only a small percentage of people who are colonized [41]. In children, the nasopharynx often becomes colonized within the first months of life [42]. The pneumococcal carriage rates in children in developing countries are generally 2-3 times higher than those found in children from developed countries [41]. In one study in The Gambia, it was found that pneumococcal carriage was greater than 80% during the third month of life [15]. In another study in Bangladesh, it was found that 50% of the children had been colonized by pneumococci at least once by the age of 8 weeks [43].

Pneumococcal conjugate vaccine (PCV) is a conjugate vaccine used to protect infants, young children and adults against disease caused by *S. pneumoniae*. Immunizing a large percentage of a population through the implementation of a PCV immunisation program is one approach to reducing the pneumococcal disease burden. Recommendations for PCV use from the World Health Organization (WHO) and funding from the GAVI Alliance have resulted in an increase in PCV introductions into national immunization programs, especially in lower-income countries [44]. PCV was first licensed in 2000, and provided protection again seven of the most common pneumococcal serotypes [44]. This vaccine is commonly referred to as PCV7 and contains the following serotypes: 4, 6B, 9V, 14, 18C, 19F, and 23F. The routine use of PCV7 in the United States of America has led to a marked decrease in the incidence of invasive pneumococcal disease [45]. Additionally, the introduction of PCV7 in South Africa in 2009 was found to be associated with reduced rates of invasive pneumococcal disease in young children and adults [46].

In 2012, the Pneumococcal Carriage Group (PneumoCarr) published a paper looking at the fundamental link between pneumococcal carriage and disease. After reviewing the evidence for the direct effects of pneumococcal vaccination (8 pneumococcal conjugate vaccine trials with data on the concurrent direct vaccine effect on colonization and disease), the authors concluded that the magnitude of direct PCV effect on vaccine type pneumococcal colonization is around 50% [47]. The efficacy of PCV against *S. pneumoniae* infection can be broken into two components: vaccine efficacy against acquisition of pneumococcal carriage, and vaccine efficacy against pneumococcal carriage progressing to *S. pneumoniae* [47].

As nasopharyngeal colonization is a necessary before infection with *S. pneumoniae* can occur [48], preventing colonization from ever happening can be an important measure to preventing *S. pneumoniae* infection. HAP exposure is one major risk factor for developing ARI, and understanding the impact HAP exposure has on colonization can help us better understand the quantitative relationship between exposure and disease. There have been multiple studies aimed at looking at the effects of second-hand cigarette smoke on pneumococcal carriage. A systematic review and meta-analysis conducted on 5 previous cross-sectional studies that looked at the impact second-hand tobacco smoke has on pneumococcal carriage found a significant positive association [49].

Recently, there has been more research done looking at the effects HAP exposure has on pneumococcal carriage, bringing to light this heavy health burden in developing countries. In 2014, The Lancet Respiratory Medicine Commission published an article in *The Lancet Respiratory Medicine* entitled "Respiratory risks from household air pollution in low and middle income countries"[50]. The authors reviewed evidence for the association between HAP and respiratory tract infections in children and infants. Two of the studies they reviewed used neonatal mortality as an endpoint because ALRIs are the leading cause of mortality in children aged 2 months to 5 years worldwide. One review published in 2013 found a pooled odds ratio (OR) of 1.14 (95% CI 0.87-1.48) for neonatal mortality in households using solid fuels [51]. A second study reported that neonatal death in India was strongly associated with household use of coal, with an OR of 18.54 (CI 6.31-54.45) [6].

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Another meta-analysis was conducted on 27 studies using morbidity endpoints in children from households using solid fuels. The study reported a summary OR of HAP and pneumonia (ALRI) of 1.78 (95% CI 1.45-2.18) [19]. Another meta-analysis of eight studies produced a summary risk ratio for acute respiratory infections of 3.53 (1.93-6.43) [52]. A 2013 case-control study with ALRI in Nepalese children 36 months or younger looked at electric cookstoves, kerosene and solid fuel [53]. They found a significant association of ARLI with kerosene (OR 1.87, 95% CI 1.24-2.83) and solid fuels (1.93, 1.24-2.98). All this evidence from these studies has confirmed the strong association HAP has on ARLI, and the necessity to address this global health problem.

1.6 The Gambia - a Case Study

Fuel and Cookstoves in The Gambia

Wood represents the major source of domestic energy in The Gambia. It accounts for over 80% of total energy consumption and more than 90% of household energy consumption in the country [54]. In the rural areas, this proportion is as high as 97% [54]. Approximately 70% of the population lives in rural areas, obtaining their wood locally from farmland, fallow land, bush, or the collection of deadwood from nearby forest, accounting for 60% of total wood use. Analysis has suggested that up to 90% of the woody vegetation harvested in The Gambia is used for fuel [40]. In an attempt to govern the harvesting of wood in The Gambia and to increase the efficiency of the wood utilized for energy purposes, the government of the Gambia banned the production of charcoal in all regions of the country in 1980, yet charcoal is still being manufactured illegally or is brought in from Senegal. According to the Office of the President of The Gambia in February 2016, the ban on charcoal production "still remains in force", despite 60% of the rural population relying on charcoal production for their daily living needs [55]. Today, the majority of the population in The Gambia is still using the traditional 3-stone cookstove with firewood to cook their meals. Charcoal is primarily used for smaller cookstoves, making attaya (the local tea), and ironing.

In October 1982, The Gambia launched the first National Cookstoves Project (with financial assistance from UN Sundano-Saheian Office- (UNSO) [54]. This project was a direct result of the 1980 ban on charcoal production, and the need to create more efficient cookstoves. Since then, many organizations (both government and non-government) have been involved with numerous development programs and projects aimed at addressing the rapid deforestation issues that were becoming more visibly apparent. Many variations of alternative biomass cookstoves were introduced, all aimed at using lesser fuel to help curb the deforestation trends. These cookstoves also aimed to lessen the wood collection burden for women and children in rural areas, and to reduce fuel expenses in urban areas. Concurrently, there were other smaller cookstove projects happening in The Gambia, but

the objective of reducing exposure to HAP was seldom addressed in these earlier project proposals.

Almost all cookstove programs came to an end during the late 1980s when government funding ran out and interest in alternative biomass cookstoves decreased [56]. During the 1990s, though there was little national interest in cookstove programs in The Gambia, some smaller, more localized cookstove programs were being initiated by nongovernmental organizations (NGOs) and private companies. When this study was conducted in 2011, a few cookstove projects were in existence, most of which are no longer running at the time of this thesis. One such project was the Mayan Turbo Cookstove project, which was funded by the Tourism Industry Carbon Offset Services and Serenity Holidays [57]. They partnered with REAP (Resource Efficient Agricultural Production) to disseminate locally made cookstoves to Gambian communities. These cookstoves were designed to burn agricultural by-products of rice husks and groundnut shells. An example of a current cookstove project in The Gambia is the Gasifier Cookstove Project, which is being implemented by Concern Universal in The Gambia, with support from the Biomass Energy Initiative for Africa of The World Bank (BEIA) [58]. Berkeley Air (a monitoring and evaluation partner for clean cookstove and fuel programs in developing countries) is charged with collecting data during the baseline monitoring campaign, including measurements of household air pollution, fuel consumption and cookstove usage. The primary objective of these alternative biomass cookstove projects is to reduce fuel consumption, though most have also included emission reduction as a secondary objective. Although these alternative biomass cookstoves are being promoted and disseminated to local populations, many of the organizations do not have the capacity to test their cookstoves to determine whether pollutant emissions from them are actually lower than the tradition 3-stone cookstove.

Much less work has gone into developing alternative biomass fuels in The Gambia. Groundnut production is a large industry in West Africa, accounting for 6.9% of its gross domestic product (GDP) in The Gambia in 2002 [59, 60]. During the past 10 years, there have been a few small projects that aimed to turn crop waste into energy (see Section

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3.1.3- Fuels Tested). As with the local cookstove programs, these organizations lacked the resources to test the biomass briquettes made of groundnuts to determine how they compare to wood and charcoal in terms of pollutant emissions. The shells are plentiful in most of West Africa, and, if the biomass briquettes prove to be a cleaner fuel than wood, groundnut shells would show great promise as a possible large-scale fuel source for the local population.

Pneumococcal Carriage in The Gambia

Prior to the introduction of PCV7 in The Gambia in 2009, a number of studies were carried out to determine the characteristics of pneumococcal carriage in the Gambian population. A longitudinal study to determine nasopharyngeal Carriage of *S. pneumoniae* in infants was carried out in rural Gambia. It found that almost two-thirds of the isolates identified in the study were either of a vaccine or vaccine-related serotypes [15]. Another study that looked at the nasopharyngeal Carriage of *S. pneumoniae* in Gambian villagers found a prevalence of 72% overall, and a prevalence of >90% among children aged <5 years [61]. A population-based survey was also conducted prior to the introduction of PCV into routine immunization, which found the prevalence of nasopharyngeal carriage to be 72% among children aged <5 years, 42% in children aged 5-17, and 13% in adults \geq 18 years [62].

From 2000-2004, a randomized trial was conducted in The Gambia to assess the efficacy of a 9-valent (PCV9) pneumococcal conjugate vaccine in children. The study showed 77% efficacy against invasive pneumococcal disease caused by vaccine serotypes and 50% efficacy against invasive pneumococcal disease overall [63]. In 2006, WHO recommended that PCV7 be included in all routine immunization programs, especially in countries with a high prevalence of pneumococcal disease [44]. In 2009, The Government of The Gambia introduced PCV7 into the national expanded program of immunization (EPI). In 2010, PCV9 became available, which contained the original 7 serotypes, and included two more: 10 and 13. By 2012, 21 (36%) of 59 high-mortality countries and 38 (37%) of 102 countries in which >10% of deaths in children aged <5 years were attributable to pneumonia had introduced PCV [44]. PCV's adoption into

childhood immunization programs worldwide has been faster than that of any other new vaccine [64].

Since the introduction of routine pneumococcal vaccinations in children in The Gambia, several studies have looked at whether vaccination protects against the carriage of vaccine type serotypes. Between 2003 and 2008, a cluster-randomized trial was conducted to determine the impact of PCV7 vaccination of pneumococcal carriage in rural Gambia. A time trend analysis showed a marked fall in the prevalence of vaccine type pneumococcal carriage in all age groups following vaccination, indicating a "herd-effect" in non-vaccinated older children and adults [65]. Additionally, no significant serotype replacement was identified. Serotype replacement occurs when a vaccine targets a specified number of serotypes (in this case 7 serotypes), leaving a niche for other invasive serotypes to occupy. Between 2008 and 2014, a population-based surveillance for invasive pneumococcal disease was conducted in the Upper-Region of The Gambia. It found that the Gambian PCV program reduced the incidence of invasive pneumococcal disease in children aged 2-59 months by around 55% [66]. In 2011, The Gambia switched to PCV13 in its routine immunization program. WHO and UNICEF estimate that in 2013, The Gambia reached a PCV vaccination coverage of 96% [67].

Medical Research Council Unit The Gambia

The Medical Research Council Unit The Gambia (MRCG) was established in The Gambia in 1947, and is the UK's single largest investment in medical research in a developing country. The Unit's research focuses on infectious diseases of immediate concern to The Gambia and the continent of Africa, with the aim of reducing the burden of illness and death in the country and the developing world as a whole. The unit's main operational base is located in Fajara, which is approximately nine miles from Banjul, the capital city of The Gambia. There are three smaller field stations in Basse, Keneba, and Wali Kunda, all of which are located inland from Fajara. The Fajara station is equipped with a fully functioning laboratory complex (full GCLP accreditation and ISO 15189 accreditation standards), which is where all the nasopharyngeal samples for this study were taken, stored, and analyzed. Additionally, this main operational base houses a large

data management center, which uses a SQL Server based system and OPENCLINICA to manage the data. As a research fellow with MRCG, the author was based at the Fajara field station, and worked directly with the laboratory and data management staff.

1.7 Scope of Doctoral Work

This thesis evaluates whether the use of biomass briquettes made from groundnut shells³ and alternative biomass cookstoves⁴ reduces $PM_{2.5}$ concentrations in participating domestic cookhouses, and whether, in consequence, nasopharyngeal carriage of *S*. *pneumoniae* in mothers and children who are using the alternative cookstoves/briquettes is reduced. See

Figure 4 and Figure 5 for diagrams of the questions the thesis attempts to answer.





Figure 5: Gaps in our understanding of exposure-disease link



³ Also referred to as biomass briquettes throughout the paper

⁴ At the start and duration of the study, the researchers use 'Improved' cookstove to represent the cookstove that was tested. After noticing its' little, if any effect on HAP, the author changed it to alternative biomass cookstoves. They are more simply referred to as alternative cookstoves throughout the paper

The author was responsible for the conception on the thesis study, as well as the execution of the pilot study, main study, analysis and final write-up. While designing study, she consulted her supervisors MRC staff (medical doctors, laboratory technicians, etc) as well as other researchers who had previously conducted 'improved stove' studies. All the questionnaires were designed by the author. During the execution of the pilot study, focus groups, and main study, the author led the investigation and sought out advice when necessary. She worked closely with the entire MRC staff during the duration of the study, specifically the data team to ensure the data was inputted correctly, and the laboratory team, to ensure the NPS samples were analyzed on a timely basis. The author was responsible for cleaning all the data. During data analysis, the author did all the analysis on her on, but checked in frequently with the statistician in London to verify that the work was conducted properly. Lastly, the thesis was written entirely by the author, which input from various members of her PhD team, most specifically her two supervisors.

1.8 Aims and Objectives

Overall Aim

The first aim of this study was to assess whether biomass briquettes made from groundnut shells burn 'cleaner' than wood. The second aim was to evaluate whether reduced exposure to harmful pollutants leads to a reduction in pneumococcal carriage levels, which may ultimately lower the incidence of severe pneumonia among children under 5 in developing countries.

Primary Objectives

- 1. To compare PM_{2.5} concentrations in both control and intervention households
- 2. To assess the prevalence of Pneumococcal carriage in women before and after the intervention
- 3. To assess the prevalence of Pneumococcal carriage in children before and after the intervention

Secondary Objectives

- 1. To calculate the cost effectiveness of using an alternative biomass cookstove with biomass briquettes compared to a 3-stone cookstove with firewood
- 2. To conduct an analysis of local perceptions towards the biomass briquettes
- 3. To assess serotype-specific pneumococcal carriage prevalence in women and children

CHAPTER 2: DESIGN & METHODS

2.1 Study Setting and Population

The Gambia is located in West Africa and is the smallest country on mainland Africa (refer to map of Africa in Figure 6). It has 50 km of Atlantic Ocean coastline on its west side, and is surrounded on the remaining three sides by Senegal (Figure 6). It is approximately 11,300 km² and extends 400km inland along the Gambia River. The capital of The Gambia is Banjul. The country has a population of 1.85 million with an annual population growth of 3.2 % [68]. The average life expectancy in 2013 was 58.8 years with a median age of 19.9 years [69]. The adolescent population between 10 and 19 years comprises 23.2% of the total population, with roughly 18% under the age of 5 [70]. The crude birth rate in 2013 was 42.7/1000, infant mortality (under one year of age) was 49 deaths per 1000 births [69], and under-5 mortality rate in 2013 was 74 per 1000 live births. Muslims make up 90% of the population, and the main ethnicities are Mandinka (42%), Wolof (18%), and Fula (18%).

Figure 6: Map of The Gambia within Africa



http://johniezzi.wordpress.com

The Gambia has a slave trade history similar to that of other West African nations. The Empires of Ghana (5th to 11 centuries) and Mali (13th to 15th centuries) dominated the region that is now The Gambia. By the mid-15th century, the Portuguese had built settlements on the Gambia River and quickly monopolized trade along the West African coast, exchanging guns and cloth for gold and slaves. By early the 17th century the English, Dutch and French were also trading in West Africa, though this ended for the Dutch by the 1650s. For 150 years the Europeans made huge profits by transporting African slaves across the Atlantic. It was finally the British who took control of The Gambia and eventually abolished the slave trade in 1807. The Gambia became a British protectorate in 1820 and a colony in 1886. In 1965, The Gambia gained its independence from the United Kingdom [71, 72]. Since then, there has been relative stability in The Gambia. President Jawara led the country from 1970 until a coup in 1994 overthrew his government. Yahya Jammeh became president and presided until 2017, when he was replaced by Adama Barrow [73].

On the coastal region where the study was conducted, The Gambia has a hot tropical rainy season between June and November, and a cooler dry season from November to May. Inland, the cool season is shorter, and daytime temperatures reach quite high between March and June. Approximately 40% of the land in The Gambia is arable, of which less than half is cultivated [74]. Though The Gambia economy relies most heavily on tourism and nationals working abroad, about three-quarters of the population depend on the agricultural sector for their livelihood. Agriculture accounts for approximately 21.6% of its total GDP and employs about 75% of the labor force [74]. The Gambia has a gross national income per capita of US\$510 [69], leaving roughly a third of the population living below the international poverty line of US\$1.25 a day. The UNDP's Human Development Report for 2013 ranks The Gambia 172 out of 187 countries on its Human Development Index [75], putting it in the 'Low Human Development' category. This index compares life expectancy, years of schooling, Gross National Income (GNI) per capita and other factors.
The study was conducted in the Kombo East District of The Gambia, under the auspices of MRCG. Kombo East District is a rural area located approximately 100km from Banjul, and has a population of roughly 30,000 residents (based on a 2012 census taken by a demographer at MRCG). Refer to Figure 7 for a map of this area. Kombo East is predominantly Mandinka, which is the largest ethnic group in The Gambia. A majority of the Mandinka population lives in family compounds in traditional autonomous and self-ruled villages, which are typically led by chiefs (Alkalos) and elders of the community villages. The compounds are often composed of over 20 family members as most of the married Mandinka men are polygamous and have up to 4 wives living in the same compound. The women share the cleaning, farming, cooking and childcare, and raise the children together as one large family. The Mandinka people are often rural subsistence farmers, relying on agriculture and small-scale husbandry for their livelihood. This particular group of Mandinka is located on a main thoroughfare not far from the larger towns, which enables them to transport and sell their crops to larger populations.





http://en.wikipedia.org

Kombo East District was chosen for this study because:

- Its close proximity to MRCG and the biomass briquette factory (approximately 100km) facilitated the transportation of the briquettes as well as ensuring that the NPS samples arrived at the MRC Unit in a timely manner
- Much of the population had already been involved in or were aware of previous MRCG studies, so they were sensitized to the work done at MRCG
- 3. There was an up-to-date census, which helped with the recruitment process
- 4. The villages were adequately sized in order to recruit enough participants (approximately 30,000 people total)
- 5. MRCG fieldworkers were familiar with the area and spoke the local language, which aided with the execution of the fieldwork
- Most of the women cooked with traditional 3-stone cookstoves and wood in enclosed cookhouses separate from the main house, which were prerequisites for becoming a participant in the study

The sample size of the study determined the scope of our study catchment area. Based on an annual birth number of 77,000 and an infant mortality of 72 per 1000 live births, there were roughly 31 babies per 1000 population born each year that lived past one year of age. A sample size of 200 babies in one year required a catchment of around 6,400 people (refer to section 2.7.1 to reference how the sample size was calculated). Based on the 2012 census, the total population Kombo East was 27,944. From these calculations, 9 villages with similar characteristics (demographics, distance to main road and cooking practices), and, when combined, totalled an appropriate population number. The villages chosen to participate in this study were: Mandina Ba, Kuloro, Berending, Pirang, Faraba Kairaba, Faraba Banta, Faraba Sutu, and Kafuta.

2.2 Timeline

Figure 8: Timeline of the study

| Study | Time | Events | | |
|---------------|-----------------------|--|--|--|
| Pilot Studies | Spring 2011 | Pilot Study Phase 1 | | |
| | Fall 2011 | • Pilot Study Phase 2 (with biomass briquettes) | | |
| Carriage | December 2011 | Conducted demonstrations and focus groups | | |
| Study | February (week 1 & 2) | Sensitized villages and women | | |
| | | • Recruited participants: Information Sheet, Consent Form, | | |
| | | Locator Form | | |
| | | • Randomly allocated mothers into either intervention or | | |
| | | control group | | |
| | February (week 3) | Collected 1 st NPS | | |
| | February (week 4) | • Trained intervention groups on using alternative biomass | | |
| | | cookstoves and biomass briquettes | | |
| | | Began Fuel distribution | | |
| | March-May (15 weeks) | • Distributed fuel on a weekly basis | | |
| | | • Measured HAP in each participating cookhouse (one 48 | | |
| | | hour measurement per cookhouse) | | |
| | | Administered Household Questionnaire | | |
| | | Administered Intervention Assessment Questionnaire | | |
| | | (intervention group only) | | |
| | June (week 1 & 2) | Collected 2nd NPS | | |
| | | Concluded study | | |

2.3 Study Design

2.3.1 Choice of Study Design

Choosing an appropriate study design is paramount to running any successful study with results that are as valid and precise as possible. Epidemiological studies fall into two main categories: observational studies and experimental studies [76]. Observational studies draw inferences about exposures on study participants based on natural group allocation. Behaviors are observed in a systematic manner without any interference by the researchers. Generally, observational studies tend to be less expensive to run, and because there are no interventions on behalf of the researchers, they are less intrusive to participants. Examples of observational studies include: Case-control studies, cohort studies, cross-sectional studies and ecological studies. For this particular study, it was necessary to consider whether any of the observational study designs would be appropriate for the study. Confounding is a potential problem with all observational studies, regardless of the study design.

The first study design considered was a case-control study. The main objective of this study design is to estimate the strength of association between the exposure of interest and an outcome [77]. A case-control study attempts to identify all people who have developed the disease of interest in a defined population, and then compare them to a disease-free group (the control or reference group) selected from the same population. All the participants' exposures to the suspected risk factor of interest are then examined to determine whether the exposure increased the probability of developing the disease. This study design has advantages if group allocation is outside the control of the researcher, the outcome being studied is rare, for mortality studies, and for looking at multiple risk factors for a single outcome. In this particular study, a case-control design would not have been appropriate for a number of reasons, the main being that briquettes were not widely available in The Gambia, and therefore there would not have been an exposed study population large enough to study. Additionally, as the prevalence of pneumococcal carriage is quite high, it would have been difficult to include all carriers in a defined population.

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The second kind of observation study considered was a cohort study. The essence of this study design is to follow a group of people over a period and observe specified health outcomes [77]. For a prospective cohort study, participants of both groups are disease free at the start of the study and differ only with respect to exposure of interest. At the completion of the study, the two groups are compared and a determination is made whether the exposure of interest had any effect on disease outcome. For a retrospective study, a population has already developed the disease of interest. The researchers identify a 'cohort' of people back at a predetermined time point before the onset of disease and establish their exposure status at that time. The exposure status is then used to determine whether exposure is associated with occurrence of disease. A cohort study design is ideal when wanting to observe the temporal sequence between exposure and outcome. It also allows the researchers to calculate the incidence of disease over a set period of time. This study design is also effective for researching rare diseases. However, it was not an ideal study design for this study because 1) there are many known risk factors associated with pneumococcal carriage other than exposure to household air pollution. This would have made it difficult to calculate the association of exposure to household air pollution; 2) babies as young as 2 months old were enrolled in our study, making it impossible to trace back to exposure; and 3) as for the case-control study design, the use of briquettes was quite limited in The Gambia, making it difficult to identify enough people who were not exposed to the particulates from indoor cooking fires.

The third study design considered was the cross-sectional study. The main objective of this study design is to assess the burden of disease in a set population [78]. Data from the study population was collected once, which gives a general estimate of the prevalence of an outcome or exposure at any given point. The main problem with this study design is that it is difficult to determine the temporal sequence of exposure and outcome. Because of this, it is not possible to calculate an accurate association between exposure and outcome. One of the main objectives of the IAP study was to determine whether the use of briquettes in place of firewood reduces pneumococcal carriage in children and their mothers, so the cross-sectional study design was not appropriate.

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A fourth study design considered was an ecological study. This study design is based on the measurement of one or more variables within a number of set groups, or populations living in different areas, such as counties, states or regions [79]. This kind of study allows researchers to compare between groups, as opposed to an individual level. One example of an ecological study would be comparing the prevalence of obesity between one or more ethnic groups in The United States. This study design is intended to provide an indication of the trends within a particular population or demographic group, but not among individuals within the groups. Although an ecological study would have been able to provide an overall pneumococcal prevalence level among participating populations, it would have been incapable of assessing the effectiveness of an intervention in reducing pneumococcal carriage.

Because of the limitations of observational studies, experimental studies were also considered; including community based epidemiologic studies and randomized controlled trials. With a cluster randomized intervention study, the intervention is allocated on a cluster or community level, meaning everyone in a designated area receives the intervention [80]. This study design enables researchers to assess the effectiveness of an intervention by comparing the incidence of disease in the intervention communities compared to the incidence of disease in the control communities. One example of a community based epidemiologic study might be the installation of a water pump in selected communities in a developing nation. The researchers would be able to calculate the incidence of severe diarrhea among participants (i.e. community members) living in a village with a water pump and compare it with the incidence of severe diarrhea among participants living in communities without a water pump. Cluster randomized studies can handle interventions like a pump which cannot be given to individual households but only to a whole community. They can also take into account mass effects such as herd immunity. For the HAP study, a community based epidemiologic study would not have been the ideal study design because it would have required that all members of the selected community agree to use the intervention (alternative cookstove and briquettes). Any non-compliance would have been detrimental to the overall calculations and led to

invalid results. The intervention in the HAP study was not only invasive but it required major behavior changes among the mothers participating in the study. Therefore, a community-based approach was not ideal.

The other type of experimental study, a randomized controlled trial (RCT) is considered the gold standard for measuring an intervention's impact. It is the most rigorous way of determining whether a cause-effect relation exists between treatment and outcome [81]. The strength of an RCT is based on the process of randomization, which is unique to this type of epidemiological study design. It enables researchers to test the efficacy and/or effectiveness of an intervention within a set population, thereby allowing them to assess whether the intervention affects the risk factor of interest. Random allocation of subjects to study groups is used to ensure that the intervention and control groups are similar in all respects (distribution of potential confounding factors) with the exception of the preventative measure being tested. When done correctly with large enough study samples, random allocation is an effective approach to reducing bias while simultaneously generating an internally valid impact estimate, though bias is still possible without blinding.

Random allocation can be achieved in multiple ways. One of the easiest and most basic approaches is simple random allocation. Group assignment is made by chance without regard to extenuating circumstances, such as personal preferences, prior involvement in studies, etc. Good methods of creating allocation sequence include using a random numbers table or a computer software program, both of which can generate a random sequence. Manual methods such as tossing a coin or throwing a die can also be used. Whichever the method chosen for group allocation, the most important factor is making sure the method is random and cannot be manipulated for individual interest.

In a standard RCT, study participants are randomly assigned to one of two groups: the experimental group receiving the intervention that is being tested, and a comparison group (controls), which receive a conventional treatment or placebo. The control mimics the counterfactual. The counterfactual is defined as what would have happened to the

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same individuals at the same time had the program not been implemented [82]. In other words, the control group does not receive any intervention. These two groups are then followed prospectively for a set period of time to assess the effectiveness of the intervention in the experimental group compared with the standard or placebo treatment in the control group.

There are many benefits to using a randomized trial: 1) as both study populations are treated the same excepting for the intervention, any differences in outcome can be directly related to the intervention; 2) it is the strongest type of epidemiological study from which to draw conclusions of causality; 3) it provides a clear temporal sequence as the exposure clearly precedes outcome; 4) it minimizes bias from the use of blinding; 5) it can measure disease incidence and multiple outcomes; and 6) randomization helps control for confounding, even by factors that may be unknown or difficult to measure. Some weaknesses of a RCT include: 1) ethical constraints concerning the manipulation of exposure at random; 2) it can be expensive and time consuming compared to other study designs; 3) it is inefficient for rate diseases or diseases with a delayed outcome; and 4) subjects in a RCT may be more willing to comply with intervention and therefore may not be representative of all individuals who might receive the intervention. Overall, the author judged that an RCT was the most suitable study design for this particular study. As one of the primary aims of the study was to compare PM_{2.5} concentrations in both control and intervention households, it was appropriate to test them in a typical Gambian population that was solely reliant on traditional wood/3-stone cookstove for all their cooking needs. Furthermore, this study design enabled the participants to be followed closely for a set period of time to ensure they were following the study protocol and abiding by all necessary standards. Another primary objective of the study was to assess the prevalence of Pneumococcal carriage in women before and after the intervention. This study design enabled the researchers to randomize the study population, which ideally controlled for all possible confounders. Randomization was achieved by allocating women alternately to each group, in the order in which they were officially enrolled in the study. By taking biological samples from all the participants at the start of the study (to assure the two groups are similar), and then again at the

completion of the study, any differences between the two groups in the 2nd biological samples can be attributed to the intervention. The third primary objective was to test the effectiveness of the alternative cookstove/briquettes compared to the traditional 3-stone cookstove/wood. Once again, randomization ensured that measures were taken to reduce any biases or confounders among the cooking methods that might alter the study results.

The final study design chosen was a Randomized Control Trial, consisting of two groupsthe intervention and the control groups. The intervention group would receive two alternative cookstoves and biomass briquettes made from peanut shells while the control group would continue using wood over the tradition 3-stone stove. NPS samples would be collected at the start and termination of the study. Throughout the 14 weeks, household characteristics would be collected from all participants, as well as HAP measurements. At the end of the study, the women from the intervention group would be administered an assessment questionnaire. Refer to Figure 8 for the complete timeline.

2.3.2 Subjects and Inclusion Criteria

The inclusion criteria were:

1. Women with a child or children between 2 and 8 months of age during the recruitment period

The study populations chosen to participate in this study were women and their babies (between 2 and 8 months at the start of the study) because of their exposure to HAP. The women (and their babies who are often tied to their backs) spend large portions of their days and evenings in their cookhouses cooking with wood and traditional 3-stone cookstoves. Furthermore, babies of this age are more prone to be carriers of pneumococcal infection. According to a study conducted in The Gambia in 2005, the prevalence of *S. pneumoniae* carriage was 97% among children aged <1 year [61]. In another study also conducted in The Gambia,

researchers found the prevalence of pneumococcal carriage to be >80% among infants in the third month of life and remained at 80%-90% until the age of 11 months. The mean age at first acquisition of carriage was 33 days [15]. Based on the results of these two studies, infants 2-8 months at enrollment were chosen for this study. By 2 months of age, babies have been shown to be carriers of pneumococcal infections. And at 8 months at recruitment, they were still under a year of age four months later when the 2^{nd} NPS sample is collected.

2. Women residing in one of the nine selected villages

These nine villages were our study catchment area where fuel would be distributed on a weekly basis. Anyone living outside of this catchment would not have access to her allocated fuel.

3. The mother relies solely on wood and 3-stone cookstoves for all her cooking.

This is important because the wood/3-stone cookstove is not only our control but is also our reference point at the start of the study. Before the intervention began, all women and babies were swabbed, which gave us the pneumococcal carriage prevalence for women using wood/3-stone cookstove. If they owned and used a gas cookstove, they were not allowed to participate in the study because it was assumed that their carriage prevalence would be lower at the start of the study. This is based on previous research findings that gas cookstoves are cleaner (refer back to 1.4) and therefore the author hypothesized that the risk of being a pneumococcal carrier would be considerably less for those using a gas cookstove.

4. The mother cooks the meals in an enclosed cookhouse.

If the woman cooked her meals in an open-air cookhouse, the author hypothesized she would be exposed to fewer PM than a woman cooking in an enclosed cookhouse because the particulates would disperse into the open air.

5. The mother will not be travelling outside of her village during the next 3 months. It was imperative that the women and their babies were followed for 3

straight months to verify they are only using the fuel allotted to them. If a woman was allocated to the intervention group (which entailed using briquettes) and traveled for 1 month to another village where she used wood, it could affect the results because she and her baby would no longer have been exposed exclusively to briquettes during the study period. Furthermore, sometime during the 3-month period, the study team had to measure the HAP in the cookhouse area and administer a Household Questionnaire to the woman. If she was travelling, the timing of the HAP Measurement and Questionnaire would no longer be random, which would possibly affect the study result.

6. The mother has agreed to participate in the study.

Consent was vital in this study.

While recruiting the participants, households were allocated in a 1:1 ratio alternately to the intervention group (using an alternative cookstove and briquettes) and the control group (the traditional 3-stone cookstove and wood) in the order they were recruited (i.e. control, intervention, control, intervention). The laboratory staff and data personnel were blinded to group allocation of the participants, HAP measurements and pneumococcal carriage status.

2.3.3 Non-Participation and Withdrawals

During the initial information meetings, the women were informed that they were not obliged to participate in the study and that it was completely voluntary. There were a total of 266 mothers who initially signed up for the study. 15 women were ultimately dropped before official enrollment: one woman declined to have her baby swabbed, six women had to withdraw because they lacked permission from their spouses, and eight women travelled before the first swabbing. Of the 251 mothers who officially enrolled in the study, 17 withdrew during the course of the study, all from the control group. Ten of these women had travelled so were unable to complete the study. Three of the women decided they no longer wanted to participate due to personal reasons. Four of the women had to pull out of the study because their spouse no longer wanted them to participate. Of the 251 enrolled women, 234 (93.2%) were ultimately available for analysis. See Figure 20 for a flowchart of the participants.

2.4 Study Stages

2.4.1 Pilot studies (to be discussed in Section 3.1)

2.4.2 Initial Recruitment

The Alkalos (village chiefs) of all nine villages were approached before the start of the study. This enabled the fieldworkers to fully explain the purpose of the study and to obtain permission from the Alkalos to proceed with the study in their respective villages. Informal informational meetings were then held for the village population in each of the participating villages, whereby residents were able to get their questions and concerns addressed. At the end of the meetings, women who met the criteria and wished to participate in the study had to agree to adhere to their allocated fuel for the duration of the study, as well as agree to give pneumococcal carriage samples at the start and termination of the study. They were then asked to complete a consent form, which officially enrolled them in the study.

During the recruitment period, all participants had the study thoroughly explained to them and given an information sheet (Appendix A). All the interviews with the women during the study were conducted in Mandinka, which is the mother tongue in the participating villages. There were no participating women who did not speak Mandinka or who requested the interviews be conducted in another language other than Mandinka. After making sure they understood the study and asking if they had any questions or concerns, they were invited to sign the consent form (Appendix B). Any woman who was unable to sign her name was able to place her thumbprint on the form in lieu of a signature. At this time, Locator forms (Appendix C) were completed for each woman, which detailed the location of her compound. This locator form would assist the fieldworkers throughout the study in locating the compounds for fuel distribution and PM measurements. The women were also issued ID cards, which allocated the participants into either the control or intervention group. The fieldworkers followed a list and alternated which group each woman was allocated to. The only exception to the 1:1 ratio (i.e. every second participant is placed in the control group) was if there was more than one woman from her compound participating in this study. In this case, all the women from the same compound would be allocated to the same group, as it is logistically impossible for women using the same cookhouse to be using different fuels.

2.4.3 1st Pneumococcal Carriage Sampling

After the completion of the recruitment period, 3 trained nurses assisted the fieldworkers with the first NPS sampling. All the women were notified on the day they were recruited as to which day the field team would be visiting their villages for swabbing. In most of the villages, ~75% of the women/babies showed up in a timely manner for the swabbing. The other women were then tracked down at their compounds or gardens and transported by an MRC vehicle to the swabbing venue. The fieldworker completed the NPS form for each mother/baby, and then a nurse conducted the swabbing. This 1st swabbing took approximately 5 days to complete. In all, 252 mother/baby pairs (including 5 twins) samples were collected, totaling 509 NPS samples. During this 1st NPS swabbing, the women in the intervention group were also informed of the date and time the fieldworkers would be back to train them on how to properly use the briquettes and cookstove.

2.4.4 Training Women to Use Alternative Biomass Cookstove and Biomass Briquettes

Prior to the training, all three fieldworkers were trained at the GreenTech factory on how to light the briquettes and maintain a constant flame. They then took this information to each of the villages and taught all the women in the intervention group how to properly use the alternative cookstoves and briquettes. During these training sessions, the women were able to practice lighting the briquettes, feeding the alternative cookstove and maintaining constant heat. Once the women felt comfortable with this new technology, they were given two alternative cookstoves and a bag of 30kg of briquettes to take home and practice with. The women had approximately one week to become familiar with using the briquettes/alternative cookstoves, and were visited periodically during this time by the fieldworkers to address any issues.

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2.4.5 Fuel Distribution

After the one-week practice period, all the participating women began receiving fuel on a weekly basis for the duration of 16 weeks. The women in the control group received 7 bundles of wood/week, while the women in the intervention group received 60kg of briquettes. This amount of fuel was generally sufficient enough to sustain the cooking cookstoves of most of the compounds for one week. A few of the larger compounds received more than 60kg of briquettes, as it was necessary to be sure that they would not run out of briquettes by the week's end. This would assure us that they were using briquettes for all of their cooking. During these weekly fuel distribution visits, the fieldworkers monitored the women to observe if they were using their allocated fuel, as well as to detect if there were any problems to be addressed.

2.4.6 HAP Measurements

During the 14-week study period, all participating households were measured for $PM_{2.5}$ emissions over a 48-hour period (the specifics of this are discussed in Section 4.3), and information was recorded on the IAP Measurement Form (Appendix E). Households received the HAP measurement equipment on Mondays and Thursdays, and it was collected on Wednesdays and Saturdays. At the start of the 48 hours, the field workers set the HAP measurement equipment up in the cookhouse of each participant, in accordance with the protocol. All the equipment was installed approximately 100cm from the cookstove. During these 48 hours, the women were instructed not to tamper with the pumps, and to continue cooking as they wound normally do. At the end of 48 hours, the field workers retrieved the equipment and noted any problems that had arisen over the course of the 48 hours. After collecting the equipment the field workers cleaned and prepared the filters for the following day.

When the Household Questionnaires were conducted during the 16-week study period, a cookhouse description section was included. It was important to collect this information because certain cookhouse characteristics could potentially affect the household pollution

levels in the tested cookhouses. The dimension of each cooking area was calculated by multiplying length by width (m²). The volume of the each cookhouse area was calculated by multiplying length by weight by height (m³).

2.4.7 Household Characteristics Questionnaire

During the 14-week study period, each household was visited in random order in order to conduct the Household Characteristics Questionnaire. Table 1 lists all the information collected on this form.

2.4.8 Intervention Form

Also during the 16-week study period, all the mothers in the intervention group were administered a questionnaire, which inquired about the ease and feasibility of using the alternative cookstoves and briquettes.

2.4.9 2nd Pneumococcal Carriage Sampling

After all the HAP Measurements had been taken and the Household Questionnaires and Intervention Forms were administered, a 2nd NPS sample was collected at 14 weeks after the 1st NPS sample collection. The same three nurses once again assisted the fieldworkers with this process, which took approximately one week to complete. At this time, fuel distribution came to an end, and the women were thanked for participating in the study.

| Child's Information | | | |
|--|--|--|--|
| Gender | | | |
| Breastfeeding practices | | | |
| Weight | | | |
| Height | | | |
| Mother's Information | | | |
| Date of birth | | | |
| How many years of school completed | | | |
| If she can read or write | | | |
| Whether she smokes | | | |
| Household Characteristics | | | |
| Number of people living in the compound | | | |
| Number of people living in the same household | | | |
| Number of people who share the house with the child | | | |
| Number of people who sleep in the same room as the child | | | |
| Number of people who share the same bed as the child | | | |
| Number of people <5 in the compound | | | |
| Who looks after child most of the time | | | |
| Does the child hang out in or around the cookhouse | | | |
| Where the child spends most of their time while the mother is cooking | | | |
| Where the mother does most of her cooking during the rainy and dry seasons | | | |
| Whether the mother shares the cooking area with other households | | | |
| Number of cookstoves used in the cookhouse | | | |
| Whether the mother cooks for neighbours or to sell on the street | | | |
| Whether windows are opened while cooking | | | |
| Whether other smokers live in the house, and if so, how many and where do they smoke | | | |
| Whether rubbish is burned in the compound | | | |
| The hours the cookstove is in use during the day | | | |
| The number of days the mother is responsible for cooking | | | |
| The dimensions of the cookhouse | | | |
| The height of cookhouse | | | |
| Number of doorways | | | |
| Number of windows | | | |
| The size of gap between walls and ceiling | | | |

Table 1: Household characteristics collected during study

2.5 Training and Quality Assurance

2.5.1 Field Work

For this study, three fieldworkers and three nurses were trained to carry out their respective responsibilities. The fieldworkers participated in a 3-day training seminar and administered a Standard Operating Procedures (SOP) for the Carriage Study (Appendix M). The three fieldworkers had worked previously on other studies at MRCG so they were already familiar with all the different departments within the Unit. Furthermore, one of the fieldworkers had already worked with the HAP equipment on previous studies (Effects of community-wide vaccination with PCV-7 on pneumococcal nasopharyngeal carriage in the Gambia: a cluster-randomized trial [65]; Childhood pneumonia and crowding, bed-sharing and nutrition: a case-control study from The Gambia) [83] so he was able to take the lead and train the other two fieldworkers. During these three days, the fieldworkers practiced using the HAP equipment and familiarized themselves with the questionnaires, information sheets and consent forms. They were also informed of the schedule of events during the duration on the study, when and how to collect data, and any other information relevant to the study. The three nurses (whom had already participated in previous NPS collection studies) reacquainted themselves with these procedures. They worked with the fieldworkers in establishing a system for NPS collection in the field. They were also educated about risk factors and other medical issues relevant to this study. For the duration of the study, the nurses were responsible for following up on the wellbeing of the study participants.

As the pneumococcal carriage survey was carried out in accordance with the WHO protocol for evaluation of pneumococcal carriage [84], it adhered to high levels of quality assurance, including measures for avoiding contamination during swabbing, transportation of specimens using a cold chain, and serotyping in the laboratory. The three trained fieldworkers were responsible for training the women on how to use the briquettes and cookstove, conducting all the interviews, collecting the HAP measurements and distributing the fuel during the 14 week study period. Furthermore,

they assisted the three trained nurses with the NPS collection at the start and end of the study.

Many carriage studies had previously been conducted at the MRC Unit so all field workers and laboratory technicians had previously received relevant training. Prior to the start of the study, a refresher course was held to verify that all the field workers and nurses were up-to-date with the proper specimen collection procedures.

For the intervention study, periodic visits were carried out at all the households to assure that the exposed and unexposed participants were complying with all the terms of the study, including using only the designated fuel, performing all the cooking tasks, and not tampering with the HAP equipment. Strict protocols were followed to assure that HAP equipment was properly set and adjusted before setting it up in each of the households.

2.5.2 Data Processing and Management

The author worked closely with the data management team at MRC. The field workers followed strict protocol and filled the forms out to the best of their ability while in the field with the participants. At the end of each day, the forms were handed over to the PI of the study, who made sure all the forms were completed, that they were properly corrected should any errors have occurred, and that the data entered were appropriate responses for each of the questions. The forms were then signed over to the data management team and the data were doubled entered in OpenClinica version 2.5. After data entry, the PI cleaned the data to make sure there were no errors. Any errors detected were forwarded to the data manager who located the original forms to compare and apply corrections if necessary. All data entry and data management followed the data management protocol at MRC.

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2.6 Measurement of Exposure and Outcome

2.6.1 Measurement of Exposure

The exposure of interest can be defined as the main factor that may be associated with an outcome of interest [49]. How do nature, dose and rate of the exposure affect an individual's chance of developing the outcome of interest? The exposure of interest may be associated with either an increased or decreased occurrence of disease or other specified health outcome, and may relate to the environment (e.g. air pollution), lifestyle (e.g. smoking), and inborn or inherited characteristics (e.g. fair skin). There are a variety of exposures of interest that have a direct (or indirect) effect on our health and wellbeing. These include, but are not limited to: environmental exposures, demographic variables (e.g. income, education), genetic traits, and behavioral traits (e.g. smoking, diet).

Often exposures can be readily measured using biological tests or other means to give a precise measurement of exposure. But often times, true exposures (or the exposure of interest) can be difficult to measure, such as socioeconomic status. In these cases, researchers often use proxy variables or indicators to give them an idea of the level of exposure. For example, when measuring the socioeconomic status of an individual, one might use income brackets to classify the participants into specific groups, though the numbers or groups might not accurately represent the participants. For any epidemiological study, it is crucial to define clearly, not only the primary exposure and outcome that the researcher is interested in, but also any other exposures that might influence the outcome.

There are many ways to collect exposure data, and the method one chooses depends greatly on the exposure of interest. Some common ways are with questionnaires (selfadministered or via interviews), diaries, biological measurements, and measurements in the environment. Each of these methods has its pros and cons, and all can be useful for obtaining certain information.

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The primary exposures of interest in this study were particulate matter from cooking cookstoves ($PM_{2.5}$) and Carbon Monoxide (CO). These environmental exposures were measured in the cookhouses using specialized equipment, which will be explained in detail below. Other exposures that were looked at that might have a direct impact on the outcome includes: whether the participants smoke, socio-economic indicators, and whether they burn rubbish in their yards. This information was collected through questionnaires that were administered by the trained fieldworkers in an interview format. These questionnaires also address the duration of exposure to the cooking fires.

2.6.2 Household Air Pollution

For this study, the author was interested in measuring the particulate matter of less than 2.5 micrometers in diameter, otherwise referred to as $PM_{2.5}$. These particulates and liquid droplets are emitted from the cookstoves/fuel during the cooking process. To measure integrated $PM_{2.5}$ concentrations, gravimetric Casella pumps (set at 1.8 liters per minute (lpm)) were used, attached with a cyclone, 37mm 3-piece clear styrene cassette, and Teflon filter (see

Figure 9). The Teflon filters were pre-weighed in the Harvard School of Public Health Laboratory and then sent back for re-weighing at the end of the study. The difference in the weight of the two measures gave us a $PM_{2.5}$ level for each cookhouse. The cassettes were assembled at MRC with care not to taint the pre-weighed filters. This was achieved by assembling the cassettes in an enclosed room using sterile tweezers to transfer each filter from the petri dish it arrived in to the prepared cassettes. The cassettes fitted with the filters were firmly placed on a cleaned cyclone, which was then attached by a rubber hose to either a Casella.

The assembled pumps were placed in the sampling cookhouses approximately 100cm from the cooking fires. The pumps were set to draw continuous air at 1.8 litres per minute (lpm), one minute every 6 minutes for 48 hours straight. If the pumps ran as designed, there would be 480 total minutes of sampling. This measurement would give a good idea

of how much $PM_{2.5}$ was released into the cookhouse during a 48-hour period, which helps determine the level of exposure for each woman. The cyclone was cleaned after every 48 hours measurement, and fitted with a new filter cassette prior to testing a new cookhouse. Periodic blanks and duplicates were collected throughout the study period.

CO concentrations were measured using Drager CO 50/a-D Diffusion Tubes with a detection range of 50-600 ppm-h (see

Figure 9). They were placed near the Casella or SKC Pump for the 48-hour period. This gave a time-weighted average for exposure to CO. Measurements were taken at MRC by the 3 fieldworkers who individually measured the CO concentrations using a ruler. Averages of those three measurements were recorded.

The HAP measurement forms were completed by the fieldworkers at the time of $PM_{2.5}$ and CO collection. These forms collected information on the start date, start time of the pump, start flow rate, distance from edge of fire to pump (cm), stop date, stop time, pump run time (minutes), stop flow rate, and any problems the pump might have encountered (i.e., pump was off, pump was running badly, pump was running but had fallen, pump was running but had been moved, and other). All this information was considered when calculating the $PM_{2.5}$ exposure.

All participants enrolled in the study were scheduled to have the HAP measured in their cookhouses. The order in which households were measured for HAP was selected at random to eliminate any bias. The author hypothesized that a woman who had been using the alternative cookstoves and briquettes for a longer period might use the cookstove more efficiently than someone who had just received the cookstove, thereby resulting in a lesser $PM_{2.5}$ measurement.

Figure 9: HAP measurement equipment (for Phase II)



(Casella Pump, Cassette and Drager CO Diffusion Tubes)

2.6.3 Other Measurements of Exposure

Aside from collecting PM_{2.5} and CO measurements, the author also collected information pertaining to biological measurements, household and behavioral information, and cookhouse characteristics. Participant information for the child included age, gender, height, weight, and whether the child was currently breastfed. This information was important to collect because it can directly affect whether the child is a carrier of pneumococcus. If the child is underweight and not receiving proper nutrition, he might be more susceptible to infection than a healthier baby. Information collected for the mother included her age, years of schooling completed, whether she could read and/or write in English, and whether she smoked. It is possible that the more schooling a mother has, the more likely she is to know about proper nutrition, or when to take her child to a medical professional. And if she smokes, she might be more at risk respiratory infection. All these factors can play a role in pneumococcal carriage. Other questions asked include: whether other people living in the compound. Exposure to these kinds of smoke might also increase the risk for pneumococcal carriage.

Household informational questions revolved around the number of people living in the compound, house or bedroom, sharing the same food bowl, etc. These questions are important because a known risk factor of pneumonia is the number of people sharing a bedroom or bed. A systematic review and meta-analysis published in 2013 discussed 36 studies that investigated 19 risk factors for severe ARLI. It found that more than seven persons per household almost doubled the risk for children under 5 years of age developing ARLI [85]. The more people in a confined space, the more likely a sick

person will infect others. There also included questions pertaining to where the child spends most of their time while the mother is cooking. If the child is normally tied to the mother's back in the cooking cookhouse, or playing nearby, he/she is more likely to be exposed to the cooking smoke than a child who usually plays on the opposite side of the compound. Other important information collected was whether the woman normally cooked inside an enclosed cookhouse or outside (which would result in less exposure), whether the cookhouse was shared with other families (which would increase the time smoke is being emitted from the cookhouse), and whether the cookhouse was attached to the main house. If so, then it is more likely the smoke will linger in the living quarters, thereby increasing exposure. Lastly, questions were asked pertaining to the number of windows and doors in the cookhouse (and if they are usually open), the size of gap between wall and roof, material of roof and the dimensions of the cookhouse, all which directly affects the ventilation during cooking.

The final information collected on this form pertained to the amount of time a woman spends in the cookhouse. Table 2 depicts how the data was captured. The amount of time a woman spends in the cookhouse has a direct effect on her exposure to $PM_{2.5}$ and CO.

Prior to analysis, it was determined that the analysis would be adjusted: 1) Breastfeeding status of child at the start of the study, 2) The number of Pneumococcal Vaccine doses the child had received at the start of the study, and 3) The age of the child at the start of the study. Lack of exclusive breastfeeding had been found to be a risk factor for ALRI [85], as well as child not receiving the full PCV7 doses [66]. It was also decided to include age of child because of the potential two-year difference in the ages of the children throughout all the groups. Even though the ages should be evenly distributed between the intervention and control groups because of randomization, any difference could have a large effect on the prevalence of pneumococcal carriage among the children.

| Table 2: Description of daily cooking activities and location of child in t | the morning, | mid- |
|---|--------------|------|
| day and evening | | |

| | Purpose of | Duration of the | Days per week | Location of the child most of the time |
|----------|-----------------------|-----------------|-----------------|--|
| | cookstove use | fire burning | the mother is | 1= on mother's back |
| | (Tick neither, one or | (nearest whole | responsible for | 2= near the cookstove (within one |
| | both boxes. Clarify | hour) | cooking | meter) |
| | activity if other) | | | 3= not near cookstove but around |
| | | | | cookhouse |
| | | | | 4= away from the cookstove but inside |
| | | | | 5= away from the cookstove but outside |
| | | | | 6= different compound |
| Morning | Cooking | | | |
| (5:00am- | Other _ | | | |
| 10:00am) | | | | |
| Mid- | Cooking | | | |
| Day | Other | | | |
| (10:00a | | | | |
| m- | | | | |
| 5:00pm) | | | | |
| Evening | Cooking | | | |
| (5:00pm- | Other | | | |
| 5:00am) | | | | |

2.6.4 Measurement of Outcome

Selecting a 'measurement of outcome' or 'endpoint' is an important decision when designing a clinical study. It can have a huge effect on the reliability and interpretability of the trial, as well as its evaluation of the potential benefits or risks of an intervention [86]. There are a number of characteristics of well-chosen outcomes. Foremost, outcomes should be well defined and reliable, and sensitive to the effects of an intervention. They should be easy to measure and interpret. Finally, outcomes should provide reliable evidence about whether the intervention has the potential to benefit the participants [86] . Measurement of outcome can be collected in a variety of methods, from records (e.g. death or birth records) to biological measurements. Often times, the outcome of interest can be difficult to measure and might require a large study population set over a long time period. In this case researchers often use an intermediate end-point (or surrogate endpoint) as a substitute for a clinically meaningful endpoint. To effectively use an intermediate endpoint, the researcher must first show that the association between an exposure and the intermediate endpoint is representable to that of exposure and actual outcome of interest; i.e. positive intermediate endpoint leads to outcome of interest. It must be shown that "the achievement of substantial effects on the intermediate endpoint reliably predicts achievement of clinically important effects on a clinically meaningful endpoint" [86].

For this study, the primary outcome is severe pneumonia. The researchers are ultimately interested in assessing whether a potential decrease in exposure to HAP from cooking fires decreases the likelihood that mothers and young children will develop severe pneumonia. But, because severe pneumonia is so difficult to measure and would require a large sample size, the research team used pneumococcal carriage as the intermediate endpoint. This endpoint was chosen for a number of reasons. First is its direct association to severe pneumonia. In order for a person to develop severe pneumonia, they must first be a carrier of *S. pneumoniae*, which is the bacterium responsible for severe pneumonia [48]. Another reason pneumococcal carriage was chosen as an endpoint is because it is relatively simple and inexpensive to test for, and can be administered quickly to large populations. Lastly, MRC has previously been involved in numerous pneumococcal carriage studies so the laboratory is already equipped and its staff well trained in administering these lab tests. Studies include a longitudinal study of Gambian infants [15], a population-based surveillance study [66], a cluster-randomized trial [65], among others.

2.6.5 Pneumococcal Carriage

A nasopharyngeal swab sample was taken from all participants before the intervention began and after 16 weeks, which was at the completion of the study. The samples were collected, transported and analyzed in accordance with the World Health Organization (WHO) protocol for evaluation of pneumococcal carriage [84]. A Standard Operating Procedures (SOP) manual for 'Specimen collection and transference to Laboratory' was created for the field and nurse staff (Appendix N).

A calcium alginate swab on a flexible aluminum shaft (pediatric use) was used (Fisher brand®; Fisher Scientific, Pittsburg, PA, USA). For each participating mother, the procedure was carefully explained and all questions addressed. The sample was taken from the mother first, and then from the child sitting on the mother's lap. With the subject's head tilted slightly backward, the nurse would swab the posterior pharynx of the nose, leaving the swab in for five seconds (Figure 10), and then placing it in a vial containing 1ml of STGG transport medium (skim milk-tryptone-glucose-glycerol). The excess wire handle was cut off using sterile scissors; the cap tightened and then placed in a cold box equipped with cold packs. The samples were transported to the MRC Unit within 8 hours and stored at -70°C until they were tested in batches by subculture onto selected media (5 μ g/ml gentamicin blood agar) and incubated overnight at 37°C in 5% CO₂ for isolation of *S. pneumoniae*.

Pneumococci were identified by their morphological characteristics and optochin sensitivity. Alpha-hemolytic colonies that were optochin sensitive or bile soluble were confirmed pneumococci. Colonies from the same sample that were morphologically different were subcultured separately to identify multiple serotypes. Serotyping was performed using the latex agglutination technique [87] and when necessary confirmed by the Quellung reaction [88]. Figure 10: Photos of swabbing (mother and child)



2.7 Methodological Considerations

2.7.1 Power and Sample Size

The sample size has been calculated based on; 1) a pilot study where the author observed a decrease in pollutant emissions using an intervention compared to wood, and 2) the expected reduction of pneumococcal in children and their mothers as a result of reduced exposure to pollutant levels in the cookhouse. Our baseline carriage estimates were based on previous studies in The Gambia (75% in infants between 2 and 10 months of age were pneumococcal carriers) [15, 61, 63]. To calculate the hypothesized carriage reduction, data were used from two studies: one study looked at the influence of smoking and exposure to tobacco smoke on S. pneumoniae and H. influenzae carriage rates in children and their mothers in Israel [89], and the second looked at the PM_{2.5} levels from tobacco smoke in a Scottish Pub [90]. Both studies detected an effect from smoke on carriage. From these studies, the author hypothesized an absolute reduction in carriage of 20% in the intervention arm compared to the control arm. As estimated sample size of 111 in each arm would provide sufficient power (85%) to detect an effect of this magnitude at the 5% level of statistical significance. Sample size calculations were performed using the Stata command "sampsi". To allow for 10% of dropout, 125 in each arm were recruited, totaling 250 babies and 250 mothers.

Based on a pilot study conducted earlier in the year, it was suggested that a 40% reduction in PM _{2.5} levels was reasonable to expect in ideal conditions. Therefore, the sample size would need to be 47 per group (90% power), which easily falls within the study sample size that was based on pneumococcal carriage. To accommodate for more 'real conditions', a 30% reduction in this study was expected.

2.7.2 Selection Bias

All women with children between the ages of 2 and 8 months were invited to attend an information meeting. During this meeting, it was determined whether the women and

children met the criteria, thereby making them eligible to enroll in the study. These meetings also enabled the women to decide freely whether they wished to participate. Selection bias might have occurred during the recruitment phase for a couple of reasons. The first is if word of mouth did not reach the most rural households. These families might have different characteristics or behaviors other than the families located in the more central parts of the village. The second reason is if the women whose spouses refused to let them participate in the study shared common characteristics among themselves that the author were unable to account for, such as lower education status. In general, over 90% the women who attended an information meeting and met the criteria enrolled in the study.

Additionally, the criterion of having to use a traditional 3-stone cookstove with wood might exclude some higher-class women who might have access to propane cookstoves, and who therefore might not be exposed to the same pollutants as the rest of the village population, which may possibly lead to a lower prevalence of pneumococcal carriage. But because this study is measuring the effect which exposure to $PM_{2.5}$ emitted from wood would have on the health of the population, is it reasonable to exclude this group.

2.7.3 Missing Data

Missing or incomplete data are common problems in randomized controlled trials. With these study designs it is often necessary to collect information from the participants at various points during the course of the study. There are three main types of missing data in a randomized controlled trial. The first is when the data are missing completely at random. This pertains to an individual who has enrolled in the study, but then chooses not to participate, irrespective of which group he was a part. For example, in our study, a woman and child enrolls in the study, is allocated to the intervention group, but then has to relocate to another province because of her husband's job. The second kind of missing data are when data are missing at random. Because a randomized controlled trial often recollects data at selected times in the study, a participant often fails to show up or not participate for reasons out of their control. Taking the previous example, if a participant

is travelling during the 2nd NPS swab, the missing data are not associated with whether the participant was allocated to the intervention or control group. The third type of missing data in a randomized control trial are when the missing data are directly related to the group the participant is allocated to. For our study, if the participants were unable to attend the 2nd NPS swabbing because they are all sick, and they also happen to all be in the same intervention group, the intervention itself might be having a direct effect on their health, which could affect whether the participant is a pneumococcal carrier. In this case, the missing data might have a direct impact on the study analysis.

To avoid missing data in a randomized control study, it is important to address adherence issues during the study design phase. If, for example, one is conducting the study during the harvesting season, the researchers will have a hard time collecting data and biological samples from the participants if they are busy in the fields. The better adherence from the participants, the more complete and comprehensive the study results will be.

In our study, there were a total of 239 women who completed the study, 122 in the control group and 117 in the intervention group. Of the 122 in the control group, 118 had all the data collected, 3 were missing the 2^{nd} NPS swab, and one was missing the Household Air Measurement. Of the 117 women in the intervention group, 115 had all the data collected, one was missing both the 2^{nd} NPS swab and Assessment Form, and one was missing the Household Air Measurement.

2.7.4 Information Bias

There are many issues pertaining to measurement of exposure to consider when designing and implementing a study pertaining to HAP exposure. One major concern is how the information is collected. How to determine when and for how long someone has been exposed to HAP, or for this study, PM_{2.5} and CO? As we want to establish an association between exposure to these pollutants and the presence of *S. pneumoniae*, we need to establish a reliable way to collect the exposure information. Unfortunately, without the existence of a 24-hour camera to capture the exact times and durations a woman spends

in the cookhouse, or ways to measure her exact exposure to other pollutants outside the cookhouse, the author must rely on questionnaires, or in other words, her recollection of how much time she spends in the cookhouse. Such questions lead to information bias (specifically recall bias, which is one form of information bias). This results when the person providing the information must give her own account of how much time she spends in the cookhouse, which can vary greatly from the actual duration. Recall bias can affect our study in many ways, including the woman's exposure to HAP, as well as her child's exposure. Recall bias might also result in inaccurate measurement exposures to other pollutants that might affect the outcome of interested. For example, if a woman claims in on the questionnaires that she is a non-smoker, but she does indeed smoke but did not want to reveal the truth due to societal stigmatization, this inaccurate recording of information might directly affect the study results. She and her child's positive pneumococcal carrier results might be directly related to their exposure to cigarette smoke. Another example related to our study pertains to fuel use in the cookhouse. If a woman is allocated to the intervention group (briquettes) and she continues to use wood, or resorts to wood when she runs out of briquettes, this could result in false positive measurement results (under the hypothesis that briquettes lead to few pneumococcal carriage cases). As mentioned earlier, without equipment to record exactly what is going on in the cookhouse or compound, the author must rely solely on the woman's word for much of our data, which might lead to information bias.

2.7.5 Confounding

A confounding variable is defined as an extraneous variable which is independently associated with both the exposure and the outcome and which does not rely on the casual pathway. This affects the variables being studied so that the results you get do not reflect the actual relationship between the variables under investigation. One method of minimizing confounding in a study is by randomizing subjects into either control or intervention group. Randomized studies completely remove any accusation of conscious or subconscious bias from the researcher, (unless the studies are unblended), thereby assuring external validity. Because the study is a randomized trial, confounding factors should have been addressed during the randomization process. If the sample size is sufficient enough, the author can be assured that both the control and intervention groups contain roughly the same populations. Examples of potential confounding factors that need to be highlighted in this study, therefore making sure they are equally distributed into both groups, include: whether the child is breastfed, number of pneumococcal vaccine doses, age of child, and whether the mother is a smoker.

2.8 Data Analysis

Analysis of Primary Endpoints

The primary analysis was an 'intention to treat' analysis - i.e., it included everyone that was enrolled in the study for whom outcome data were available, including those who might not have used the intervention appropriately.

- 1) To test whether biomass briquettes effectively reduced $PM_{2.5}$ in Gambia, weighed filters were collected over the 48-hour period in all the households during the intervention study. The means of the two groups (control and intervention) were compared using a two-sample t-test with p-value of 0.05. The size of the effect was the difference in means between the two groups, together with 95% confidence interval. The author adjusted for size and number of pots used, size of cookhouse, and number of windows/doors/spaces between wall and ceiling (see Table 21).
- 2) To determine whether there is a difference in pneumococcal carriage levels women and children under one years of age in both the intervention and controls groups, regardless whether the PM _{2.5} levels have been shown to be statistically lower in the intervention arm, the author used a z-test to compare the prevalence of pneumococcal carriage in both groups at the end of the study period (16 weeks). The ratio of the prevalence and 95% confidence intervals was presented. Adjustments for breastfeeding, number of pneumococcal doses and age of child were made.

Analyses of Secondary Endpoints

 To assess the cost difference between use of wood and biomass briquettes, the author calculated the price of fuel (biomass briquettes and wood) and the amount of fuel used for cooking an average meal. This gave us an approximation of the cost difference of using an alternative biomass cookstove with biomass briquettes compared to the traditional 3-stone cookstove and wood. Also factored in was the price and longevity of a cookstove.

 To assess how well the participants accepted the alternative biomass cookstoves and biomass briquettes, analysis was done with the data from the Intervention Assessment Form.

2.9 Ethical Considerations and Study Approvals

2.9.1 Ethical Principles

There are four primary ethical principles that all research studies should adhere to [91]. The first is autonomy and respect for the participants. This includes the participant being able to make a free and independent choice without coercion from the study investigators, as well as freely offering informed consent. At the start of the study, the author and her field workers visited each of the prospective villages and held an informal informational meeting in Mandinka, the local language. The potential participants were able to ask questions about the study and their obligations should they choose to participate. All questions were thoroughly answered. All the information on the informed consent form was carefully gone over so that the women had a clear understanding of the study. They were then free to enroll in the study. The only potential coercion was the fact that the women (both intervention and control groups) were to be given free fuel for the duration of the study. As fuel is expensive, this might have been a deciding factor for many women. There was no alternative to this study design as it would be unreasonable and impractical to ask the women to purchase the briquettes when they would have no assurance that this fuel would work for them.

The second ethical principle is beneficence, which maximizes the benefit and minimizes the harm. The hypothesis was that the biomass briquettes, when used with an alternative biomass cookstove, would reduce the particulate matter in the cookhouses, thereby creating a cleaner and safer cooking area for the women. This is in accordance with beneficence because of the attempt to reduce the harmful pollutants in the cooking areas.

The third ethical principle is non-maleficence, which is the avoidance to cause harm to the participants. Biomass briquettes are made entirely of grounded peanut shells, and do not contain any added chemicals or binders. Furthermore, the preliminary study showed that these briquettes did not produce any more HAP than the commonly used wood. Therefore, it is believed that the use of briquettes in this study does not cause any more harm to the participants than does the use of wood.
The fourth ethical principle is justice, which includes the equal opportunity to enjoy benefits, and provision of beneficial treatments to the populations (social justice). If the study proved that briquettes, when used with an indoor cookstove, would be beneficial to the health of the community, there would be a push to have these resources available to the public. The author worked closely with GreenTech⁵ (the company providing the alternative cookstoves and briquettes), and they had agreed to expand the distribution of the briquettes and alternative cookstoves to the study populations, which is right where the briquettes are currently being distributed. Furthermore, the price of the briquettes is very comparable to the price of wood, which most of the population is forced to purchase as the local available of wood has diminished. GreenTech has also agreed to show local artisans how to craft the alternative cookstoves in their respective villages. This would allow the manufacturing and distribution of the alternative cookstoves to be done at a fraction of the cost, as well as bringing business to the local villages.

2.9.2 Ethical Considerations and Study Approvals

The study proposal was submitted to the Scientific Coordinating Committee (SCC) of MRCG on November 18th 2011 and presented before the Committee on December 3, 2011. There was one major issue that was raised by the SCC; whether to consider restricting the enrollment of children who had at least 2 doses of PCV13, since the heterogeneity in vaccine history could impact the ability to analyze differences. It was also argued that the randomization process should address this possible situation automatically. In the end, it was decided to enroll all children who met the criteria, regardless of their vaccination history, taking note in the questionnaires how many doses of PCV13 each child had already received. The study was approved on the 4th of December in 2011 and the Gambia Government-MRC Joint Ethics Committee shortly after.

⁵ Green Tech was the independent for-profit organization that was providing the briquettes for the study

2.10 Personal Contribution and Funding

Funding for this study was granted to Harvard School of Public Health by National Institutes of Health, and then sub-contracted to the UK Medical Research Council, The Gambia. This funding was awarded as a studentship to Teresa Litchfield. Additional funding was provided by MRC.

CHAPTER 3: PILOT STUDY AND FOCUS GROUPS

3.1 Pilot Study

In the spring of 2011 a pilot study was conducted to determine whether biomass briquettes made from peanut shells were compatible with the traditional 3-stone cookstove. Before committing resources to a randomized controlled trial, it needed to be shown that not only did the briquettes work with the 3-stone cookstove, but that they burned 'cleaner' than wood. If the briquettes were not compatible with the 3-stone cookstove, other options needed to be considered. The study team searched for available alternative cookstoves in The Gambia that might work well with the briquettes. After investigating the availability of different cookstoves and fuel in The Gambia, a study was designed to test five different cookstoves when used with wood, briquettes, and charcoal (Table 3). Included in study was a rocket cookstove from the United States that was commonly used in other developing countries. A description of the cookstoves can be found in section 3.1.2.

| Cookstoves | Fuels | | | | |
|--------------------------|-------|----------------------|----------|--|--|
| | Wood | Biomass Briquettes 1 | Charcoal | | |
| 3-Stone Cookstove | Х | X | | | |
| Rocket Cookstove from US | Х | X | | | |
| Local Rocket Cookstove | Х | X | | | |
| Cylinder Cookstove | Х | X | | | |
| Clay Cookstove | Х | X | Х | | |

Table 3: Cookstove/fuel combinations tested in pilot study (Phase 1)

After conducting the initial pilot study, a second biomass briquette made from peanut shells became available on the market in The Gambia. Because these briquettes were not available during the initial pilot study, they needed to be tested with the cookstoves if they were to be considered for the larger study. A second pilot study was conducted in the fall of 2011, testing the three best performing cookstoves with the two briquettes and wood (Table 4). A description of the two briquettes is available in section 3.1.3.

| | Fuels | | | | |
|----------------------|-------|----------------------|----------------------|--|--|
| Cookstoves | Wood | Biomass Briquettes 1 | Biomass Briquettes 2 | | |
| 3-Stone Cookstove | Х | Х | Х | | |
| New Rocket Cookstove | Х | Х | Х | | |
| Clay Cookstove | Х | Х | X | | |

Table 4: Cookstove/fuel combinations tested in pilot study (Phase 2)

3.1.1 Pilot Study Objectives

The first objective of this pilot study was to test the emissions and performance of biomass briquettes as an alternative fuel source. The second objective was to test the performance of the alternative biomass cookstoves that were currently available in The Gambia to assess whether these cookstoves had lower emissions than a 3-stone cookstove. For both these objectives, a number of calculations were performed for each cookstove/fuel combination, including: $PM_{2.5}$ and CO emissions, fuel consumption, and time it took to cook each meal. If the briquettes did prove to be a cleaner burning fuel, the intention was to use them as the intervention for the main study. If they did not prove to be a cleaner burning fuel, then the cleanest cookstove/fuel combination would be used as the intervention in the main study.

3.1.2 Cookstoves Tested

Five different cookstoves were tested in this study, four of which were available locally in The Gambia. Of the four cookstoves available locally, two cookstoves were supported by outside donor organizations, one cookstove was supported by a private local organization, and one cookstove was the traditional 3-stone cookstove. The fifth cookstove was built by an American engineering company and was brought over from the United States. Figure 11 displays photos of the cookstoves tested in this study.

Figure 11: Biomass cookstoves used in study



From left: Cylinder Cookstove, Local Rocket Cookstove, US Rocket Cookstove; Ceramic Cooktove, Traditional 3-Stone Cookstove. (The long hexagonal objects visible in front of the US Rocket cookstove are biomass briquettes).

Cylinder Cookstove

The cylinder cookstove, manufactured by GreenTec, was the initial cookstove used with their biomass briquettes. According to the company, this cookstove was designed by a German farmer and handed down to a local Gambian to replicate and disseminate in country. This cookstove has a hollow cylinder chamber constructed of corrugated iron with rebar (also known as reinforcing steel) footings and a grill for the pot. The pot and grill must be removed when the fire is stoked or when fuel is added to the fire. The procedure can prove to be difficult for local women who often work with large heavy pots.

Local Rocket Cookstove

The local rocket cookstove is a replicate of a standard rocket cookstove design. The cookstove is made entirely of sheet metal, and has a vertical chimney located in the centre within a larger chamber. This design enables a pocket of air (or in some cases ash) to completely surround the chimney and act as insulation. The fuel is fed through a side hole, and is then burned in the centre of the cookstove, allowing the smoke to rise up through the chimney. The pot is placed on top of the cookstove (approximately 3 inches

from where the flames exit the chimney). The fire is stoked and fuel is added though the side chamber.

Rocket Cookstove from the US

This cookstove was brought over from the United States to assess how it compared to the local rocket cookstoves. It is of a similar design, but is made of cast iron. Like the local rocket cookstove, the fuel is fed through a side chamber and the flames rise through the chimney. The pot is placed directly atop the cookstove, and the fire is stoked and fuel added from the side chamber.

Ceramic Cookstove

This cookstove has become popular with the local urban Gambians. It is based on the Kenyan Ceramic Jiko, which was part of a cookstove dissemination project in Kenya in the early 1990s. Its exterior is constructed of sheet metal, and the interior is made of ceramic, which acts as insulation. There is a 100mm deep well at the top of the cookstove where the fuel is burned. The ashes fall through small holes and can be collected at the bottom of the cookstove. The pot is place on metal perches atop the cookstove, approximately 50 mm from the fuel. The fire is stoked and fuel added from on top, which can be performed with the pot still on the cookstove.

3-Stone Cookstove

The 3-stone cookstove is the traditional cookstove that is used widely in low and middleincome nations. The stones are placed in a triangular formation so the wood could be fed to the fire on all three sides. The pot is placed directly on the stones while the fire burns in the centre. 3-stone cookstoves are readily available as they can be made with practically any large stone, or comparable hard, non-flammable materials (i.e. concrete blocks). One major drawback of this cookstove design is its vulnerability to winds, which can affect the fire from all three sides. This problem is alleviated when the cookstove is positioned near a wind barrier (such as a wall) or used indoors where the wind cannot reach it.

3.1.3 Fuels Tested

Three different fuels were tested during the initial pilot study. Wood and biomass briquettes were tested with all 5 cookstoves, and the charcoal was tested only with the ceramic cookstove (ceramic cookstove is designed to just burn charcoal). Figure 12 displays photos of the fuels tested in this study.

Figure 12: Fuels tested in pilot study (Phase 1)



From left: Wood, Charcoal, Biomass briquettes

Wood

Wood is the most commonly used energy resource in The Gambia. *Pterocarpus erinaceus* (also known as Senegal Rosewood) was used in the study because it is the most popular wood used for cooking in among the local population [54]. The Gambia is facing rapid deforestation so wood is often imported overland from neighbouring Senegal. At this particular study site, most of the firewood came from the Casamance region, which is the region of Senegal south of the Gambian border and approximately 15 kilometres from most of the study sites. Much of this wood imported from Senegal continues on to the larger population centres in The Gambia, including Banjul, Serekunda and Brikama. The wood was tested in all five cookstoves.

Charcoal

Charcoal is available in most of The Gambia and is used primarily for ironing and making *attaya*, a local tea. Because *attaya* is brewed on tiny cookstoves requiring very little charcoal, the monthly use of charcoal for a standard family is minimal. In The Gambia, charcoal is produced from wood in a process called carbonisation, which is a method of burning wood (or other biomass) in the absence of air. During this process, firewood is gathered, cut to size, and placed in an underground or above ground kiln. The kiln is fired and the wood heats up and begins to undergo pyrolysis. The production process may take up to a few weeks, during which half the energy of the wood is lost. At the end of the process what is left is charcoal, which is smaller, lighter, blackened pieces of burnt wood, but has higher energy content per weight than wood. Because of the carbonisation process, charcoal burns 'cleaner' and more quickly than wood and must be added more frequently. This in turn requires a larger amount of charcoal to cook a pot of food. Only one of the cookstoves used in the study was designed to accommodate charcoal.

Biomass Briquettes

Briquetting is a process where a raw material (in this case peanut shells) is compressed under high pressure to form a round or square biomass briquette that can be used for heating purposes. During the compression of the material, temperatures reach a high enough temperature to allow the raw material to release various adhesives, which assist in keeping the particles together in the compressed state. However, in order for this process to be successful, the moisture content of the raw material should be 10-20% [92]. The high temperature also causes the moisture in the raw material to evaporate. At very high moisture contents, the briquettes are unable to hold their form due to expansion caused by steam pockets. For this study, both briquettes used were made from grounded peanut shells, which are abundant in most of West Africa. The briquettes tested in the initial pilot study were produced locally by a public-private enterprise. A local Gambian entrepreneur had recently received funding from an international donor to test the production and marketability of briquettes. The machine used to produce the briquettes was a smaller \$5,000 machine from China, using a hydraulic screw-press to create the briquettes. The second variety of briquettes was unavailable during the initial pilot study because the factory was still under construction; they were tested during the 2^{nd} pilot study and ultimately used for the intervention study. These briquettes were produced from a more robust £50,000 machine from Denmark, which employed a mechanical press to form the briquettes. They are currently in production and being sold to the local population in Fajara, The Gambia.

A note about the two machines: the hydraulic machine is expensive and logistically difficult to fix in countries with limited resources. At the end of our study, this smaller machine had broken down and the owner did not have the funds or means to fix it. As for the second more robust briquette machine, the owner deliberately went with a mechanical press because they are much easier to maintain and fix in The Gambia. The performance of the two briquettes will be discussed later in the results chapter. Photos of the two machines used to produce the briquettes can be seen in Figure 13.





From left: example of Screw-Press Biomass Briquette Machine, Mechanical Biomass Briquette Machine in The Gambia

3.1.4 Methods

Two identical cookhouses similar to local cookhouses in terms of building materials, size, ventilation and design, were constructed on the MRCG campus (see Figure 14). In cookhouse 1, a trained field worker conducted the water boiling test (WBT) in accordance with the protocol developed for the Shell Foundation Household Energy and

Health Program [93] (Appendix O). The WBT is designed to ascertain how well energy is transferred from the fuel to the cooking pot. This is an efficacy test because it is assessing how well a cookstove can perform in ideal conditions (controlled laboratory). In cookhouse 2, a trained local woman conducted the controlled cooking test (CCT), also created for the Shell Foundation Household Energy and Health Program [94] (Appendix P). The CCT is designed to compare the performance of an alternative biomass cookstove to a traditional cookstove in a standardized cooking task. It is an effectiveness test because it is testing the real potential of the cookstoves in the field.



Figure 14: The two testing cookhouses constructed on the MRCG campus

WBT and CCT

The WBT entails 3 separate tests: 1) the *cold-start high-power test* measures how long it takes for water to boil using cold cookstoves; 2) the *hot-start high-power test* measures how long it takes for water to boil using a hot cookstove; and 3) the *low-power test* measures how much fuel is used to keep water simmering for 45 minutes. This combination of tests measures a cookstoves performance at both high and low power outputs, which are associated with a cookstoves ability to conserve fuel. In particular, the WBT measures the time to boil, burning rate, specific fuel consumption, firepower, turndown ratio and thermal efficiency. In the first phase, the *cold –start high-power test*,

the fieldworker began with the cookstove at room temperature and used pre-weighed fuel to boil 5 liters of water in a standard pot. He then immediately replaced the boiled water with a fresh pot of cold water to perform the second phase, the *hot-start high-power test*. Again he used pre-weighed fuel to boil 5 liters of water in a standard pot. The third phase, the *low-power test*, immediately followed. The field worker simmered the pot of water from the previous test for 45 minutes with pre-weighed fuel. These tests were performed three separate times for each cookstove/fuel combination and an assortment of measurements was taken throughout. All the tests were done in random order (refer to Table 5) to minimize biases due to time of day, ambient temperature, humidity, and other external factors that might affect the results.

The CCT involves repeating the same cooking task repeatedly for each cookstove/fuel combination so that each cookstoves can be measured alongside the traditional 3-stone cookstove. In order to minimize influence of other factors, one cook was selected to cook the same meal three separate times for each cookstove/fuel combination. The same premeasured quantity of ingredients was used for each meal. All the cooking tasks were performed in the same cookhouse with the same ventilation. At the start of the test, the cook pre-weighed all her ingredients and fuel. The timer was then set and the cook proceeded to cook the meal, using the same methods for each test. At the completion of the meal, the cook stopped the timer, and weighed the cooked food, charcoal and unused fuel.

| | | W | WBT Cookhouse | | | CCT Cookhouse | |
|------------|-----------|------------------|---------------|-----------------------|------------------|-------------------|---------------------|
| Date | Day | cookstove | Fuel | Duplicate Blank | cookstove | fuel | Duplicate Blank |
| 28/03/2011 | Monday | Cookstove Tec | Wood | Blank Test 1-1 | Clay | Charcoal | Duplicate Test 1 |
| 29/03/2011 | Tuesday | Rocket | Briquette | Duplicate Test 1-2 | 3 stone | Wood | Blank Test 2 |
| 30/03/2011 | Wednesday | Gasifier | Charcoal | Blank Test 2-3 | Cookstove Tec | Briquette | |
| 30/03/2011 | Thursday | Clay | Wood | Duplicate Test 2-1 | Rocket | Charcoal | |
| 01/04/2011 | Friday | | | | | | |
| 04/04/2011 | Monday | 3 stone | Briquette | Blank Test 3-2 | Gasifier Clay | Wood Briquette | Duplicate Test 3 |
| 05/04/2011 | Tuesday | Cookstove Tec | Charcoal | Duplicate Test 3-3 | Clay | Briquette | Blank Test 1 |
| 06/04/2011 | Wednesday | Rocket | Wood | Blanks Test 1-3 | Cookstove Tec | Charcoal | |
| 07/04/2011 | Thursday | Gasifier | Briquette | Duplicate Test 1-1 | Rocket | Wood | |
| 08/04/2011 | Friday | | | | | | |
| 11/04/2011 | Monday | Clay | Charcoal | Blanks Test 2-2 | Gasifier | Briquette | Duplicate Test 2 |
| 12/04/2011 | Tuesday | 3 cookstove | Wood | Duplicate Test 2-3 | Clay | Wood | Blank Test 3 |
| 13/04/2011 | Wednesday | Cookstove Tec | Briquette | Blank Test 3-1 | 3 Stone | Briquette | |
| 14/04/2011 | Thursday | Rocket | Charcoal | Duplicate Test 3-2 | Cookstove Tec | Wood | |
| 15/04/2011 | Friday | | | | | | |
| 18/04/2011 | Monday | Gasifier | Wood | Blanks Test 1-2 | Rocket | Briquette | |
| 19/04/2011 | Tuesday | Clay | Briquette | Duplicate Test 3-1 | Gasifier | Charcoal | |

Table 5: First fuel and cookstove testing schedule

HAP Measurement Tools and Procedures

In both cookhouses, $PM_{2.5}$ concentrations were measured in two ways. The first method used light-scattering, DustTrak 8520 monitors (TSI Inc., Shoreview, MN, USA)) to measure continuous $PM_{2.5}$. The second method measured integrated $PM_{2.5}$ concentrations

using gravimetric Casella pumps (Apex Personal Sampling Pump, Keison International Ltd, UK) (see Figure 15). All measurements were taken at the same distance from the fire for all tests.

Figure 15: HAP measurement equipment used to measure PM_{2.5} and Carbon monoxide during the WBT and CCT in the constructed cookhouses (for Phase I)



(DustTrak, Casella Pump, Cassette and Drager CO Diffusion Tubes)

Continuous PM_{2.5} concentrations were measured and recorded at 1-minute intervals. The internal laser photometer of a DustTrak monitor measured airborne particle mass concentration in air with a 90° light-scattering laser diode. DustTraks were operated at a flow rate of 0.8 litres per min (1pm) and were fitted with an external mini personal exposure monitor (PEM). In each mini PEM, a level greased well served as the impaction surface. DustTraks were calibrated daily to a zero filter and the PEMs were regularly cleaned out. Filter cassettes for gravimetric PM_{2.5} measurement were assembled and pre-weighed in the Harvard School of Public Health Laboratory. To collect samples, filter cassettes were connected to a cyclone and a Casella personal sampling pump drew continuous air at 4.0 1pm. The cyclones were cleaned at least once every 48 hours, and were fitted with a new filter cassette prior to each test. Flow rate was set at 4.0 1pm at the start of each morning using a calibrated rotameter. Periodic blanks and duplicates were collected in both cookhouses. CO concentrations were measured using Drager CO 50/a-D Diffusion Tubes (Drager, USA) with a detection range of 50-600 ppm-h (see Figure 15).

All HAP measurements were taken at the same location in each cookhouse, which was approximately one metre from the cooking fire. At the start of each morning, a separate DustTrak was turned on in each cookhouse and ran for the duration of the day. The time on the DustTraks was synchronized with clocks in the cookhouse in order to accurately relate the HAP emissions on the DustTrak readouts with the tasks that were performed at specific times. The Casella filters were fitted with new filters at the start of each test (at the start of each of the phases for the WBT, which amounted to three different filters for each WBT and one filter for each of the CCT tests). The field workers were instructed to start the Casella pumps after the fuel was lit and when the pot was placed on the fire, which was the same time the actual tests began for the WBT and CCT. The Casella pumps were turned off and filters removed the moment the WBT or CCT came to an end. For CO measurements, the glass tips were broken off the tubes at the same time the Casella pumps were turned on, and the tubes were removed from the cookhouses and stored in accordance with protocol at the same time the Casella pumps were turned off.

3.1.5 Pilot Study Results and Final Intervention Decision

The initial two pilot studies proved to be challenging in capturing true $PM_{2.5}$ emissions during the WBTs and CCTs. Foremost, the WBTs were not as rigorously conducted as was required. Though the person conducting the tests in the WBT cookhouse ran the HAP testing equipment correctly, he was not sufficiently attentive to tending to the cookstoves and stoking the fires appropriately. There were numerous times the primary researcher visited the testing cookhouses to find the smoke billowing from the windows and door because the tester was not properly attending to the fires. In contrast, the cook at the CCT cookhouse was attentive to the cookstoves at all times and tended to the fires appropriately. One reason for the difference between the two testers is that tester in the WBT cookhouse was a male who spent very little time around a cookstove. Though he was trained on how to use each of the cookstoves and fuel, he still lacked the skills and patience to attend to them properly. The tester in the CCT cookhouse was a middle age female who had been cooking for her family for many years. She was well trained in using cookstoves, and was able to learn quickly how to use the different cookstoves and fuels. She was accustomed to attending to fires for long periods of time, and was aware of how to stoke and maintain them in the most efficient way. The difference in testing between the two testers was most significant when wood was tested. The WBT tester

would often have a large fire going or big plumes of smoke rising from the cookstoves, while the CCT tester maintained a constant and appropriate flame during the testing procedures. Because of this discrepancy, it was difficult to use the data from the WBT cookhouse in the analysis.

Another difficulty faced was that the Casella pumps were inadvertently set to an incorrect flow rate, thereby resulting in incorrect $PM_{2.5}$ measurements. Unfortunately, the results obtained did not accurately represent the true emissions and the data could not be used directly. It was not possible to apply a simple conversion adjustment to obtain usable material. Additionally, the records with the flow rates that were used in this study had gone missing so the study team was unable to thoroughly defend where the error happened. It is only known that, because the flow rates were incorrect, the data gathered with these pumps could not be judged to be accurate. Although the absolute measures of $PM_{2.5}$ were not reliable because of the flow rate anomaly, a crude estimate calculated, allowing for comparisons to be made between the relative $PM_{2.5}$ outputs. With that said, Figure 16 displays a crude chart depicting total $PM_{2.5}$ concentrations (in $\mu g/m^3$) by fuel and cookstove type during the WBTs (45 minute water simmer). As can be noted, all five of the tests using wood measured much greater concentrations of $PM_{2.5}$ than the other three fuels.

Figure 16: Total $PM_{2.5}$ concentrations (in $\mu g/m^3$) by fuel and cookstove type during WBTs (45 minute water simmer)



Note: 3- 3-stone, c- Ceramic, nr- US Rocket, r- Local Rocket, s- Cylinder

In contrast, Figure 17 displays a crude chart depicting total $PM_{2.5}$ concentrations (in $\mu g/m^3$) by fuel and cookstove type during the CCTS (~120 minutes of cooking a pot of food). This chart shows very different results. The wood had very similar total $PM_{2.5}$ concentrations as the two briquettes. The main reason for the discrepancy between the results of the wood in the two tests is very likely to be because the tester in the WBT cookhouse was not as efficient as the tester in the CCT cookhouse, as discussed earlier. Only the charcoal showed much lower concentrations, which was expected because the ceramic cookstove was designed to efficiently burn charcoal.





Note: 3-3-stone, c- Ceramic, nr- US Rocket, r- Local Rocket, s- Cylinder

CO measurements were also taken in the CCT cookhouses. The averages of the three separate measurements are displayed in Table 6. The average CO measurement with the briquettes was 6.7ppm and the average for the wood was 7.5ppm (Table 6). This indicates that briquettes might emit less CO than wood, though it is difficult to assess the true difference from such a small study sample. Aside from measurements taken from the Casella, SKC pumps, and CO tubes, other relevant and important information was gathered.

| Cookstove | | | | | Fuel | | | | |
|-----------------|------|-----------|---------|------|--------|----------|------|----------|---------|
| | | Briquette | | | Wood | | | Charcoal | |
| | Mean | Median | IQR | Mean | Median | IQR | Mean | Median | IQR |
| | | | | | | | | | |
| 3-Stone | 6.5 | 6.5 | 5.3-7.8 | 8.7 | 9.0 | 7.0-10.0 | | | |
| Ceramic | 5.3 | 5.0 | 5.0-6.0 | 8.7 | 9.0 | 8.0-9.0 | 8 | 7.5 | 7.0-9.3 |
| Cylinder | 6.7 | 6.0 | 6.0-8.0 | 6.7 | 7.0 | 6.0-7.0 | | | |
| Local Rocket | 7.3 | 7.0 | 5.5-9.3 | 8.2 | 8.0 | 6.0-10.5 | | | |
| US Rocket | 8.0 | 7.5 | 7.0-9.5 | 7.8 | 9.0 | 5.3-9.0 | | | |

Table 6: CO (ppm) measurements in CCT, by fuel (Mean, Median, and IQR)

The Difference between the Two Biomass Briquettes

During the initial testing phase (spring 2011), the first biomass briquettes (Briquette 1) appeared to release less smoke than the wood when used with all the cookstoves. One reason might be the way the briquettes are pressed. They were fabricated using a machine with a hydraulic pressed, which made them more compressed, thereby burning similar to wood. The briquettes held together well and did not break apart easily when poked or prodded by the cook.

For the 2nd round of testing (fall 2011), a second kind of biomass briquette (Briquette 2) was tested, also make from peanut shells. These briquettes were fabricated from a machine using a mechanical press, which made them less compact than Briquette 1. Consequently, Briquette 2 broke apart easily when tampered with in the cookstove, thereby creating a lot of smoke. These briquettes only performed well in the rocket cookstove, where they were able to burn on their own without being poked or prodded. They performed very poorly with the other cookstoves, especially the 3-stone cookstove. The reason Briquette 2 was chosen was because the machine tested with Briquette 1 broke down and was no longer manufacturing briquettes. This was the main reason why GreenTech decided to go with the mechanical press, as the machines were much easier to maintain and fix in the resource limited countries. When Briquettes 2 were used correctly

for cookstoves designed to accommodate briquettes, they appeared to burn 'cleaner' than wood.

Large Variability within Same Cookstove/Fuel Combination

A major factor in the performance of the cookstoves/fuel was testing variability. As can be seen from the box plots (Figure 16 and Figure 17), the results of a cookstove/fuel combination varied greatly. There were a few reasons for this. 1) The user factor. Though the same woman cooked the same pot of food, and at least 3 times for each cookstove/fuel combination, there was still a huge difference in the PM generated when using the same combination. It is probable that there was less variability in the cookstove/fuel combinations that she was accustomed to using (wood/3-stone cookstove, wood/clay cookstove) because of her knowledge in maintaining the fires in those stoves. With the cookstoves that were new to her, she was probably less able to maintain the fires similarly for each test leading to a lot of variability. 2) The sensitivity of Briquette 2. These briquettes were extremely prone to breaking apart, thereby creating a lot of smoke. The less the briquettes were tampered with, the less smoke created. This could be a major reason why there was so much variability with Briquette 2. As the woman continued using them, she probably adapted methods to reduce tampering, thereby reducing smoke emissions.

Comparing Fuel/Cookstove Combinations as Opposed to Fuel and Cookstoves Separately

Each fuel performed distinctly different when used with the different cookstoves. Therefore, comparisons had to be made between all the different fuel/cookstove combinations. For example, though Briquette 2 performed very well with the new rocket cookstove, it performed poorly with the 3-stone cookstove or clay cookstove, especially if the briquettes had to be tampered with during the cooking process. Therefore, the overall performance was poor. Briquette 1 and wood had comparable burning properties and worked similarly with each cookstove, but Briquette 2 performed differently, however.

3.2 Focus Group Discussion

Before conducting the larger study in a rural population of The Gambia, it was necessary to get feedback from the study population to conclude whether the chosen intervention would be accepted and used by the women. It is futile to test an intervention if the target population is unwilling or not interested in using the chosen intervention. It can also jeopardize the integrity of the study if a percentage of the study population refuses to adhere to the study protocol because of their negative opinions toward the intervention. At this point in the study design, it was unclear whether the intervention would be briquettes alone (to be used with the traditional 3-stone cookstove) or briquettes coupled with the locally made rocket cookstove. By testing the two methods in the field and involving local women, it was hoped that this testing period would help secure a final decision.

The information collected was qualitative data and therefore needed to be collected using qualitative research methods. The strength of qualitative research is its ability to provide general descriptions of how people experience a given research issue [95]. One type of qualitative study is referred to as an 'inductive process' where the researcher relies on what is observed in the field to develop a theory [96]. In this study, the research team needed to observe the cooking techniques and behaviors of the women in order to make an educated decision as to what intervention to include in the larger study. In many quantitative research situations, it is not feasible to involve all members of the population being studied, so a subset of the population is sampled. Examples of qualitative methods using subsets include participant observations, in-depth interviews and focus groups [96].

Participant observations are a good way to attain information on the natural behavior of people [95]. It gives the researcher a general idea of how people are naturally behaving before any intervention is introduced. One scenario in which this qualitative method might be used is observing people's hand washing practices before deciding on an intervention. By observing a population, a researcher can assess what percentage of the population regularly washes their hands, where the hand washing normally occurs, and

when is the population most likely to wash hand. This information can then be used to design an interventional program or study. Participant observation was not a feasible option for this part of the study because the women were asked to cook using the alternative cookstoves and/or fuels, and were therefore not behaving naturally.

In-depth interviews are another qualitative method researchers use to collect information from participants [97]. They involve intensive individual interviews with a small number of respondents in order to explore their perspectives on a particular idea, program or situation. The researcher generally has a list of questions he/she wants to ask the participants and will address them individually. The questions are either open or closed and researcher led or participant led. This method enables the researcher to collect information that the participant might not want to share with other people, such as safe sex practices. By having a one-on-one discussion, the researcher can delve deeper into topics than what he/she might be able to do with a larger group. For this part of the study, in-depth interviews were not conducted because the research team did not think they would reveal any more information than what the women would offer as a group. This topic was not taboo or unsafe to talk about collectively and therefore didn't justify interviewing the participants individually about their preferred cooking methods.

Using focus groups allows the researcher to collect information from a larger group, thereby generating a more general idea of the thoughts and behaviors of a population [95]. Focus groups tend to be less structured, composed primarily of open-ended questions that allow the participants to take the discussion in the direction they want. The researcher is there to guide the group and offer more questions. This approach was chosen for a number of reasons. Foremost, it was decided that a smaller sample of women testing the cookstoves/fuels would generate a solid consensus about the preferred cooking methods. Secondly, as the women were asked to practice these new methods in a large common space, they would already be conversing during the cooking process and sharing opinions. Therefore, a large focus group discussion at the end of the testing process was deemed the best approach for capturing the true opinions of the women. And

thirdly, it was most economical to test a sub-set of the population and facilitate just one discussion.

In December of 2011, a focus group was assembled in a compound in one of the participating villages. Approximately 10 local women participated. The field workers demonstrated how to light and burn the briquettes using the traditional 3-stone cookstove and the local rocket cookstove (refer to Figure 18 to view photos of this demonstration). The three field workers engaged for this study had previously been trained by the technicians at the briquette factory so they were equipped to answer questions the women had. After the initial demonstrations, the women were invited to test the briquettes and cookstoves themselves. Many cookstoves were set up around the compound and the women spent a couple of hours lighting and testing the briquettes. The women were also encouraged to boil water using the briquettes so see whether they thought the water boiled as quickly as if they were using wood.

Figure 18: Photos of the focus group demonstration and discussion (testing biomass briquettes with both the traditional 3-stone stove and a biomass rocket stove)



At the end of the testing phase, the women gathered with the field workers to discuss their experiences with the briquettes and cookstoves. A prepared questionnaire guided the field workers in their focus group discussion. Please refer to Figure 19 to view the responses from the women. Overall, the women reacted positively to cooking with the briquettes and local rocket cookstove. They agreed that, though the briquettes were harder to light and produced more smoke at the start, they eventually burned 'cleaner' than wood. The women thought the briquettes worked much better with the local rocket cookstove than the traditional 3-stone cookstove because of the wind. They also thought that they would be willing to purchase the briquettes if they were equal in cost or less costly than wood.

At the completion of the focus groups, it was decided that the intervention for the study would consist of both the briquettes and local rocket cookstove. The briquettes, when coupled with the traditional 3-stone cookstove proved to be too inefficient and difficult for the women to maintain a constant flame.

Figure 19: Focus group responses

- 1. What did you first think of the biomass briquettes before you used them?
 - Seeing the briquettes for the first time, we wondered how the briquettes will work... probably difficult.
 - It is the first time we saw the fuel
 - We doubted it would work
- 2. Did they perform like you thought they would?
 - They thought the briquettes would quickly finish immediately after it starts because it is made of peanut shells.
 - You would use more of this fuel than usual with other fuels
- 3. What did you like about the briquettes?
 - Produces less smoke
 - Its economically viable- that with just little briquettes, the cooking can get done
 - Environmentally friendly
 - It generates more heat than wood
- 4. What did you not like about the briquettes?
 - The charcoal produced with the briquettes after the cooking is never useful for anything compared to the wood
 - Produces a lot of smoke before it gets lit, but this depends on how you start it. Perhaps it is cause by stacking too many briquettes.
- 5. How difficult or easy was it to learn to use the briquettes?
 - Most of the women found it very easy to understand the method to start the briquettes
 - It was very easy to learn
- 6. How much smoke do they create in comparison to wood?
 - Briquettes produce less smoke than wood
- 7. How were they to light?
 - It's quicker to light the briquettes than wood
- 8. Do the briquettes work with the 3-stone cookstove?
 - Yes, it works well with the 3-stone but not as efficiently as with the rocket.
 - The heat spreads when there is wind... i.e. loses a lot of heat
- 9. If not, what can be done to make it work better?
 - *To have the briquette work better, one will have to use the rocket cookstove.*
 - To do the cooking quickly and fast with less fuel consumption, you need to use the rocket
 - The rocket will help the briquettes not to be wasted

- 10. Would women in the study be able to use the briquettes with the 3-stone for 3 months?
 - Yes, the women will be able to use the briquettes
- 11. If they were available for as much or less than the cost of wood, would you buy them?
 - Yes, we would buy the briquettes when it is available... at the same or less than the cost of wood if it is known to them
- 12. Do you have any other comments or questions?
 - Wondered if the study would be available to non-breastfeeding mothers

Note: The answers were transcribed verbatim from the field workers' questionnaires and differ in tenses depending on who recorded the answers

CHAPTER 4: MAIN STUDY RESULTS

4.1 Description of Participants

4.1.1 Entry into Study

The study participant entry profile is shown in Figure 20. At the start of the study, 266 eligible mothers took interest during the information meetings and consented to participation. Of those 266 women, 252 mother/child groups presented for the 1st NPS swabbing and group allocation. One mother/child pair withdrew at this point (not wanting to undergo swabbing), leaving a total of 251 mother/child groups. Of the remaining 14 women who did not present for swabbing, 8 travelled and 6 opted out of the study. Of the 251 women officially enrolled, 136 were randomly allocated to the control group while 115 were randomly allocated to the intervention group (see Figure 20). An exception was made to individually randomized allocation when two or more participating women were living in the same compound and therefore using the same cookhouse. Under these circumstances, it was deemed necessary for these women to be using the same fuel/cookstove combination so they would not be exposed to the alternative cookstove/fuel combination in their cookhouses ('contamination' in epidemiological terms). There were 10 households with 2 mothers enrolled in the study and one household with 3 mothers enrolled, resulting in a total of 12 (4.8%) reallocations. Subsequently, only one HAP sample was taken in these dual and multiple-occupied compounds.

Of the 136 in the control group, 119 (87.5%) completed the study and 17 (12.5%) withdrew. Of the 115 in the intervention group, all 115 (100%) completed the study. One reason why there were no withdrawals in the intervention group might be that the women were excited about using the briquettes and cookstoves, and therefore wanted to stay in the study to keep receiving them. The control group received wood so they might not have had that motivation to remain in the study.

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Figure 20: Participants' flowchart (mother/child pairs)



4.1.2 Baseline Characteristics of Participants

Baseline Characteristics of Children

A baseline questionnaire was taken of all study participants at the start of the study. This was done to assess whether certain characteristics were similar in both the control and intervention groups. A total of 256 children and 251 mothers were included in this baseline assessment (5 sets of twins accounted for the five more children than mothers). This baseline information was collected at two time points. The child's sex and age was collected on the Household Questionnaire, and the number of Pneumococcal vaccine doses the child received was collected on the 1st Carriage form (Appendix D). The question as to whether the child was still breastfed was collected on both the Household Questionnaire and 1st Carriage form. The author opted to use the responses from the 1st Carriage form because it was collected together with the first carriage sample. As can be seen in Table 7, there are 11 missing Household Questionnaires in the control group and none in the intervention group.

| NPS and Forms | Control n (%) | Intervention n (%) | Total n (%) |
|-------------------------|------------------|-----------------------|----------------|
| 1 st NPS | n=276 (%) | n=231 (%) | n=507 (%) |
| Complete | 276 (100) | 231 (100) | 507 (100) |
| Missing | 0 (0) | 0 (0) | 0 (0) |
| $2^{nd} NPS$ | n=276 | n=231 | n=507 |
| Complete | 242 (87.7) | 231 (100) | 473 (93.3) |
| Missing | 34 (12.3) | 0 (0) | 34 (6.7) |
| Household Questionnaire | n=136 | n=115 | n=251 |
| Completed | 125 (91.9) | 115 (100) | 240 (95.6) |
| Missing | 11 (8.1) | 0 (0) | 11 (4.4) |
| IAP Form | n=132 | n=113 | n=245 |
| Completed | 116 (87.9) | 109 (96.5) | 225 (91.8) |
| Missing | 16 (12.1) | 4 (3.5) | 20 (8.2) |

Table 7: Collected NPSs and forms, by group (control and intervention)

Note: The number of swabs in both groups incorporates mothers and children, including four twins in the control group and one twin in the intervention group

After comparing the baseline characteristics of the children between the control and the intervention group, no statistically significant differences in any of the characteristics were found between the two groups (Table 8). The age and sex of the children were

evenly distributed between the two groups. Just under half of the children had been exclusively breastfeed, while just over half had received a mix of breast milk and other liquids. Less than 1% of each group was not breastfed at all. Only the number of Pneumococcal vaccine doses the children received showed any difference: 8.6% of the control group had never been vaccinated, whereas 13.8% of the intervention group had never been vaccinated. Over 40% of both groups (40.7% of control group and 49.1% of the intervention group) had received all three vaccinations.

| Characteristic | Control n=140, (%) | Intervention n=116, (%) | P-Value * |
|----------------------------|-----------------------|----------------------------|-----------|
| Sex of Child | | , , , | |
| Male | 69 (49.3) | 59 (50.9) | 0.59 |
| Female | 58 (41.4) | 57 (49.1) | |
| Missing | 13 (9.3) | 0 (0.0) | |
| Age of Child (by group) | | | |
| 2-3 months | 45 (32.1) | 41 (35.3) | 0.57 |
| 4-5 months | 43 (30.7) | 31 (26.7) | |
| 6-7 months | 26 (18.6) | 28 (24.1) | |
| ≥ 8 months | 13 (9.3) | 16 (13.8) | |
| Missing | 13 (9.3) | 0 (0.0) | |
| Breastfeeding | | | |
| Exclusive | 63 (45.0) | 49 (42.2) | 0.9 |
| Mix | 76 (54.3) | 66 (56.9) | |
| Not Breastfed | 1 (0.7) | 1 (0.9) | |
| Pneumococcal Vaccine Doses | | | |
| 0 Doses | 12 (8.6) | 16 (13.8) | 0.26 |
| 1 Dose | 36 (25.7) | 22 (19.0) | |
| 2 Doses | 28 (20.0) | 17 (14.7) | |
| 3 Doses | 57 (40.7) | 57 (49.1) | |
| Unknown | 7 (5.0) | 4 (3.4) | |

Table 8: Baseline characteristics of children, by group (control and intervention)

* P-value for Pearson chi-squared across all categories excluding missing data

Notes: Numbers of 'missing' differ according to time at which information was collected. Number of participants in control and intervention groups differs from the numbers in Figure 20 (Participants' Flowchart) because of the 5 twins, which accounts for four extra children in control group and 1 extra child in intervention group.

4.1.3 Household Information

During the course of the study, a questionnaire was administered to gather household information (Appendix F). This questionnaire inquired about possible risk factors that might have an effect on pneumococcal carriage, such as the number of people sharing a bedroom, whether most of the cooking is done inside or outside, and where the child spends much of his/her time. Because the participants were randomly allocated to either the control or intervention group, the numbers were similar (Table 9). There were 3 risk factors that were found to have a significant difference between the two groups: the number of occupants residing in compound (p=0.01), the number of occupants residing in one household (p=0.003). For all three risk factors, there were more people and children under the age of 5 in the Control group than in the Intervention group. Though these risk factors were not taken into consideration during the analysis, it would be worthwhile to perform those calculations at a later date.

On average, households and compounds were composed of between 10 and 19 people. There were usually less than 10 residents in each house, with less than 5 children under the age of five in most households. The mother was universally the primary caregiver of the child. Generally the child spent the most time in the cookhouse, but also spent time on the mother's back or away from the cookhouse while the mother cooked. During both the rainy and dry season, a majority of women cooked in separate cookhouses away from the main house. Most of the women did not share a cookhouse with other women from different compounds. Most women used two cookstoves at one time, and only cooked for their families (not to sell to others). About 50% of the households had smokers living in the compound, and a majority of the households burned rubbish in the compound. Refer to Table 9 for the results from all the questions asked on the Household Information Questionnaire. Note that there are only 124 controls in this table compared to the 136 controls in Figure 20 because of the 11 households that had multiple women enrolled.

Another risk factor that was assessed was whether there were smokers in the household, and if so, whether they smoked inside the homes. Of the 110 households with smokers,

56.6% of the households in the control group and 48% of households in the intervention group had smokers who smoked both inside and outside the house. Most of the households had only one smoker.

| Characteristic | Control n=129 (%) | Intervention n=116 (%) | P-Value * |
|--|----------------------|---------------------------|-----------|
| Number in Compound | | | |
| <10 | 16 (12.40) | 19 (16.38) | 0.01 |
| 10-19 | 44 (34.11) | 59 (50.86) | |
| 20-29 | 36 (27.91) | 19 (16.38) | |
| >29 | 33 (25.58) | 19 (16.38) | |
| Number in Household | | | |
| <10 | 24 (18.60) | 34 (29.31) | 0.00 |
| 10-19 | 59 (45.74) | 69 (59.48) | |
| 20-29 | 46 (35.66) | 13 (11.21) | |
| Number in House | | | |
| <10 | 107 (82.95) | 95 (81.90) | 0.59 |
| 10-19 | 19 (14.73) | 20 (17.24) | |
| 20-29 | 3 (2.33) | 1 (0.86) | |
| Number Under 5 years of age in Compound | | | |
| 1-2 | 40 (31.01) | 46 (39.66) | 0.003 |
| 3-4 | 34 (26.36) | 44 (37.93) | |
| >5 | 55 (42.64) | 26 (22.41) | |
| Who looks after the child most of the time | | | |
| Mother | 103 (79.84) | 97 (83.62) | 0.52 |
| Other Family Member | 25 (19.38) | 19 (16.38) | |
| Missing | 1 (0.78) | 0 | |
| Does the child hang around the cookhouse | | | |
| Ν | 55 (41.64) | 39 (33.62) | 0.13 |
| Υ | 73 (56.59) | 77 (66.38) | |
| Missing | 1 (0.78) | 0 | |
| Where child is while mother cooks | | | |
| Away From Cookhouse | 64 (49.61) | 46 (39.66) | 0.15 |
| In Cookhouse | 6 (4.65) | 2 (1.72) | |
| Near Cookhouse | 21 (16.28) | 27 (23.28) | |
| On Your Back | 37 (28.68) | 41 (35.34) | |
| Missing | 1 (0.78) | 0 | |

 Table 9: Household information, by group (control and intervention)

| Cooking Location during Rainy Season | | | |
|---------------------------------------|-------------|-------------|------|
| Inside Main House | 4 (3 1) | 2 (1 72) | 0.5 |
| Inside Senarate Cookhouse | 124 (96 12) | 114(9828) | 0.5 |
| Outside Under A Roof | 1 (0 78) | 0 | |
| Cooking Location during Dry Season | 1 (0.70) | Ĭ | |
| Inside Main House | 2 (1.55) | 2 (1.72) | 0.82 |
| Inside Separate Cookhouse | 125 (96.90) | 113 (97.41) | |
| Outside In The Open Air | 1 (0.78) | 0 | |
| Outside Under A Roof | 1 (0.78) | 1 (0.86) | |
| Share Cook Area | | | |
| No | 118 (95.2) | 106 (92.2) | |
| Yes | 6 (4.8) | 9 (7.8) | |
| Number of cookstoves used at one time | | | |
| 1 | 15 (11.63) | 4 (3.45) | 0.09 |
| 2 | 111 (86.05) | 110 (94.83) | |
| 3 | 1 (0.78) | 2 (1.72) | |
| 4 | 1 (0.78) | 0 | |
| 5 | 1 (0.78) | 0 | |
| Cook To Sell | | | |
| No | 99 (76.74) | 85 (73.28) | 0.53 |
| Yes | 30 (23.26) | 31 (26.72) | |
| Open Windows | | | |
| No | 74 (57.36) | 65 (56.03) | 0.83 |
| Yes | 55 (42.64) | 51 (43.97) | |
| Burn Rubbish | | | |
| No | 41 (31.78) | 50 (43.10) | 0.07 |
| Yes | 88 (68.22) | 66 (56.90) | |
| Smokers In House | | | |
| No | 67 (51.94) | 65 (56.03) | 0.52 |
| Yes | 62 (48.06) | 51 (43.97) | |
| Number of smokers (n=113) | | | |
| 1 | 44 (70.97) | 38 (74.51) | 0.4 |
| 2 | 10 (16.13) | 10 (19.61) | |
| 3 | 3 (4.84) | 1 (1.96) | |
| 4 | 5 (8.06) | 1 (1.96) | |
| 5 | 0 | 1 (1.96) | |
| Where the smokers smoke (n=113) | | | |

| Inside | 4 (6.45) | 3 (5.88) | 0.56 |
|-------------------------|------------|------------|------|
| Outside | 23 (37.10) | 24 (47.06) | |
| Both Inside and Outside | 35 (56.45) | 24 (47.06) | |

* P-value for Pearson chi-squared across all categories excluding missing data

Note: The number of controls differs from the number of controls in Figure 1 (Participant's Flowchart) because of the ten households with two women enrolled and one household with three women enrolled

4.1.4 Cooking Activities

The cooking activities and cooking patterns of the mothers were assessed using the Household Information Questionnaire. The cooking activities were recorded in 3 periods: morning, day and evening. Within each period, the purpose of the cookstove use, duration of the fire, days per week mother cooked, and location of child while mother cooked were captured.

During the mornings, the cookstove was not lit in 9.6% - 28.6% of the household, most likely because a cold breakfast is often served without the need of the cookstove. In households where a cookstove was used in the mornings, it was usually lit for only one hour. During this time, young children were generally either inside away from the cookstove, outside away from the cookstove or on their mother's back. During the day, the cookstove was almost always lit for 2-3 hours. This is the time when the mothers prepare the main course of the day. During this time, the children were usually outside away from the cookstove was lit for 1-2 hours, and the children were inside the cookhouse, outside, or on their mothers' back. Table 10 shows the breakdown of the morning, daytime and evening cooking activities.

Table 10: Cooking activities, by group (control and intervention)

| MUT HILL | Mo | rning |
|----------|----|-------|
|----------|----|-------|

| Variable | Control n=125 (%) | Intervention n=115 (%) | P-Value* |
|-----------------------------------|----------------------|---------------------------|----------|
| Cookstove Purpose | | | |
| Cook | 99 (79.2) | 102 (88.7) | 0.131 |
| Other | 3 (2.4) | 2 (1.7) | |
| Cookstove not in use | 23 (18.4) | 11 (9.6) | |
| Duration of fire (hours) | | | |
| 1 | 95 (76.0) | 97 (84.3) | 0.15 |
| 2 | 7 (5.6) | 7 (6.1) | |
| Cookstove not in use | 23 (18.4) | 11 (9.6) | |
| Mornings per week mother cooks | | | |
| 0 | 34 (27.2) | 20 (17.4) | 0.00 |
| 1-2 | 35 (28.0) | 13 (11.3) | |
| 3-4 | 24 (19.2) | 22 (19.3) | |
| ≥5 | 32 (25.6) | 60 (52.2) | |
| Location of Child while Mother is | | | |
| Cooks | | | |
| Inside Away from Cookstove | 37 (29.6) | 40 (34.8) | 0.18 |
| Outside Away from Cookstove | 36 (28.8) | 31 (27.0) | |
| Different Compound | 0 (0) | 0 (0) | |
| On Mother's Back | 26 (20.8) | 28 (24.4) | |
| Near Cookstove in Cookhouse | 2 (1.6) | 5 (4.4) | |
| Near Cookstove (within 1 meter) | 0 (0) | 0 (0) | |
| Cookstove not in use | 24 (19.2) | 11 (9.6) | |

* P-value for Pearson chi-squared across all categories excluding missing data

| Variable | Control n=125 (%) | Intervention n=115 (%) | P-Value* |
|---------------------------------|----------------------|---------------------------|----------|
| Cookstove Purpose | | | |
| Cook | 125 (100.0) | 112 (97.4) | 0.07 |
| Other | 0 (0) | 0 (0) | |
| Cookstove not in use | 0 | 3 (2.6) | |
| Duration of fire (hours) | | | |
| 1 | 1 (0.8) | 4 (3.5) | 0.22 |
| 2 | 60 (48.0) | 53 (46.1) | |
| 3 | 62 (49.6) | 54 (47.0) | |
| 4 | 2 (1.6) | 1 (0.9) | |
| Cookstove not in use | 0 | 3 (2.6) | |
| Days per week mother cooks | | | |
| 0 | 2 (1.6) | 4 (3.48) | 0.00 |
| 1-2 | 45 (36.0) | 18 (15.7) | |
| 3-4 | 38 (30.4) | 28 (24.4) | |
| ≥5 | 40 (32.0) | 65 (56.5) | |
| Location of Child while Mother | | | |
| Cooks | | | |
| Inside Away from Cookstove | 2 (1.6) | 4 (3.5) | 0.32 |
| Outside Away Cookstove | 69 (55.2) | 50 (43.5) | |
| Different Compound | 0 (0) | 0 (0) | |
| On Mother's Back | 39 (31.2) | 39 (33.9) | |
| Near Cookstove in Cookhouse | 12 (9.6) | 18 (15.6) | |
| Near Cookstove (within 1 meter) | 2 (1.6) | 1 (0.9) | |
| Cookstove not in use | 0 | 3 (2.6) | |

* P-value for Pearson chi-squared across all categories excluding missing data

| Variable | Control n=125 (%) | Intervention n=115 (%) | P-Value* |
|---------------------------------|----------------------|---------------------------|----------|
| Cookstove Purpose | | | |
| Cook | 104 (83.2) | 95 (82.6) | 0.89 |
| Other | 4 (3.2) | 5 (4.4) | |
| Cookstove not in use | 17 (13.6) | 15 (13.0) | |
| Duration of fire (hours) | | | |
| 1 | 85 (68.0) | 87 (75.7) | 0.24 |
| 2 | 23 (18.4) | 12 (10.4) | |
| 3 | 0 (0) | 1 (0.9) | |
| Cookstove not in use | 17 (13.6) | 15 (13.0) | |
| Days per week mother cooks | | | |
| 0 | 28 (22.4) | 33 (28.7) | 0.00 |
| 1-2 | 36 (28.8) | 11 (9.6) | |
| 3-4 | 31 (24.8) | 22 (19.1) | |
| ≥5 | 30 (24.0) | 49 (42.6) | |
| Location of Child while Mother | | | |
| Cooks | | | |
| Inside Away from Cookstove | 8 (6.4) | 8 (7.0) | 0.83 |
| Outside Away from Cookstove | 70 (56.0) | 63 (54.8) | |
| Different Compound | 1 (0.8) | 1 (0.9) | |
| On Mother's Back | 26 (20.8) | 22 (19.1) | |
| Near Cookstove in Cookhouse | 2 (1.6) | 5 (4.4) | |
| Near Cookstove (within 1 meter) | 0 (0) | 1 (0.9) | |
| Cookstove not in use | 18 (14.4) | 15 (13.0) | |
| | | | |

Evening

* P-value for Pearson chi-squared across all categories excluding missing data

Overall, the cookstove was lit for longer hours during the day, followed by evening (Table 11). During the hours of cooking, the babies spent the majority of the time outside away from the cooking cookstove or on their mothers' back. In other words, they were either not directly exposed to the cooking smoke, or they were in direct contact with the cooking smoke.

| Time of Day | Control n=125 | | Intervention n=115 | |
|-------------|------------------|-----------|-----------------------|-----------|
| | Mean (hours) | Std. Dev. | Mean (hours) | Std. Dev. |
| Morning | 2.93 | 2.63 | 4.46 | 2.78 |
| Day | 3.83 | 2.19 | 4.97 | 2.31 |
| Evening | 3.0 | 2.49 | 3.73 | 2.96 |

Table 11: Number of hours Per Day Women Cook, by Time of Day (Control and Intervention)

4.1.5 Discussion

Overall, the baseline characteristics appear to be similarly distributed in both the control and intervention groups. This was anticipated because of random allocation into either group at the start of the study. There is one risk factor that does show a significant difference between the two groups: Days per Week Mother Cooks (p=0.00 for all three time periods). The women in the intervention group appear to cook more days per week than the women in the control group. This can lead to a false negative if the women in the intervention group appear to cook more days per week than the women in the control group. This can lead to a false negative if the women in the intervention group are spending more time in the cooking houses and therefore more exposure to the cooking smoke. If there was a difference in PM_{2.5} measurement between a traditional stove/wood versus 'improved' stove/briquettes, it might not be captured if the women in the intervention group are exposed for a longer period of time. In Table 11, it also shows a difference in the number of hours women from the control group are cooking, versus women in the intervention group. For all three time periods, the women in the Intervention group are cooking for longer periods of time. This, when compounded with the number of days women are cooking in the kitchen, further supports a possible false negative and the need to do further analysis in the future.

One area of concern is the uneven distribution of participants in the control and intervention groups at the start of the study. 136 mothers were allocated to the control group while 115 were allocated to the intervention group. As mentioned earlier in section 2.4.1: Initial Recruitment, the only time the random allocation was manipulated was when there were multiple mothers from the same compound in the study. One possible
explanation for the uneven distribution of participants in the two groups is the allocation process the field workers used when there were multiple women from the same compound. When this occurred, the field workers might have automatically allocated those women to the control group, and then continued the allocation process, resulting in more women in the control group. The field workers were instructed to allocate the same fuel to women living in the same compound, yet it was not made clear as to how/which fuel should be allocated in these circumstances. More careful oversight should have been provided to this allocation process. Though in the end, because a large number of control participants opted to drop out, the final numbers in both groups were very similar (119 in control group vs. 115 in the intervention group).

Another area of concern is the difference in numbers of participants from the control group who completed the study compared to the number of participants in the intervention group. In the control group, 12% of the mothers did not have their 2nd NPS sample taken, 8.1% did not complete the Household Information Form, and 12.1% did not have their cookhouses tested for HAP concentrations. In comparison, all the mothers in the intervention group had their 2nd NPS taken and had completed the Household Information Form, and only 3.5% did not have their cookhouses tested. One reason for this difference might be that those in the intervention group wanted to keep receiving the briquettes for the duration of the study, which required them to stay enrolled in the study. The women who withdrew from the study no longer showed interest in participants in the control group and actively try to keep them involved in the study.

4.2 Pneumococcal Carriage

4.2.1 Pneumococcal Carriage in the Study Population

Pneumococcal Carriage Prevalence in Children and Mothers

Two separate nasopharyngeal swabs samples (pre- and post-intervention) were taken from all participating mothers and children and sent to the Medical Research Council's laboratory for testing. 440 (86.8%) of the samples collected pre-intervention and 418 (88.6%) collected post-intervention were included in the analysis. The percentage of the samples that were usable is unusually low, possibly due to transportation issues. Because of the distance to the laboratories, and the heavy workload in the field, the field staff periodically had difficulties getting the samples to the laboratory in a timely manner, which might have resulted in unanalyzable swabs. The researcher was unaware of this issue, and was therefore unable to address it promptly. Had the issue been brought to the researcher's attention, modifications could have been made to the specimen collection protocol to alleviate this problem.

At the start of the study, 58.8% of the children and 21.6% of mothers with analyzable samples (Table 12) tested positive for pneumococcal carriage. The control and intervention groups of both the children and mothers had similar prevalence levels of pneumococcal carriage as might be expected from the randomization. These numbers were lower than the 80% pneumococcal carriage levels found in the Gambian population in 2008 [15]. The lower pneumococcal carriage levels might be attributed to the introduction of the pneumococcal vaccine in The Gambia in 2009. This will be discussed in more detail in the following section of the paper entitled '*PCV7 and Specific Serotypes'*.

| Pneumococcal Carriage | Control | Intervention |
|-------------------------|-----------|--------------|
| Pre-Intervention | n (%) | n (%) |
| Children | n=127 | n=116 |
| Positive | 74 (58.3) | 69 (59.5) |
| Negative | 38 (29.9) | 32 (27.6) |
| Mothers | n=118 | n=109 |
| Positive | 26 (22.0) | 23 (21.1) |
| Negative | 92 (78.0) | 86 (78.9) |

Table 12: Pneumococcal carriage of children and mothers pre-intervention, by group (control and intervention)

When the 2nd NPS were collected post-intervention (16th week of the study), 74.6% of children and 24.4% of mothers tested positive for pneumococcal carriage (Table 13). There was no difference in the prevalence of carriage in women between the control and intervention groups (24.3% vs. 24.5%, p = 0.97), and neither was there any difference in children (74.8% vs. 74.5%, p = 0.96). One reason why the percentage of children and mothers tested positive for pneumococcal carriage are higher at the completion of the study compared to the start of the study might be due to seasonal factors. The study completed at the end of the dry season, which is generally when a higher prevalence of pneumococcal carriage can be found. A study conducted in The Gambia collected 4,495 NPS samples from 636 children over an 18-month period. They found the prevalence of carriage to be significantly higher during the dry than the rainy season for any pneumococcal carriage [57.6% versus 47.8% (p<0.001)], pneumococcal vaccine serotype carriage [10.3% versus 6.5% (p< 0.001)] and non-vaccine serotype carriage [49.7% versus 42.7% (p<0.001)]. Differences remained significant in the adjusted analysis [98]. Another reason for the difference in pneumococcal carriage among the pre- and postintervention participants may be due to random error, which are parameters beyond the control of the study and may have interfered with the study result.

| | | | | (control |
|-----------------------|-----------|--------------|---------|------------|
| Pneumococcal Carriage | Control | Intervention | P-Value | and |
| Post Intervention | n (%) | n (%) | | interventi |
| Children | n=111 | n=98 | | on) |
| Positive | 83 (74.8) | 73 (74.5) | 0.96 | |
| Negative | 28 (25.2) | 25 (25.5) | | 111 |
| Mothers | n=107 | n=102 | | 111 |
| Positive | 26 (24.3) | 25 (24.5) | 0.97 | |
| Negative | 81 (75.7) | 77 (75.5) | | |

Table 13: Pneumococcal carriage of children and mothers post-intervention at week 16, by group

During the course of the study, information was collected on potential risk factors for pneumococcal carriage. The three factors that were deemed most important to consider were whether the child was currently being breastfed at the time the pneumococcal sample was collected, the total number of doses of the pneumococcal vaccine the child had received, and the age of the child (section 2.7.5 Confounding). As can be seen in Table 14, none of these factors were associated with pneumococcal carriage of the children at the end of the study. 87.1% of the total children post-intervention were receiving a mix of water and milk, and 85.2% of these children had received all three of the pneumococcal vaccine.

| Characteristic | Category | Positive for Pneumococcal Carriage | | | |
|--------------------------|-----------------|------------------------------------|--------------|---------|--|
| | | Control | Intervention | P-Value | |
| | | n (%) | n (%) | | |
| Number | | 83 | 73 | | |
| | | | | | |
| Breastfeeding status of | Exclusive | 38 (35.6) | 29 (31.4) | 0.46 | |
| child at end of study | Mix | 44 (46.8) | 44 (41.2) | | |
| | Not Breastfed | 1 (0.5) | 0 | | |
| Number of Pneumococcal | 0 Doses | 0 | 2 (0.9) | 0.27 | |
| Vaccine Doses child had | 1 Dose | 2 (1.6) | 1 (1.4) | | |
| received at end of study | 2 Doses | 12 (10.1) | 7 (8.9) | | |
| | 3 Doses | 67 (69.2) | 63 (60.8) | | |
| | Unknown | 2 (1.1) | 0 | | |
| | 2-3 months | 9 (10.1) | 10 (8.9) | 0.82 | |
| Age of child at | 4-5 months | 18 (16.5) | 13 (14.5) | | |
| start of study | 6-7 months | 26 (27.1) | 25 (23.9) | | |
| | \geq 8 months | 29 (28.7) | 25 (25.3) | | |
| | Missing | 1 (0.5) | 0 | | |

Table 14: Prevalence of Pneumococcal Carriage of all 213 children, by exposures of interest (breastfeeding, number of pneumococcal vaccine doses and age of child)

* P-value for Pearson chi-squared across all categories excluding missing data

| Exposure | Intervention v. Co | ontrol Group |
|------------|--------------------|--------------|
| | OR (95% CI) | P-value |
| Breastfed | | |
| Exclusive | 0.7 (0.1-4.0) | 0.71 |
| Mix | 1.0 (0.5-2.0) | 0.93 |
| PCV7 Doses | | |
| 2 | 0.3 (0-4.3) | 0.34 |
| 3 | 1.0 (0.5-2.0) | 0.95 |
| Age Group | | |
| 1 | 1.0 (0.3-2.9) | 0.96 |
| 2 | 2.3 (0.7-7.7) | 0.16 |
| 3 | 0.5 (0.1-1.8) | 0.24 |
| 4 | 0.6 (0.1-4.0) | 0.55 |

Table 15: Univariate analysis of associations between carriage-related exposures and pneumococcal carriage post-intervention in children

PCV7 and Specific Serotypes

Of the total of 256 babies swabbed at the start of the study, 44.5% had already received the recommended 3 doses of PCV7 (Table 16). This number rose to 85.8% by the end of the study, indicating that many of the babies were still receiving their vaccinations while they were enrolled in the study. Only 10.9% of the study babies had not received any of the three doses of PCV7 at the start of the study, though that number dropped dramatically to 0.8% by the end of the study. There were no major differences in doses between the control and intervention groups, both at the start of the study (1st NPS collection) and the end of the study (2nd NPS collection).

| Doses | Control | Intervention | P-Value* |
|-------------------|------------|--------------|----------|
| | n (%) | n (%) | |
| Pre-Intervention | n=140 | n=116 | |
| 0 doses | 12 (8.6) | 16 (13.8) | 0.26 |
| 1 dose | 36 (25.7) | 22 (19.0) | |
| 2 doses | 28 (20.0) | 17 (14.7) | |
| 3 doses | 57 (40.7) | 57 (49.1) | |
| Unknown | 7 (5.0) | 4 (3.4) | |
| Post-Intervention | n=125 | n=116 | |
| 0 doses | 0 | 2 (1.7) | 0.35 |
| 1 dose | 3 (2.4) | 1 (0.9)) | |
| 2 doses | 14 (11.2) | 9 (7.8) | |
| 3 doses | 104 (83.2) | 102 (87.9) | |
| Unknown | 4 (3.2) | 2 (1.7) | |

Table 16: PCV7 doses pre- and post-intervention, by group (control and intervention)

* P-value for Pearson chi-squared across all categories excluding missing data

Another important observation to make was whether PCV7 affected pneumococcal carriage. At the start of the study, 67.7% of the children tested positive for pneumococcal carriage and 32.3% tested negative. The number of doses of PCV7 the children had received was similar among those who tested positive for pneumococcal carriage and those who tested negative (Table 17). Of the 153 children who tested positive for pneumococcal carriage, 45.8% of them had received the full 3 doses of PCV7. Of the 73 children who tested negative for pneumococcal carriage, 45.2% had received the full dosage of PCV7. Of the 103 total children who received the full 3 doses of PCV at the start of the study, 68% tested positive for pneumococcal carriage while 32% tested negative. These numbers suggests that receiving the full allotment of PCV7 (3 doses) does not reduce a child's chances of testing positive for pneumococcal carriage. These finding are consistent with other findings, including a study in The Gambia that found no significant difference in pneumococcal carriage between children who were unvaccinated and those who received three doses of PCV9 at infancy [62].

At the end of the study, 74.6% of the children tested positive for pneumococcal carriage. There was no difference between the children who tested positive and had received the full 3 doses of PCV7 (83.3%) and the children who tested negative had received the full 3 doses of PCV7 (90.6%). Of the total 178 children who had received 3 doses of PCV7 by the end of the study, 73% tested positive for pneumococcal carriage and 27% tested negative.

| Doses | Positive | Negative | Total |
|-------------------|---------------|--------------|------------|
| | n (%) | n (%) | n (%) |
| Number | n=309 | n=126 | n=435 |
| Pre-Intervention | 153 (67.7%) | n=73 (32.3%) | n=226 |
| 0 doses | 12 (7.8) | 12 (16.4) | 24 (10.6) |
| 1 dose | 34 (22.2) | 17 (23.3) | 51 (22.6) |
| 2 doses | 31 (20.3) | 9 (12.3) | 40 (17.7) |
| 3 doses | 70 (45.8) | 33 (45.2) | 103 (45.6) |
| Unknown | 6 (3.9) | 2 (2.7) | 8 (3.5) |
| Post-Intervention | n=156 (74.6%) | n=53 (25.4%) | n=209 |
| 0 doses | 2 (1.3) | 0 | 2 (1.0) |
| 1 dose | 3 (1.9) | 1 (1.9) | 4 (1.9) |
| 2 doses | 19 (12.2) | 3 (5.7) | 22 (10.5) |
| 3 doses | 130 (83.3) | 48 (90.6) | 178 (85.2) |
| Unknown | 2 (1.3) | 1 (1.9) | 3 (1.4) |

Table 17: Pneumococcal vaccine doses in children pre- and post- intervention, by pneumococcal carriage

Lastly, it was important to assess whether those children who had received PCV7 were carriers of the serotypes contained in the vaccine (4, 6B, 9V, 14, 18C, 19F, and 23F). Of the 153 children tested positive for pneumococcal carriage at the start of the study, only 13 of them were carriers of any of the 7 serotypes found in PCV7. Of the 156 children found positive at the end of the study, 14 of them were carriers of a PCV7 serotype (Table 17). As can be noted, those who received 0 doses of PCV7 compared to those who received all 3 doses of PCV7 did not differ in terms of being carriers for the serotypes contained in the vaccine. The reason for this might be that these serotypes had been reduced significantly in the population as a whole due to people receiving the

immunization. The unvaccinated population was therefore protected from these serotypes because of the high vaccination coverage in the population, otherwise known as herd immunity. These findings are consistent with others studies conducted around the world. A study in Kenya suggested likely herd protection effects of PVC since carriage of vaccine-type pneumococci in children and older individuals was reduced by two-thirds following an extensive catch-up campaign [99].

Table 18 displays the entire breakdown of pneumococcal carriage serotypes found among the women and children, both post and pre intervention. Table 19 shows the serotypes found among children and mothers.

| Serotype | Number of Doses Pre-Intervention | | | | Num | ber of Dose | s Post-Interv | rention |
|----------|----------------------------------|----------|----------|-----------|---------|-------------|---------------|-----------|
| | 0 Doses | 1 Dose | 2 Doses | 3 Doses | 0 Doses | 1 Dose | 2 Doses | 3 Doses |
| | n=24 (%) | n=51 (%) | n=40 (%) | n=103 (%) | n=2 (%) | n=4 (%) | n=21 (%) | n=210 (%) |
| 4 | 0 | 0 | 1 (2.5) | 0 | 0 | 0 | 0 | 0 |
| 6B | 0 | 1 (2.0) | 0 | 2 (1.9) | 0 | 0 | 0 | 2 (1.0) |
| 9V | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 0 | 1 (2.0) | 0 | 0 | 0 | 0 | 1 | 0 |
| 18C | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 19F | 1 (4.2) | 1 (2.0) | 1 (2.5) | 1 (1.0) | 0 | 0 | 0 | 3 (1.4) |
| 23F | 0 | 2 (3.9) | 0 | 2 (1.9) | 0 | 0 | 1 | 3 (1.4) |

Table 18: PCV7 Doses and serotypes among children (pre- and post-intervention)

| Serotypes | | Mothers | | | Children | | |
|-----------|--------------|--------------|-----------|--------------|--------------|-----------|--------------|
| | Pre- | Post- | Total | Pre- | Post- | Total | Total of all |
| | Intervention | Intervention | n (%) | Intervention | Intervention | | Samples |
| NT | 9 (16.4) | 9 (17.0) | 18 (16.7) | 9 (6.2) | 22 (14.2) | 31 (15.5) | 49 (15.9) |
| 1 | | 1 (1.9) | 1 (0.9) | | | | 1 (0.3) |
| 2 | 1 (1.8) | | 1 (0.9) | | | | 1 (0.3) |
| 3 | 5 (9.1) | 5 (9.4) | 10 (9.3) | 2 (1.4) | 1 (0.6) | 3 (1.5) | 13 (4.2) |
| 4 | | | | 1 (0.7) | | 1 (0.5) | 1 (0.3) |
| 5 | | 2 (3.8) | 2 (1.9) | | 1 (0.6) | 1 (0.5) | 3 (1.0) |
| 6A | 2 (3.6) | | 2 (1.9) | 10 (6.9) | 6 (3.9) | 16 (8.0) | 18 (5.8) |
| 6B | | | | 3 (2.1) | 2 (1.3) | 5 (2.5) | 5 (1.6) |
| 7C | | | | | 1 (0.6) | 1 (0.5) | 1 (0.3) |
| 8 | 1 (1.8) | | 1 (0.9) | | 1 (0.6) | 1 (0.5) | 2 (0.6) |
| 9A | | 2 (3.8) | 2 (1.9) | 4 (2.8) | 1 (0.6) | 5 (2.5) | 7 (2.3) |
| 10 | | | | 1 (0.7) | | 1 (0.5) | 1 (0.3) |
| 10A | 1 (1.8) | 2 (3.8) | 3 (2.8) | 4 (2.8) | 5 (3.2) | 9 (4.5) | 12 (3.9) |
| 10C | | | | | 1 (0.6) | 1 (0.5) | 1 (0.3) |
| 10F | | | | | 1 (0.6) | 1 (0.5) | 1 (0.3) |
| 11A | 2 (3.6) | | 2(1.9) | 3 (2.1) | 5 (3.2) | 8 (4.0) | 10 (3.2) |
| 11D | 3 (5.5) | | 3 (2.8) | 5 (3.4) | 1 (0.6) | 6 (3.0) | 9 (2.9) |
| 11F | | | | | 4 (2.6) | 4 (2.0) | 4 (1.3) |
| 12B | | 1 (1.9) | 1 (0.9) | | | | 1 (0.3) |
| 12F | | | | 3 (2.1) | 2 (1.3) | 5 (2.5) | 5 (1.6) |
| 13 | 4 (7.3) | 3 (5.7) | 7 (6.5) | 4 (2.8) | 6 (3.9) | 10 (5.0) | 17 (5.5) |
| 14 | | 1 (1.9) | 1 (0.9) | 1 (0.7) | 1 (0.6) | 2 (1.0) | 3 (1.0) |
| 15A | 1 (1.8) | 2 (3.8) | 3 (2.8) | 4 (2.8) | 7 (4.5) | 11 (5.5) | 14 (4.5) |
| 15B | 2 (3.6) | | 2 (1.9) | 10 (6.9) | 6 (3.9) | 16 (8.0) | 18 (5.8) |
| 15C | | | | 4 (2.8) | 3 (1.9) | 7 (3.5) | 7 (2.3) |
| 16F | 1 (1.8) | 4 (7.5) | 5 (4.6) | 8 (5.5) | 10 (6.9) | 18 (9.0) | 23 (7.5) |
| 17F | | | | 4 (2.8) | 3 (1.9) | 7 (3.5) | 7 (2.3) |
| 18A | 1 (1.8) | | 1 (0.9) | | | | 1 (0.3) |
| 18C | | 1 (1.9) | 1 (0.9) | | | | 1 (0.3) |
| 19A | 2 (3.6) | 1 (1.9) | 3 (2.8) | 10 (6.9) | 12 (7.7) | 22 (11.0) | 25 (8.1) |
| 19C | 2 (3.6) | 3 (5.7) | 5 (4.6) | 10 (6.9) | 6 (3.9) | 16 (8.0) | 21 (6.8) |
| 19F | | 1 (1.9) | 1 (0.9) | 4 (2.8) | 3 (1.9) | 4 (2.0) | 5 (1.6) |
| 20 | 1 (1.8) | | 1 (0.9) | 1 (0.7) | | 1 (0.5) | 2 (0.6) |
| 21 | 2 (3.6) | 1 (1.9) | 3 (2.8) | 6 (4.1) | 4 (2.6) | 10 (5.0) | 13 (4.2) |
| 23A | 2 (3.6) | 2 (3.8) | 4 (3.7) | 2 (1.4) | 3 (1.9) | 5 (2.5) | 9 (2.9) |
| 23B | | | | 1 (0.7) | 3 (1.9) | 4 (2.0) | 4 (1.3) |
| 23F | 1 (1.8) | | 1 (0.9) | 3 (2.1) | 5 (3.2) | 8 (4.0) | 9 (2.9) |
| 24A | | | | | 2 (1.3) | 2 (1.0) | 2 (0.6) |
| 24F | 2 (3.6) | | 2 (1.9) | 3 (2.1) | | 3 (1.5) | 5 (1.6) |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

Table 19: Serotypes among children and mothers (pre- and post-intervention)

| 28F | | 1 (1.9) | 1 (0.9) | | 1 (0.6) | 1 (0.5) | 2 (0.6) |
|-------|---------|----------|---------|----------|----------|-----------|-----------|
| 31 | | | | 2 (1.4) | 2 (1.3) | 4 (2.0) | 4 (1.3) |
| | | | | | | | |
| 33B | | | | 1 (0.7) | | 1 (0.5) | 1 (0.3) |
| 33F | | | | 1 (0.7) | | 1 (0.5) | 1 (0.3) |
| 34 | | 2 (3.8) | 2 (1.9) | | 4 (2.6) | 4 (2.0) | 6 (1.9) |
| 35 | | | | | 1 (0.6) | 1 (0.5) | 1 (0.3) |
| 35B | 3 (5.5) | 6 (11.3) | 9 (8.3) | 10 (6.9) | 13 (8.4) | 23 (11.5) | 32 (10.4) |
| 35F | 1 (1.8) | 1 (1.9) | 2 (1.9) | 3 (2.1) | 1 (0.6) | 4 (2.0) | 6 (1.9) |
| 36 | | 1 (1.9) | 1 (0.9) | | 1 (0.6) | 1 (0.5) | 2 (0.6) |
| 37 | 4 (7.3) | 1 (1.9) | 5 (4.6) | | | | 5 (1.6) |
| 38 | | | | | 11 (0.6) | 1 (0.5) | 1 (0.3) |
| 39 | 1 (1.8) | | 1 (0.9) | 2 (1.4) | 1 (0.6) | 3 (1.5) | 4 (1.3) |
| 40 | | | | 2 (1.4) | | 2 (1.0) | 2 (0.6) |
| 41 | | | | 1 (0.7) | | 1 (0.5) | 1 (0.3) |
| 46 | | | | 1 (0.7) | | 1 (0.5) | 1 (0.3) |
| 47A | 1 (1.8) | | 1 (0.9) | 5 (3.4) | 1 (0.6) | 6 (3.0) | 7 (2.3) |
| 47F | | | | | 1 (0.6) | 1 (0.5) | 1 (0.3) |
| 110 | | | | 1 (0.7) | | 1 (0.5) | 1 (0.3) |
| 156 | | | | 1 (0.7) | | 1 (0.5) | 1 (0.3) |
| Total | 55 | 53 | 108 | 145 | 155 | 200 | 308 |

There are a couple of key results to note here. Firstly, there is no difference in prevalence of pneumococcal carriage post-intervention between the control and intervention groups in both the children and mothers. This means that the intervention (briquettes and alternative cookstove) did not have a negative or positive effect on pneumococcal carriage among children who had received all three doses of PCV7 and those who had received 0-2 doses. This can be due to herd immunity and small sample size (the study was designed to find a difference in pneumococcal carriage between intervention and control group as opposed to specific serotypes among groups). Lastly, those who received 0 doses of PCV7 compared to those who received all 3 doses of PCV7 did not differ in terms of being carriers for the serotypes contained in the vaccine. Once again, this could be due to herd immunity and small sample size. It is important to note though that these findings in this study are consistent with findings in studies with a larger sample sizes.

4.3 Household Air Pollution

Indoor air pollution measurements were taken in all but two of the cookhouses of the participating mothers. The reason measurements were not taken in two of the cookhouses (one control and one intervention) was that the field workers were unable to secure a time that would work for the women before the study ended.

This data indicates that the respective cookhouses of the control and intervention groups are similar in terms of characteristics that might influence the concentration of particulates from the cooking fires (Table 20). The cookhouse size in cubic meters had a similar distribution between the control and intervention groups. The same distribution existed for the number of doors, windows, and width of gap between ceiling and walls.

| Characteristic | Control | Intervention | P-Value* |
|--|------------|--------------|----------|
| | n=129 (%) | n=116 (%) | |
| Cookhouse Volume (m ³) | | | |
| <10 | 45 (34.9) | 44 (37.9) | 0.79 |
| 10-19.9 | 71 (55.0) | 59 (50.9) | |
| 20-29.9 | 7 (5.4) | 7 (6.0) | |
| 30-39.9 | 3 (2.3) | 1 (0.9) | |
| 40-49.9 | 2 (1.6) | 2 (1.7) | |
| \geq 50 | 1 (0.8) | 3 (2.6) | |
| Number of Door | | | |
| 1 | 114 (88.4) | 99 (85.3) | 0.41 |
| 2 | 13 (10.1) | 17 (14.7) | |
| 3 | 1 (0.78) | 0 | |
| 4 | 1 (0.8) | 0 | |
| Number of Windows | | | |
| 0 | 51 (39.5) | 47 (40.5) | 0.96 |
| 1 | 41 (31.8) | 35 (30.2) | |
| 2 | 21 (16.3) | 18 (15.5) | |
| 3 | 9 (7.0) | 7 (7.0) | |
| 4 | 6 (4.7) | 7 (6.0) | |
| 5 | 1 (0.8) | 1 (0.9) | |
| 6 | 0 | 1 (0.9) | |
| Size of gap between walls and ceilings | | | |
| 0 | 60 (46.5) | 51 (44.0) | 0.43 |
| 0.1-9.9 | 12 (9.3) | 11 (9.5) | |
| 10-19.9 | 46 (35.7) | 44 (37.9) | |
| 20-29.9 | 8 (6.2) | 5 (4.3) | |
| 30-39.9 | 3 (2.3) | 2 (1.7) | |
| ≥40 | 0 | 3 (2.6) | |

Table 20: Cookhouse characteristics, by group (control and intervention)

* P-value for Pearson chi-squared across all categories excluding missing data

There were a total of 224 indoor air pollution samples taken over the 16-week study period. Of those 224 samples, 4 had to be dropped (3 in the control group and 1 in the intervention group) due to problems with the pump (low battery). This was indicated on the pump when the field workers returned to the site to collect the equipment. There were 4 more samples dropped due to scratches on the filters rendering them unsuitable for analysis. This might have occurred while transferring the filters to the plastic dishes to be sent to the laboratory. Therefore, the total number of HAP samples included in the study was 216 (109 from the control group and 107 from the intervention group). Additionally, there were 12 duplicates and 13 blanks collected (Table 21).

| Characteristic | Control | Intervention | Total |
|------------------------------|---------|--------------|-------|
| | n=118 | n=124 | n=241 |
| HAP Samples (good condition) | 109 | 108 | 217 |
| Blanks | 3 | 10 | 13 |
| Duplicates | 6 | 6 | 12 |

Table 21: Description of filters, by group (control and intervention)

The first analysis was to establish whether biomass briquettes effectively reduce $PM_{2.5}$ in the target population. To do so, it was first necessary to calculate the net mass in micrograms of each filter using the following calculation.

netmass =
$$1000 * [(off weight - on weight) - (BP off - BP on) * 0.004]$$

The "on" weight refers to the weight of the filter prior to being used while the "off" weight refers to the weight of the filter after being used. To calculate the "on" weight, each of the filters was weighed twice in a controlled environment and the two weights were averaged together to determine the "on" weight of that filter. If these two masses were not within 5µg of each other, the filter was weighed a third time. After the third weighing, the average of the two masses within 5µg was used to determine that final "on" weight. After the study, the used filters were sent back to the laboratory, whereby the same weighing system was used to determine the "off" weights of the filters. The BP in the equation refers to the barometric pressure (inches Hg) in the weighing room at the time each of the filters was weighed. The number was included with the "on" and "off" measurements.

After calculating the net mass of each filter, the mass concentration of the filter was computed using the following equation:

Mass concentration =
$$[net mass - average of blanks]/volume in m3$$

To calculate the average of the blanks, the net mass of all the blank filters were first calculated, and then an average was taken of all the blanks. The thirteen blanks averaged -5.837 PM_{2.5} (μ g/m³). The negative number is attributed to moisture mass loss while in the field. Means of the two groups (intervention and control) were compared using a 2-sample t-test with a p-value of <0.05 considered significant. The size of the effect was the difference in means between the two groups, together with the 95% confidence intervals. A regression analysis was also run for the dimension of the cookhouse, number of doors, numbers of windows, and gap between wall and ceiling. The only factor that was shown to affect the HAP concentrations was the dimension of the cookhouse, showing that the larger the cookhouse, the lower the HAP concentration levels.

Thirteen blanks were collected during the course of the study. Of the thirteen blanks, one had to be excluded from the study because its weight was outside the normal parameters (18.016 PM_{2.5} (μ g/m³)). Of the remaining twelve blanks, the average net mass was 0.97 PM_{2.5} (μ g/m³). The average net mass of the blanks was then used to calculate the mass concentration of all the filters.

Duplicates

Thirteen duplicates were collected during the study. One of the duplicates was unusable because the pump had malfunctioned during the testing period. Of the remaining twelve duplicates, six were from the control group and six were from the intervention group.

| Outcome | Group | | | | Difference | 95% CI for | P-value | | |
|----------------------------|-------|---------|-----|--------------|------------|------------|---------|---------------|-----|
| | | Control | l | Intervention | | in Means | Mean | | |
| | Mean | SD | n | Mean | SD | n | - | Difference | |
| $PM_{2.5} \ (\mu g/m^3)^*$ | 573.1 | 134.3 | 119 | 659.8 | 827.7 | 108 | -86.6 | -348.6, 175.3 | 0.5 |

Table 22: HAP measurements, by group (control and intervention)

Adjusted for size and number of pots used, size of cookhouse, and number of windows/doors/spaces between wall and ceiling; *Over a 48-hour period



Figure 21: Histograms of HAP measurements, by group (control and intervention)

Frequency of $PM_{2.5}$ (µg/m³) measurements in all households measured over 48 hours Any emissions that measured above 1500 µg/m³ were excluded from the analysis

As can be seen in Table 22, the mean $PM_{2.5} (\mu g/m^3)$ of the control group is slight lower than the mean $PM_{2.5} (\mu g/m^3)$ of the intervention group (573.1 ($\mu g/m^3$) vs. 659.8 ($\mu g/m^3$)), though it is not significant as the p-value is greater than 0.05. In Figure 21, the histograms show a slight different distribution of $PM_{2.5} (\mu g/m^3)$ emissions in the control versus intervention cookhouses. The intervention group has 35% of the cookhouses producing <150 $\mu g/m^3$ while the control group only has 25% of their cookhouses falling in that range. But as mentioned above, these differences are not significant.

| Pneumococcal Carriage | Number | Mean* | Std. Dev. |
|-----------------------|--------|-------|-----------|
| Negative | 50 | 219.0 | 146.4 |
| Positive | 133 | 402.1 | 316.9 |

Table 23: HAP and Pneumococcal Carriage in Children (Descriptive)

5 HAP emissions that measured above 1500 µg/m³ were excluded from the analysis

* PM_{2.5} (µg/m³) measurements in all households measured over 48 hours

| Pneumococcal Carriage | SS | df | MS | F | P-Value |
|-----------------------|------------|-----|-----------|------|---------|
| Between groups | 1217673.1 | 1 | 1217673.1 | 15.4 | 0.00 |
| Within groups | 14310340.6 | 182 | 79062.7 | | |

5 HAP emissions that measured above 1500 μ g/m³ were excluded from the analysis

Table 25: HAP and Pneumococcal Carriage in Mothers (Descriptive)

| Pneumococcal Carriage | Number | Mean* | Std. Dev. |
|-----------------------|--------|-------|-----------|
| Negative | 144 | 337.4 | 276.9 |
| Positive | 43 | 378.3 | 329.7 |

5 HAP emissions that measured above 1500 μ g/m³ were excluded from the analysis

* PM2.5 (µg/m3) measurements in all households measured over 48 hours

| Table 26: HAP and Pneumococcal | Carriage in Mothers (| (ANOVA) |
|--------------------------------|-----------------------|---------|
|--------------------------------|-----------------------|---------|

| Pneumococcal Carriage | SS | df | MS | F | P-Value |
|-----------------------|----------|-----|---------|-----|---------|
| Between groups | 55235.6 | 1 | 55235.6 | 0.7 | 0.42 |
| Within groups | 15528550 | 185 | 83938.1 | | |

5 HAP emissions that measured above 1500 μ g/m³ were excluded from the analysis

Tables 23-26 describe the correlations between HAP measurements in the cookhouses and the pneumococcal carriage status of the children and their mothers. As can be seen from the results, there is a significant association between the levels of $PM_{2.5}$ emitted in the cookhouses and whether a child is positive for pneumococcal carriage (p=0.00). The results for the mothers show now significant difference (p=0.42). These results are consistent with the numerous research studies that have identified a strong correlation between HAP and severe pneumonia.

| Table 27: HAP Quintiles and Pneumococcal Carriage in | n Mothers |
|--|-----------|
|--|-----------|

| HAP Quintile | Pneumococcal Carriage | | P-Value |
|--------------|-----------------------|----------|----------------|
| | Positive | Negative | |
| Quintile | 10 | 37 | 0.99 |
| Quintile 2 | 11 | 37 | |
| Quintile 3 | 11 | 36 | |
| Quintile 4 | 11 | 34 | |

Chi- Squared Test of Independence

5 HAP emissions that measured above 1500 μ g/m³ were excluded from the analysis

Table 28: HAP Quintiles and Pneumococcal Carriage in Children

| HAP Quintile | Pneumococcal Carriage | | P-Value |
|--------------|-----------------------|----------|---------|
| | Positive | Negative | |
| Quintile | 29 | 17 | 0.00 |
| Quintile 2 | 29 | 16 | |
| Quintile 3 | 32 | 15 | |
| Quintile 4 | 43 | 2 | |

Chi- Squared Test of Independence

5 HAP emissions that measured above 1500 μ g/m³ were excluded from the analysis

Tables 27 and 28 examined the association between quintiles (based on distribution) for HAP and prevalence of pneumococcal carriage among the women and children. The quintiles were cut of at 131, 289, 454 and 1500. There was no significant difference with the women (p=0.99). However, there was a significant difference found among the children (p=0.00). This indicates that children exposed to greater levels of PM_{2.5} in the cookhouses were more likely to be pneumococcal carriers than the children who were exposed to lower levels of PM_{2.5}.

4.4 Cost Analysis

The cost of fuel must be factored into the overall study analysis. Even if the fuel used as the intervention in the study were found to be 'cleaner' and 'healthier' than the leading fuel, the population would be unlikely or unable to adopt a new fuel if it is unaffordable. In countries like The Gambia where a large population lives below poverty level, it is unreasonable to presume that the population would embrace new technology, food, or other necessities if it does not save them money. In this study, the control group was supplied wood while the intervention group was supplied two cookstoves and briquettes throughout the 16 weeks. At the time of the study, wood was purchased for 20 Dalasis per bundle, with each bundle containing approximately 8 pieces of wood. Each household in the control group received 7 bundles a week, which amounted to 140 Dalasis per week. For the intervention group, each household received 50 kg of briquettes (2 bags at 25 kg each) per week during the 16-week study period. At 5 Dalasis per kg, the total value of their weekly briquette allocation was 250 Dalasis. In addition to the briquettes, each household in the intervention group received two cookstoves, at 350 Dalasis a cookstove. At the time of this study, it was unknown how long the cookstoves would last. It was estimated that each household would need to replace the cookstove every two years. If the cookstoves cost 350 Dalasis each and each household used two cookstoves simultaneously for two years, the household would need to spend 350 Dalasis per year replacing cookstoves. And finally, the cookstoves are unable to accommodate extra-large pots designed for commercial cooking. If there were cookstoves designed to hold a larger pot, the amount of briquettes needed to fuel the cookstove would need to be considered. From the experiences in this study, women found that the briquettes burned best and lasted longest at a lower, even temperature. The approximate cost per year for briquettes and alternative cookstoves compared to wood and a 3-stone cookstove can be seen in Table 29. This table excludes the extra costs of using extra-large pots with the briquettes.

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| Fuel | Cost of Fuel | | | Cost of C | Cookstoves | Total | |
|------------|--------------|--------------|---------------|---------------|------------|-----------|-------------|
| | Total | Dalasis/unit | Total Dalasis | Total Dalasis | Cost of | Cookstove | Total costs |
| | Units/Week | | per week | per year | two | costs per | per year |
| | | | | | cookstove | year | |
| | | | | | S | | |
| Wood | 7 bundles | 20 | 140 | 7,280 | 0 | 0 | 7,280 |
| Briquettes | 50 kilos | 5 | 250 | 13,000 | 750 | 350 | 13,350 |

Table 29: Cost analysis of wood and briquettes

According World Bank data, the gross national income (GNI) for Gambians in 2013 was US \$510, which was 16,300 Dalasis per year [100]. This calculation was based on the exchange rate in 2013 of 32.6 Dalasis to the dollar. This amount breaks down to approximately 1,358 Dalasis per month. When factoring in the demographics of the study population (large rural families with little income), it is estimated that their individual income is quite lower than the estimated GNI in The Gambia. Note though that multiple adults live in one household, so the household income would be greater than the GNI. As can be seen from the numbers above, any increase in fuel price, whether large or small, can drastically cut into a family's disposable income. Therefore the likelihood that any of the households in the study population would be able to afford continued use of the briquettes and alternative cookstoves is very unlikely.

4.5 Intervention Assessment

During the last week of the study, an assessment questionnaire (Appendix H) was carried out with all the participants in the intervention group. These questions were developed to better understand what the participants thought of the briquettes and cookstove, whether they preferred using them to the traditional 3-stone cookstove/wood combination, and how well they adhered to the usage rules established during the recruitment phase of the study.

A total of 116 women completed the questionnaire (Table 30). Almost 100% of those interviewed found both the briquettes and cookstove easier to use than the traditional 3-stone cookstove and wood. Roughly 30% of the women found the briquettes difficult or very difficult to light. In terms of whether the biomass briquettes produced smoke, over 90% said the briquettes produced some or a lot of smoke while lighting, 95% said they produced little or very little smoke while cooking, and 97% said the briquettes produced less smoke while cooking than wood. All the women said they would use the cookstove if they could afford it, while all but one woman said they would use the briquettes if they cost the same as wood.

| Characteristic | Intervention |
|--|--------------|
| | n=116 (%) |
| How easy the cookstove was to use | |
| Very difficult | 0 |
| Difficult | 0 |
| Easy | 39 (33.6) |
| Very easy | 77 (66.4) |
| Easier or harder to use than the 3-stone | |
| Harder to use than the 3-stone | 1 (0.9) |
| Same to use as the 3-stone | 0 |
| Easier to use than the 3-stone | 115 (99.1) |
| How easy was it to use the briquettes | |
| Very difficult | 0 |
| Difficult | 1 (0.9) |

Table 30: Intervention assessment (intervention group only)

-

| Easy | 41 (35.3) |
|---|------------|
| Very easy | 74 (63.8) |
| Briquettes easier or harder to use than wood | |
| Harder to use than wood | 0 |
| Same to use as wood | 0 |
| Easier to use than wood | 115 (99.1) |
| Harder to use than wood | 1 (0.9) |
| How easy was it to light the briquettes | |
| Very difficult | 1 (0.9) |
| Difficult | 33 (28.5) |
| Easy | 80 (69.0) |
| Very easy | 2 (1.7) |
| Did briquettes produce a lot of smoke while lighting | |
| Very little | 3 (2.6) |
| Little | 6 (5.2) |
| Some | 42 (36.2) |
| A lot | 65 (56.0) |
| Did briquettes produce a lot of smoke while cooking | |
| Very little | 99 (85.3) |
| Little | 13 (11.2) |
| Some | 3 (2.6) |
| A lot | 1 (0.9) |
| Did briquettes produce more or less smoke than wood while cooking | |
| More smoke than wood | 3 (2.6) |
| Same smoke as wood | 0 |
| Less smoke than wood | 113 (97.4) |
| Did briquettes go out often? | |
| No | 112 (96.6) |
| Yes | 4 (3.5) |
| Would you use the cookstove if you were able to afford it | |
| No | 0 |
| Yes | 116 (100) |
| Would you use briquettes if they cost the same as wood | |
| No | 1 (0.9) |
| Yes | 115 (99.1) |

In terms of user behavior, 109 of the 116 women said all the cooks in the household used the cookstove for all their cooking (Table 31). Of those who did not, two said there were not enough cookstoves provided, one stated there were not enough briquettes provided to use the cookstove, one woman said the other woman in her compound did not like using the cookstove, one woman travelled during the study and was therefore unable to use the cookstove 100% of the time, and two women said that the other cooks in their compound did not understand how to use the cookstoves. 108 of the 116 women (93.1%) always used the briquettes throughout the study. Of the 8 who did not, four stated there were not enough briquettes provided during the course of the study, three mentioned that the other cook in the compound did not like using the briquettes, one said the other cook did not know how to use the briquettes.

| Characteristic | Intervention | |
|---|--------------|--|
| | n (%) | |
| Did all the cooks in household use cookstove for all the cooking | n=116 | |
| Never | 0 | |
| Sometimes | 1 (0.9) | |
| Most of the time | 6 (5.2) | |
| Always | 109 (94.0) | |
| If not always, why or why not | n=7 | |
| Pot was too big for the cookstove | 0 | |
| Did not like the cookstove | 0 | |
| Not enough cookstoves | 2 (26.6) | |
| Other (<i>clarified above</i>) | 5 (71.4) | |
| Did all the cooks in household use briquettes for all the cooking | n=116 | |
| Never | 0 | |
| Sometimes | 1 (0.9) | |
| Most of the time | 7 (6.0) | |
| Always | 108 (93.1) | |
| If not always, why or why not | n=8 | |
| Pot was too big for the cookstove | 0 | |
| Did not like the cookstove | 0 | |
| Not enough cookstoves | 4 (50.0) | |
| Other (clarified above) | 4 (50.0) | |
| | | |

| Table 31: User behavior | (intervention group | only) |
|-------------------------|---------------------|-------|
|-------------------------|---------------------|-------|

At the end of the assessment questionnaire, the women were asked if they had any additional comments they would like to share. Table 32 gives the summary of comments from this questionnaire. 54 women from the intervention group chose to leave a comment. Most of the women were extremely pleased with the briquettes and cookstoves. 42 women commented on how much time using briquettes save them, 21 commented of the cost and efficiency of the briquettes, 27 women commented of the health and status benefits for women using briquettes, 22 women commented on the ease of use of the biomass briquettes, and 5 women comment on other aspects (remains of briquettes can be used for other purposes, briquettes are good for the environment and they are family friendly). All the exact comments can be seen in Figure 22.

| Comments | # Of Comments |
|--|---------------|
| Time Factor | |
| Less Time to cook | 32 |
| Saves time from looking for firewood | 10 |
| Cost/Efficiency | |
| Use less briquettes than wood/briquettes last longer than wood | 17 |
| Briquettes are cost effective | 4 |
| Health/Status | |
| Less smoke than wood/cleaner | 22 |
| Benefits health | 2 |
| Helps women's economic and social status | 3 |
| Ease of use | |
| Easy to use | 14 |
| Less energy to use | 7 |
| Can use in rain/mobile | 1 |
| Other Comments | |
| Use end of briquettes for other uses (garden, make tea, iron, clean) | 3 |
| Good to environment | 1 |
| Family Friendly | 1 |

Table 32: Comments from assessment questionnaire (intervention group only)

Figure 22: List of comments from assessment questionnaire (intervention group only)

Intervention Group Assessment Comments

- 1. The cookstoves and briquettes are very easy to cook with as less time and energy is needed
- 2. As the rains are close this briquettes are very significant as it is easy to use and available. Also, very friendly to the environment
- 3. I am very thankful for being part of this study which has started impacting greatly to my health, as I spend the whole day cooking and smoke exposure was a problem but I now experience less exposure to smoke.
- 4. It has less smoke and faster to cook with cookstoves and briquettes than wood. It last for a long time than wood.
- 5. It is faster than wood and it saves time and energy.
- 6. As far as I am concern even after the study I will be more than ready to use the briquettes even if I have to buy it at Brikama. Moreover it is easy to use and I can concentrate on over domestic work till late and take a short time to cook my meals.
- 7. The cookstove and briquettes is a very good cooking materials which needs to be encourage to be practice all over as it is good for women
- 8. It is important as it cost effective and saves time and energy, as there is no need to look for firewood anymore.
- 9. It is good to cook with the new cookstoves and briquettes as it saves times.
- 10. Cooking with the new cookstoves and briquette is a big experience for me as a woman who cooks in my life and I will never forget it.
- 11. It is faster than wood and less smoke.
- 12. It is faster than wood to cook.
- 13. It is faster to use.
- 14. The new cookstoves and briquettes are good to cook with as the saves a lot of time I spend on cooking then. And it smokes less.
- 15. The briquettes are good to cook with as it smokes less.
- 16. I am glad to experience this cookstoves and briquettes as the last three months I do not go to the bush to find firewood, thus having more time for ever activities, and now we are exposed to smoke less. Also after cooking I use the end product to cook local tea "Attaya"
- 17. The new cookstoves and briquettes is a very excellent cooking device as it is clean, fast and keeps heat for a long time.
- 18. Everything about the briquette and the cookstove is easier than the three stone.
- 19. I love using the new cookstoves and briquettes to cook as it is easy and quick and clean.
- 20. It has less smoke and it is faster to cook with cookstove than the three stones.
- 21. The cookstove and the briquettes have a lot of advantage over the 3 stone and the wood- you can use it in the rain more efficiently than wood and 3 cookstove, because it is movable. You can

carry it to another location anytime the need arise.

- 22. The cookstoves and briquettes have been very useful to our livelihood as we used less of it to cook and its heat last for many hours.
- 23. The new cookstoves and briquettes have been very helpful as it saves a lot of our money and time.
- 24. It has less smoke and it saves energy and time to look for wood.
- 25. Living in an area where firewood is difficult to acquire, am very appreciative of the new cookstoves and briquettes, as a very timely intervention to a general problem of many households.
- 26. It is very easy to cook with as less time is taking to cook and the heat can last for so long. I hope briquettes will be making available for us to continue benefiting.
- 27. It is faster than wood, less smoke.
- 28. The new cookstoves and briquette is very easy to cook and make cooking fast and cost less.
- 29. It is easy to use it generates less smoke and if you light it goes for hours without going out unlike the wood.
- 30. It is very important to use the new cookstoves to cook as it takes less time to cook with and produces less smoke compared to firewood.
- 31. The cookstoves and briquettes is a very good intervention as we used a small amount of wood at a very short time.
- 32. I am glad using this new cookstoves and briquettes, as they are easy to use and makes cooking very fast. Beside the end product our ash is good for gardening as fertilizer also when you use it to clean the outer part of the cooking pots.
- 33. I am pleased to be part of a lucky group of women selected to pilot this study which has enable me to allocate less time for cooking as the cookstove and briquettes require little time and energy to cook for a family.
- 34. Before, this was the time the briquettes were given to the family- every/all the cooks were using the cookstove and the briquette, but later second cook decided not to use the cookstove/briquettes. She did never explain why she did not like to use the briquettes- only the study participant continues to use the supply.
- 35. It is faster than wood and has less smoke.
- 36. We appreciate the new cookstoves and briquettes as it helps us very much as firewood is a big problem and the heat from it last for a long time.
- 37. The only problem I understand with the briquette is that it produces a lot of smoke.
- 38. It is faster than wood
- 39. It is faster than wood and it has less smoke.
- 40. The new cookstoves and briquettes favor us very well as it is easy to cook with and saves money and time for us.
- 41. I am happy to learn thus knowledge of cooking in this study, which can improve our health status greatly.
- 42. She is very grateful for being part of this research study as it came at a time when she find it

difficult to get firewood for cooking, and even when she get some cutting them become another problem. This she describe the cookstove and briquettes as family friendly intervention.

- 43. The cookstove is very easy to use. Makes the cook area less dirty. Also the cooking period now takes less time.
- 44. It is faster than wood and the flames go for a long time before it goes out. The briquettes save energy.
- 45. I am happy to be part of this new cookstove and briquettes study as we are women engage in gardening. It enables me to have much time on the garden which results in improving my economic and social status. Beside I need less time to cook my meals and it also consumes less fuel and the heat lasts for a long time.
- 46. I am very grateful to be part of this important study, and will always be ready to use the cookstoves and briquettes as it has enable me to do a lot of garden work as I need less time to do my cooking.
- 47. It goes for a long time without the flames going out and it has less smoke and faster to cook with.
- 48. The cookstoves and briquettes have been very useful to our livelihood as we used less of it to cook and its heat last for many hours.
- 49. It has less smoke and it can go for a long time.
- 50. I am pleased to be part of this great study and I hope to continue to use this good health practice less smoke, easy to cook and less fuel (briquettes) used.
- 51. I like the briquettes and the cookstove very well because it has no smoke, it is easier to use and very fast. You can use this briquette for a long time.
- 52. I am very happy to be part of the important study as it has improves both my economic and social status as a teacher I now have to spend less time to do my cooking and also I used the end product of the briquettes to iron my clothes.
- 53. It has less smoke and it saves time and energy to look for firewood.
- 54. The cookstove and the briquette are very efficient- it is easy and very fast to cook with these.

CHAPTER 5: CONCLUSIONS AND RECOMMENDATIONS

5.1 Key Findings

5.1.1 PM_{2.5} Concentrations in both Control and Intervention Households

 $PM_{2.5}$ concentrations were found to be similar in the control and intervention households. The results indicate that the alternative biomass cookstoves and biomass briquettes used together produce similar levels of $PM_{2.5}$ (µg/m³) in the cookhouses as the traditional 3-stone cookstove used with wood. There are several possible explanations for these results. Foremost, the briquettes and alternative cookstoves might not actually burn any 'cleaner' than wood used with the 3-stone cookstove. Even though a majority of the women in the intervention group stated that the briquettes produced less smoke than wood, these subjective assessments could be biased. The women were likely to have believed that the intervention would be cleaner before the study began, and were grateful to be given a more 'sophisticated' cookstove and fuel that they believed would be beneficial to their health.

A second possible explanation for the similar PM levels in the intervention and control groups is that because the alternative cookstove and briquettes were a novelty that had never been used by this population before, the unfamiliarity led to inefficient use. The women had been using the 3-stone cookstove and wood for generations and had perfected this method. They knew exactly how much wood it took to cook a pot a food, how to light the wood without causing a lot of smoke, how to burn the wood efficiently, and how to properly place the cooking pot on the stones. As for the alternative cookstove and briquettes, they were inexperienced with how to best light the briquettes or keep them lit for the duration of the cooking process. These skills would come with time, and it is unlikely they could be perfected during the practice period before the start of the study. Therefore, during the 16-week study period, the women in the intervention group were still trying to figure out how to best use the alternative cookstove and briquettes. It would be useful to consider whether the results would be different if the women had a couple of months or a year to use the alternative cookstove and briquettes, and then to test whether they burned 'cleaner' than wood.

A third possible explanation for the similar $PM_{2.5}$ levels is the lack of 'financial commitment' from the women in the intervention group. These women were given free cookstoves and free briquettes to use during the 16-week study period. They had no responsibility in purchasing the briquettes themselves, which could have led to overusing the briquettes. They might have been unconcerned whether they used 5 briquettes or 10 briquettes while cooking a meal, which could have affected the cookstove efficiency. This population was used to purchasing their own wood, or scavenging for it in the forest, so they were more aware of how to be most efficient with the wood they used for cooking. The control group who received free wood probably still had the same attitude towards their free wood as they would have had they purchased it themselves, thereby using it conservatively.

The author's overall assessment of what factors were most likely to have resulted in these findings is a combination of the latter two explanations above. During the pilot study, the briquettes and alternative cookstove appear to have a reduction of $PM_{2.5}$ levels in the test cookhouses. Furthermore, the women in the study repeatedly asserted that the alternative cookstove/briquettes did produce less smoke than the traditional 3-stone cookstove and wood. If the newer cookstove and briquettes were used appropriately and efficiently, it is believed that they would in fact be a cleaner form of cooking than the 3-stone cookstove and wood. The lack of difference in $PM_{2.5}$ levels between the two stoves had a direct effect on pneumococcal carriage with the participants. If this is in fact the case with this study, then this study provides a strong example of how operational and behavioral realities can affect the outcome of an intervention study, and possibly even a long-term intervention program. It shows the importance of working with social scientists and other specialists to minimize the impact that these operational and behavioral concerns have on the adoption of an intervention aimed to improve the health of a population.

5.1.2 Pneumococcal Carriage in the Women and Children in Control and Intervention Groups (Post-Intervention)

The pneumococcal vaccine (PCV7) has been part of the routine vaccination schedule in The Gambia since 2009. According to the Expanded Program on Immunization vaccination schedule for children in The Gambia, babies are to receive the PCV7 vaccine at 2 months, 3 months, and 4 months of age. The Gambia health system has been shown to achieve high vaccination coverage during the first year of life [101]. In this population, like most of The Gambian population, the children not only had access to routine vaccinations, but they received them in a timely manner. There are a few main reasons for this large adherence to the vaccination schedule. First, the study villages are located on a main thoroughfare and are relatively close to the city. This enables not only the residents to travel into the cities, but for the city populations to travel to these villages as well. These close city ties allow for transference of information, such as the importance of vaccination. The close proximity also allows for a steady and reliable transport of the vaccines. The Pneumococcal vaccine is require to be kept at 2-8 °C (32-46 °F)[102], so it is imperative that a cold chain be established for the transportation of the vaccines, and that a reliable cold storage be available at the village health centers. If a village is located on or near a main thorough fare, electricity is often available to the population, which can generate a refrigerator in local health centers, using propane as a back-up. More remote health centers rely solely on propane to generate the refrigerators.

A second main reason for the large adherence to the vaccination schedule is the presence of The American Peace Corps and other International organizations in this part of the country. International nurses and healthcare workers have been continually sensitizing the villagers on the importance of vaccinations. They have also been working closely with pregnant mothers during routine antenatal visits and following up with the mothers and babies from birth. From the Writer's personal experience working in this region, village health centers are common meeting places for mothers and their children, especially on vaccination days. On these days, healthcare workers can educate a large population of mothers, as well as address any health issues the mothers or children might have.

The third reason why so many children are vaccinated is because of the presence of The Medical Research Council Field Station in this part of the country. Many pneumococcal carriage studies have been conducted in the Sibanor region, which is not far from the villages in this study. Therefore, many villagers have been educated on the importance of vaccinations, especially the PCV7. In addition, many of the field workers that work for MRC have either grown up in this part of the country, or they have worked on previous studies conducted in this region. Their close ties with this population have earned them respect among the people, which thereby enables them to educate the people in a manner that outsiders are unable to do.

The results showed that the women and children in the intervention group had the same prevalence of pneumococcal carriage as their control group counterparts postintervention. As explained above, $PM_{2.5}$ concentrations were found to be very similar in the intervention cookhouses (with alternative cookstove and briquettes) and the control cookhouses (with traditional 3-stone cookstoves and wood). The hypothesis was that lower levels of PM exposure would result in lower pneumococcal carriage levels, which was not possible to confirm in this study. Assuming the hypothesis is correct, it is not surprising that the groups had similar pneumococcal carriage levels.

There was also no difference in prevalence of pneumococcal carriage among children who had received all three doses of PCV7 and those who had received 0-2 doses, nor a difference in PCV7 serotypes present among children who had received all three vaccination doses compared to those who received 0-2 doses.

5.1.3 The Cost Effectiveness of using Alternative Biomass Cookstoves and Biomass Briquettes Compared to Traditional 3-Stone Stoves and Wood

The cost effectiveness analysis of alternative biomass cookstoves/biomass briquettes compared to 3-stone cookstove/wood showed that the alternative cookstove/briquettes combination was a much more expensive method of cooking. Because the local population either collected their wood in the sparse forest or bought the wood that came over the border from Senegal, an estimated amount spent on wood each year for a medium size family was 7,280 dalasis. In contrast, the amount of money needed for briquettes to feed the same size family was 13,000 dalasis, almost twice that of wood. This did not include the price of one or two alternative cookstoves, which would need to be replaced periodically.

Forest degradation is a real problem in The Gambia and in other developing countries that rely on wood for heat and cooking. There is a real need to explore alternative cookstoves, fuels and/or cooking methods. Though these alternative cookstoves and briquettes proved not to be an economical solution for this population, it is possible that briquettes made in a different machine, with a different product, or burned in a different cookstove would prove to be a more viable solution.

5.1.4 Assessment of Alternative Biomass Cookstoves and Biomass Briquettes

An assessment of the alternative biomass cookstoves and biomass briquettes was taken from the women in the intervention group at the end of the study. Virtually all of the women raved about the alternative cookstoves and briquettes, and claimed they produced less smoke than the traditional 3-stone cookstove and wood. Though the women made these assertions, our study did not show a decrease in smoke in the women's cookhouses. The women also claimed they would choose to use them for cooking should they be available at the same or reduced cost as wood. This assertion is hypothetical and therefore difficult to prove. Only when these alternative cookstoves and briquettes are made available to the population at a reduced rate would it be possible to determine whether the women really would choose this cooking method over the traditional 3-stone cookstove and wood. It would also depend greatly on the availability of wood in the future. If wood was impossible to forage in the local woods, and the price of wood from Senegal increased dramatically, this population might be forced to look at other cooking options, including alternative cookstoves and briquettes.

It is clear that more sociological studies need to be conducted to better understand the thinking and behavior of these women and households in order to better design future interventions. As mentioned earlier in section 5.1.1, closer examination needs to be done to minimize the impact that operational and behavioral realities have on the implementation of an intervention. This can be partially achieved by better understanding the thinking and behavior of the target population. How can interventions be designed and integrated into societies that will have lasting health benefits on the study populations?

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5.2 Internal Validity

This study was designed and conducted as a randomized controlled trial, which aimed to reduce bias while testing the alternative biomass cookstoves and biomass briquettes. This study design randomly allocated the participants into either the intervention or control group, which helped to eliminate selection bias. Although the participants were randomly allocated to either the intervention or control group, there were exceptions when multiple women lived at the same residence. In this case, they were all allocated to the control group. This selection bias might affect the overall number of women positive for pneumococcal carriage in the control group because it can be presumed that because the women and children lived in close proximity, they might all have had similar pneumococcal levels because of exposure to each other. If one woman or child in the household was positive for pneumococcal carriage, it would be more likely that the other women and children who lived in the same household were carriers themselves. These reallocated women and babies might have resulted in some observations of pneumococcal carriage not being independent. This can potentially have a large effect on the results of the study, because this only happened to 12 women (4.8% of the total women), it did not have a huge impact on the results of this study.

A second area of concern is the methods the women in the intervention used to cook with the alternative cookstoves and briquettes. Because these were new methods of cooking and the women had never used the alternative cookstoves and briquettes before, their methods of use might have been inefficient, thereby leading to higher levels of PM_{2.5} concentrations. The briquettes were given to the women in the intervention group for free so it was not advantageous to them to try and use the briquettes in the most efficient way. It is possible that with more practice and a vested interest to save fuel, the women in the intervention group would be able to be more efficient with the alternative cookstove and briquettes, thereby saving fuel (cost effectiveness) and reducing PM_{2.5} concentrations. Furthermore, had there been a difference in PM_{2.5} concentrations between the two groups, there might potentially have been a difference in pneumococcal carriage as well. It is

practice to master the new cookstove/fuel, and to have some vested interest in assuring that the cookstove and fuel are used in the most efficient way possible.

A third area of concern is the number of women and children who dropped out of the control group. As mentioned earlier (section 4.1), this might have been due to the fact that they were only receiving wood and thereby did not have as large of an incentive to continue to be part of the study. In contrast, the women in the intervention group expressed more excitement about the free alternative cookstoves and briquettes, and therefore more motivated to remain in the study throughout the 16-week study period. 17 of the 136 (12.5%) of the women enrolled in the control group withdrew from the study, compared to 0% in the intervention group, so it did potentially have a significant effect on the overall results of the study. It would have improved the validity of the study had all the women in the control group stayed throughout the duration of the study.

One method of reducing the dropout rate in the control group would be to follow up on the participants more closely to try keeping the participants in the study. Incentives might be used, or responding better to the issues that led to participants dropping out of the study. Nevertheless it is necessary to work within the practical restraint of the resources available.

Strengths and Limitations of the Study

The author was in a unique position to be in the field during the design and execution of the study. This is a great strength as it enabled her to address issues as they arose. She was also able to work directly with all the members of her research team, thereby assuring that the quality of work was as strong as possible. The author was also able to forge relationships with the participants, which might have encouraged the women to remain in the study. The author also had highly qualified personnel working at MRC The Gambia to approach should recommendations or suggestions be needed.

One major limitation of the study was the author's inexperience in conducting research studies. As has been noted throughout the thesis, the author was solely responsible for a majority of the study. Without previous experience, there were areas where more experience would have been helpful (i.e. transferring NPS samples to the laboratory in a timely manner). Another limitation of the study was the pilot study. Lack of experience led to results that were unusable.

5.3 Coherence with Other Studies

There are two main questions that this study attempted to answer; 1- Do alternative biomass cookstoves and biomass briquettes reduce HAP and 2- Do alternative biomass cookstoves and biomass briquettes reduce the prevalence of pneumococcal carriage. A recent search was conducted to understand what other recent studies have found. A few of these studies were published during the write-up period of this thesis and were therefore not available for reference at the start of the study.

5.3.1 Alternative Biomass Cookstoves and their effect on HAP

Alternative Biomass Cookstove Study in Rural Western Kenya

In November of 2016, an article was published entitled "Effectiveness of Six Improved Cookstoves in Reducing Household Air Pollution and Their Acceptability in Rural Western Kenya" [103]. The study was a single-arm pre-/post- intervention study, designed to assess acceptability and performance of six improved biomass cookstoves in two rural villages of West Kenya. Each of the six cookstoves used in the study performed well at the EPA laboratory, were centrally manufactured, required no assembly, could be easily transported, were designed to burn wood, and were considered acceptable by local women. The researchers measured mean personal and cookhouse level concentrations of PM_{2.5} concentrations and CO during a 48-hour period of each cookstove use in 45 households. They compared these levels to those observed with traditional 3-stone cookstoves and assessed acceptability through interviews and focus groups. They then evaluated association of cookstove type, fuel use, and factors relating to cooking practices with mean PM_{2.5} and CO using multivariable regression. The results showed that cookstove type, exclusive alternative cookstove use (versus traditional 3-stone cookstove use) and the amount of fuel used were independently associated with cookhouse PM_{2.5} and CO levels. Reductions (95% CI) in mean PM_{2.5} compared to traditional 3-stone cookstoves ranged by individual alternative cookstove from 11.9% (-2.8-24.5) to 42.3% (32.3-50.8). Mean cookhouse $PM_{2.5}$ ranged from $319\mu g/m^3$ to 518µg/m³ by alternative cookstove. Though the study found reductions in HAP from alternative cookstoves compared to traditional 3-stone cookstoves, the PM_{2.5} levels with

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alternative cookstoves were still considerably higher than WHO indoor air quality guidelines. In addition to the $PM_{2.5}$ levels found in the study, women thought the alternative cookstoves were easy to use, more efficient, produced less smoke, and cooked faster, compared to traditional 3-stone cookstoves. Women also reported limitations for each alternative cookstove tested in the study.

The results of this study (lower $PM_{2.5}$ levels with the tested alternative cookstoves) were different than what this study in this thesis observed. One possible reason for this difference is because the studies tested in Kenya had already been tested and proved to perform well in an EPA laboratory. Furthermore, the tested cookstoves were more sophisticated than the local cookstoves tested in this study. For example, their rocket cookstove was coupled with a thermoelectric insert enhancement, the Philips and Ecochula cookstoves both forced draft with rechargeable battery and solar-PV panel, and the Prakti cookstove was constructed with a chimney. Only the EcoZoom cookstove appeared comparable to the alternative cookstove tested for this thesis, which was one of the two cookstoves in the study that did not generate statistically significant reductions. Another possible reason for the difference might be the choice of fuels. In this thesis study, wood might have burned 'cleaner' than the briquettes if used with the alternative cookstove.

The qualitative results of both studies were similar. The women reported liking the alternative cookstoves compared to the traditional 3-stone cookstoves. Furthermore, the women in both studies stated that the cookstoves were easy to use and more efficient.

Improved Biomass Cookstove Study in Rwanda

In 2014, an article was published entitled "Assessing the Impact of Water Filters and Improved Cook Stoves on Drinking Water Quality and Household Air Pollution: A Randomised Controlled Trial in Rwanda" [104]. The researchers for this study conducted a 5-month household randomized controlled trial among 566 households in rural Rwanda to assess uptake, compliance and impact on environmental exposures of a combined intervention (high-performance water filters and alternative biomass cookstoves). The alternative cookstove was the EcoZoom design (rocket cookstove), with the addition of a
"stick support" onto which fuel wood is placed to promote airflow and a "pot skirt" which increases fuel efficiency. Additionally, the participants in the intervention group were encouraged to cook outdoors and to use dry wood only to increase the efficiency of the EcoZoom cookstove. A subset of 126 households (63 control and 63 interventions) was randomly selected for semi-continuous 24-hour PM_{2.5} monitoring to assess HAP.

The intervention was associated with a median reduction of 48% of 24-hour $PM_{2.5}$ concentrations in the cooking area (p=0.005). Indoor cooking showed a reduction of 37% of 24-hour $PM_{2.5}$ concentrations in the cooking area, though it was not statistically significant (p=0.08). Only 23.3% of intervention households reported that their main cooking area was outdoors as promoted by the intervention. Compliance was below expectations in the study. Though most households did use the alternative cookstove, most continued to use the traditional 3-stone cookstove as well (54.3% were using the alternative cookstove and 41.4% were using the traditional 3-stone cookstove when visited by the study evaluators).

The results from this study are consistent with the results from this thesis. Though there was a reduction shown in indoor cooking using an alternative cookstove, it was not significant. Furthermore, non-compliance remained an issue, as it did in all the other studies that were reviewed.

Improved Stove Intervention Study in Low and Middle Income Countries

In 2015, an article was published entitled "Improved stove interventions to reduce household air pollution in low and middle income countries: a descriptive systematic review" [105]. The researchers conducted a systematic review of the current evidence of alternative cookstove interventions aimed at reducing HAP in real life settings. Studies were included if they reported on an alternative cookstove intervention aimed at reducing HAP resulting from solid fuel use in a low or middle-income country. The review identified 5,243 records and included 36 studies that met the inclusion criteria. The review found that when well designed, implemented and monitored, cookstove interventions could have positive effects. However, the impacts are unlikely to reduce pollutant levels to WHO recommended standards. Additionally, many participants in the

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included studies continued to use traditional cookstoves either instead of, or in addition to the new alternative cookstoves.

The conclusions from this systematic review are consistent with the findings from this thesis. It is possible that if the participants in the intervention group in the thesis study had been closely monitored, there might possibly be a reduction in HAP exposure. However, this is very difficult to do, as previous studies have demonstrated, and is unrealistic in the real world. It is fair to assume that if populations reliant on fuels were given alternative cookstoves, a majority of them would continue using the tradition 3-stone stove in some capacity. This would decrease any potential positive health effects an alternative cookstove can have on these populations.

5.3.2 Alternative Biomass Cookstoves and their effect on Pneumococcal Carriage

In January 2017, a study was published in *The Lancet* entitled "A cleaner burning biomass-fuelled cookstove intervention to prevent pneumonia in children under 5 years old in rural Malawi (the Cooking and Pneumonia Study): a cluster randomised controlled trial" [106]. 10750 children (<4.5 years of age) in 8626 households across 150 clusters in 2 rural districts in Malawi were randomly allocated to intervention and control groups. Intervention households received two biomass-fuelled cookstoves and a solar panel. The primary outcome was WHO Integrated Management of Childhood Illness (IMCI)-defined pneumonia episodes in children under 5 years of age.

This study showed no evidence that an intervention comprising of cleaner burning biomass cookstoves reduced the risk of pneumonia in young children. The IMCI pneumonia incidence rate in the intervention group was 15.76 (95% CI 14.89-16.63) per 100 child-years and in the control group 15.58 (95% CI 14.72-16.45) per 100 child-years, with an intervention versus control incidence rate ratio (IRR) of 1.01 (95% CI 0.91-1.13; p=0.80).

The study results are consistent with what was found in the thesis study. Both studies showed no effect that alternative cookstoves had on pneumococcal carriage or pneumonia.

In 2011, an article was published in *The Lancet* entitled "Effect of reduction in household air pollution on childhood pneumonia in Guatemala (RESPIRE): a randomised control trial" [24]. The primary objective was to establish whether a reduction in smoke pollution with use of a chimney stove (intervention) would reduce the risk of pneumonia in children up to 18 months of age. The research team randomly assigned 534 households with a pregnant woman or young infant to receive a woodstove with chimney or to remain as controls using open wood fires. The children were followed for 18 months and assessed for physician-diagnosed pneumonia if ill. During the course of the study, there were 149 diagnosed pneumonia cases in intervention households and 180 in control households (reduction 22%, 95% CI -6% to 41%). The chimney stove reduced exposure by 50% on average, and a 50% exposure reduction was significantly associated with physician-diagnosed pneumonia (RR 0.82, 0.70-0.98). These results are consistent with what was found in this study. The author observed a significant difference in pneumococcal carriage prevalence among those children who residing with cookhouses that produced lower levels of PM_{2.5} than the children who were exposed to higher levels of PM_{2.5}, regardless of the cooking method.

5.4 External Validity and Policy Implication

Almost half of the world's population rely on biomass for cooking, and are therefore subjected to the health risks of HAP and its possible association to pneumonia. As was discussed in the previous section (see 5.3 Coherence with Other Studies), many studies have been conducted among these populations to determine whether 1) alternative biomass cookstoves can decrease HAP levels in the cooking areas, and 2) whether there is an association between HAP levels and the risk of developing ALRI, and more specifically pneumonia. The thesis study focused on a small homogeneous population, all of whom cooked the same foods, fed approximately the same number of people, cooked in similar cookhouses and had comparable cookhouses. It is difficult to apply the results of the study in terms of HAP outputs to other populations who differ greatly from the population in this study. It is possible that the cookstove and fuel tested in this study would perform better in other conditions, given the differences in demographics and geography. For example, biomass briquettes might burn better in environments less humid than where this study was conducted, or in cookhouses were there are less doors/windows to affect the flames in the cookstove. Additionally, the cookstoves might perform better with different styled pots or different cooking techniques. Lastly, the performance of the cookstoves and fuel can also be affected greatly by the kinds of food being cooked and the duration of the cooking. All these variables can differ greatly between populations. Because of these arguments, the results from the HAP part of the thesis study should be applied 'cautiously' to other populations.

This study was unable to find an association between HAP and pneumococcal carriage. The study found no difference in HAP levels between the intervention and control groups, and no difference in pneumococcal carriage levels between the groups. Had a difference been found in HAP levels between the two groups, it is plausible that this study could have found a difference in pneumococcal levels as well. Further research needs to be done to identify better cooking methods that would decrease HAP levels in the most vulnerable populations. Additionally, further research needs to be conducted to ascertain whether or not there is an association between HAP exposures and pneumococcal carriage. If so, how much HAP exposure need to decrease in order to observe health benefits?

5.5 **Recommendations**

There are several recommendations that can be made based on the findings of this study as well as the findings of other similar research studies.

1. It is important to verify whether new stoves and new fuels available on the market are in fact 'improved'.

There are many 'improved' cookstoves on the streets and markets in countries dependent on biomass fuels for cooking, as the research team observed in this study. How many of these cookstoves actually reduce HAP emissions, or reduce the amount of fuel needed, or reduce cooking time, or any of the other factors they claim to address? There is little monitoring of the manufacturing and distribution of these cookstoves in these countries, and it is possible that some of these cookstoves might be more detrimental to the health of the users than the traditional 3-stone cookstove. This can be applied to fuels as well. There are many biomass fuels being used today (dung, biomass briquettes, etc.) yet it is unsure what the health impacts on the individuals who are cooking with them. For these reasons, the author believes that more research and regulations need to be made on the cookstoves and fuels that are available in these countries. Though it is difficult to regulate what is being sold in the market, more research can be done on cookstoves that are mass-produced and distributed by larger organizations, governments and foreign donor.

2. Better and more research needs to be done to establish and improve the effectiveness of alternative cookstoves in reducing HAP emissions Though evidence was found of well designed and implemented interventions, it is difficult to firmly establish associations due to differences in outcome

measurements [105]. Success of cookstove interventions are dependent of how well households adopt a alternative cookstove, how efficiently they use it,

whether they use the alternative cookstove exclusively or alongside traditional cookstoves and for how long they continue using the cookstoves. Taking PM_{2.5} measurements during a relatively short study period while the participants are still excited about this 'novel' intervention can have very different results than taking PM_{2.5} measurements over a long period of time and after the novelty has worn off. There have been some long-term studies, though most have had follow-up periods of less than 18 months. Therefore, it is recommended that more, longer studies be conducted that can evaluate the cookstoves and HAP emissions over an extended period of time. Additionally, the means of measuring HAP has not been consistent with the many studies that were reviewed. In order for the studies to be compared alongside each other, it is essential that all the studies have similar methodology when collecting HAP emissions. Monitoring for PM_{2.5} has changed drastically over the past twenty years, with many more accurate measuring devices now available. The challenge remains of how to monitor HAP over a long period to capture an accurate reading of HAP exposure among individuals.

3. Studies need to be designed with similar outcomes in order to be easily compared amongst each other

It has been established that exposure to high HAP levels puts an individual more at risk for developing ALRIs. The problem lies with this quantification of this association. This thesis studies used pneumococcal carriage as a proxy, but how easily can that be included in a systematic review that looks at ALRIs as outcomes?

There is a great need to further investigate alternative cooking methods to help reduce HAP exposures among the 38% of the world population that rely on biomass fuels for cooking. Cleaner cooking methods can have a monumental impact on the health of these populations.

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