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Wood stove interventions and child respiratory infections in rural communities: KidsAir Rationale and Methods

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Abstract

Background—Acute lower respiratory tract infections (LRTIs) account for more than 27% of all hospitalizations among US children under five years of age. Residential burning of biomass for heat leads to elevated indoor levels of fine particulate matter ($PM_{2.5}$) that often exceed current health based air quality standards. This is concerning as $PM_{2.5}$ exposure is associated with many adverse health outcomes, including a greater than three-fold increased risk of LRTIs. Evidence-based efforts are warranted in rural and American Indian/Alaska Native (AI/AN) communities in the US that suffer from elevated rates of childhood LRTI and commonly use wood for residential heating.

Design—In three rural and underserved settings, we conducted a three-arm randomized controlled, post-only intervention trial in wood stove homes with children less than five years old. Education and household training on best-burn practices were introduced as one intervention arm (Tx1). This intervention was evaluated against an indoor air filtration unit arm (Tx2), as well as a control arm (Tx3). The primary outcome was LRTI incidence among children under five years of age.

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AUTHORS' CONTRIBUTIONS
CWN and TJW are the co-Principal Investigators and co-coordinators of the study. CWN, TJW, EOS, and DNW drafted the manuscript, contributed to the study concept and design, revised the manuscript for important intellectual content, and approved the final manuscript. PS contributed to the LRTI tracking protocol. EE and JL provided the Navajo Nation site day-to-day activity oversight and contact and reporting to the Navajo Nation Human Research Review Board. BB and SH oversaw the YK activities and reporting to the YKHC. All authors reviewed and edited the manuscript to its final version.

COMPETING INTERESTS
The authors declare that they have no competing interests.

Discussion—To date, exposure reduction strategies in wood stove homes have been either inconsistently effective or include factors that limit widespread dissemination and continued compliance in rural and economically disadvantaged populations. As part of the "KidsAIR" study described herein, the overall hypothesis was that a low-cost, educational intervention targeting indoor wood smoke $PM_{2.5}$ exposures would be a sustainable approach for reducing children's risk of LRTI in rural and AI/AN communities.

Trial registration—ClincialTrials.gov NCT02240134.

Keywords

pediatric; respiratory infection; home intervention; wood stove; filter; biomass combustion

1. Introduction

Worldwide, acute lower tract respiratory infections (LRTIs) are the most common cause of childhood illness and a leading cause of mortality, accounting for 18% of deaths among children.[1, 2] In the US, LRTIs are a leading cause of childhood morbidity, accounting for 27% of hospitalizations among children less than five years of age and outpatient visits at an annual rate of 133 per 1,000 children under five years of age.[3] Bronchiolitis and pneumonia are the most common forms of LRTI among US children, and disabling infections can last for days to weeks. These preventable childhood infections are associated with a substantial cost, including medical expenses and parent work absences required to care for the child.[4–6] Recurrent LRTIs can also have cumulative effects in children and are a recognized risk factor for asthma.[7–9]

Numerous studies in industrialized countries have demonstrated that ambient $PM_{2.5}$ is associated with increased risk of respiratory tract infections and respiratory symptoms.[10–14] Similar findings have been observed in communities where residential wood smoke has accounted for 34% to 90% of ambient $PM_{2.5}$,[15–18] including associations with frequency of respiratory symptoms or lung function decrement among children living in homes heated by a wood stove.[19–22]

Despite the common use of wood as a fuel source in the US and the observed association between wood burning and LRTIs, there are still insufficient evidence-based data on efficacious and cost-effective strategies for reducing children's exposure to $PM_{2.5}$ in homes containing wood stoves. Within rural areas of Montana, Alaska, and the Navajo Nation, research has shown that residential biomass combustion leads to elevated indoor levels of fine particulate matter ($PM_{2.5}$) that often exceed current health based air quality standards.[23–25] The "KidsAIR study" (**A**ir Quality **I**nterventions for Reducing **R**espiratory Infections) utilized low-cost interventions with the goal of reducing $PM_{2.5}$ exposures and children's risk of LRTI in rural and economically challenged areas. The inclusion of multiple study areas that were geographically and culturally diverse allowed for assessment and identification of community-specific factors that either mitigate or enhance the efficacy of the intervention focused on reducing in-home exposures to residential wood smoke. In this manuscript, we describe the methodologies employed as part of the KidsAIR study.

2. Methods

2.1 Study overview

KidsAIR was a three-arm randomized controlled, post-only intervention trial. The intervention trial was targeted at reducing indoor $PM_{2.5}$ concentrations in wood stove homes with one or more children under five years of age. Occurrence of LRTI among household children under five years of age was the primary outcome for this study in rural and American Indian/Alaska Native (AI/AN) communities. Residents of eligible homes were recruited in three study areas over a four-year period, and each home was followed for two consecutive winter periods for LRTI outcomes in children. A post-only approach was chosen because the incidence of LRTI naturally decreases as children age. Although this natural decrease effect would occur in all treatment arms, the overall declines would impact study power. The post-only approach is consistent with other trials of household air pollution interventions and children's respiratory infections [26, 27]. Thus, the home intervention occurred prior to the first winter of observation, and children were tracked for LRTI occurrence for two follow-up winter periods.

Households were randomized to one of three arms. The first treatment arm (Tx1) was an outreach/education intervention that we propose as a low cost, sustainable and easily disseminated strategy. The second treatment arm (Tx2) was an air filtration unit intervention. Air filtration has demonstrated efficacy in reducing $PM_{2.5}$, but has an uncertain and yet to be quantified relationship with reducing LRTI incidence in children, as well as questionable sustainability. The third arm was the control group (Tx3) using placebo, or sham, air filters in two of the study areas and no intervention in the third study area. The exception to the Tx3 arm was at the Alaska study site. Placebos are often not well received in Native communities, and it was requested by the communities and human studies committee to utilize a no intervention, rather than placebo, approach for the control arm. Collectively, the control group allows for evaluation of efficacy of the two intervention arms in this post-only intervention trial. Households receiving the education intervention were not blinded to their treatment assignment. With the exception of the Alaska study site, the air filter and placebo groups (Tx2 and Tx3) were blinded to their treatment assignment.

The KidsAir study was approved by the University of Montana IRB, the University of Alaska Fairbanks IRB, the University of New Mexico Health Sciences Center Human Research Protection Office and Human Research Review Committee, the Navajo Nation Human Research Review Board (NNR 15.214) and the Yukon-Kuskokwim Health Corporation (YKHC) Human Studies Committee and Executive Board.

2.2 Study locations

This described project focused on three study areas that have demonstrated associations between wood smoke exposure and LRTI among children. Study area #1 included rural communities in the Rocky Mountain region of Montana. West of the Continental Divide, Montana is composed of counties designated as either rural or frontier, with municipal populations ranging from 143 people to over 70,000.[28] As wood (Douglas fir, pine, and larch) is readily available in western Montana, wood stoves are a common source of heat in many of the rural mountain-valley communities.[29–31]

Study area #2 included selected communities in the Navajo Nation, where a greater risk of LRTI among children from wood burning households has been reported.[24, 32] The Navajo Reservation is the largest Indian reservation in the US with a population of approximately 175,000 people.[33] Much of the Four Corners area is high mountain desert, but wood burning (pine and juniper) is still very common throughout the Navajo Nation. Coal burning also occurs in some areas of the Navajo Reservation, but was not a focus of this study.

Study area #3 included AN communities in the Yukon-Kuskokwim (YK) Delta region in Alaska. The YK Delta is located in the Southwest region of Alaska and covers an area of approximately 75,000 square miles. Due to the high costs of electricity and cold winter climate, many households rely on wood stoves to heat their homes. As most communities in the YK Delta are located in remote areas, healthcare is provided to the region by the YKHC, through a unique network of 47 village clinics, five subregional clinics, and one regional hospital which is only accessible by plane, boat, or snowmachine.[34]

2.3 Community Coordinators

For the western Montana study site, two Community Coordinators were based out of the University of Montana. For both the Alaska and Navajo Nation study areas, Community Coordinators within each study area were contracted through the University of Alaska Fairbanks (Center for Alaska Native Health Research) and the University of New Mexico (Community Environmental Health Program), respectively, for the duration of the recruitment, exposure assessment, and winter follow-up periods. At the onset of the program in each study area, comprehensive training was provided by University of Montana personnel. This was followed by several site visits throughout the course of the program in each of the study areas to assess and optimize the quality of the program.

2.4 Participant selection, eligibility criteria, and informed consent/parental permission

Eligible homes included any home in the described communities that used a wood stove as a primary heating source, and had at least one child under the age of five years. Each home included a parent who was capable and willing to record symptom data for the enrolled children and wood stove usage data. Across the three study areas, the target recruitment included 324 total homes. We anticipated that there would be on average 1.5 (i.e., 1 to 2) children less than five years of age among households with at least one child in this age group, yielding an estimated 486 total children that would be tracked throughout the study.

Upon identification of eligible homes with children < 5 years old, parents were asked to complete parent permission and medical release forms. A copy of the Parental Permission form was provided to the parent/guardian(s) for their records. Community Coordinators also completed child assent procedures for children four to five years. When recruitment procedures were completed, home and child identification numbers were assigned and the descriptive data of the home and participants were forwarded to the study-coordinating center at the University of Montana. The home and participant IDs were then used for all data collection procedures throughout the program.

Program households were provided compensation for their time in meeting with Community Coordinators, completing paperwork, and providing information on child respiratory health. Households assigned to air filter or placebo interventions were also reimbursed for electricity usage. At study end, Tx1 educational tools and Tx2 filtration units used in the interventions were provided to all households.

2.4 Randomization procedures

We utilized a stratified, blocked randomization approach to assign KidsAIR participants to one of the three arms of the trial. Since LRTI incidence declines sharply after one year of age, we aimed to ensure a balance of children under the age of one year in each arm. Specifically, we included a stratum for homes with the youngest child under the age of one year and a stratum with the youngest child between the ages of one and five years. We used age on November 1st of the calendar year of entry into the study as the cut point. To ensure a similar distribution of study communities and cohorts in each arm, we also stratified on study site (western Montana, YK Delta Region, and the Navajo Nation) and by year within each site. Each stratum contained blocks of three homes to ensure that each arm contained an approximately equal number of homes.

2.5 Interventions

Following randomization, Community Coordinators in Montana, the Navajo Nation, and Alaska were notified of home assignments, and initiated the corresponding interventions. Interventions were implemented before the winter observation period began at an initial home visit.

Education Intervention (Tx1)—This intervention was based on the premise that behavioral factors were critically important determinants of proper wood stove usage, and the associated exposures and health outcomes. The education components for this intervention were based on recent observations and recommendations from tribal, local, state and federal agencies.[35–37] The intervention utilized a combination of an education campaign coupled with the distribution of inexpensive tools to the homes that enabled the residents to burn wood more efficiently. Table 1 shows the general content of the Tx1 best-burn messaging delivered to the wood burning households.

At the beginning of the sampling season, the Community Coordinator scheduled an initial wood stove training session with the Tx1 households. At this session, the coordinator discussed the concepts related to best-burn practices described in Table 1, and provided training on the tools that were given to the residence. These tools included a wood stove thermometer to ensure optimal burn temperatures, a moisture meter to ensure proper fuel moisture, and fire starters to ensure that fires were started quickly and with minimal smoke. At the western Montana and Navajo sites, participants watched three short videos that covered the Table 1 messages (Video 1: KidsAir introduction; Video 2: How to prepare your firewood; and Video 3: How to optimize your wood burning). Importantly, at the Alaska sites, a flipchart was used instead of videos. This variation in education delivery was based on community preference as well as the unreliability of internet connections and access to DVD players in some communities. Videos and flipcharts for Navajo and Alaska were adapted to cultural and local context. Following these video/flipchart presentations, participants and field staff reviewed a checklist together to reinforce the main concepts in Table 1.

Air Filtration Unit Treatment (Tx2): Within each randomly assigned home, an air filtration unit was placed in the same room as the wood stove. Throughout the study, we used different types of filtration units, including the 3M Filtrete models FAP-03 and FAP-02, Honeywell 5250, and Winix Plasmawave 5500 and 5300s. During the periods of operation, the units were operated on the “high” setting. Filters were checked by the Community Coordinator once per month and changed as necessary in an effort to maximize collection efficiency. To track air filtration use, a Kill-a-watt meter was installed to measure kilowatt usage. Kilowatt readings were then compared to laboratory-based kilowatt usage predictions for each filtration unit type to assess compliance with proper filtration use.

Control (Tx3): With the exception of the Alaska study site where no filter placebo was used, placebo air filtration units were installed at the other two sites within the wood stove room in each home. Instead of a high efficiency filter, the units were fitted with a placebo filter. Similar to the Tx2 filters, placebo filters were checked monthly by the Community Coordinators and Kilowatt meters were used to assess compliance with proper filtration settings. At the completion of each of the two winters, participants were reimbursed for the electrical costs for running the filtration units. As described earlier, placebo filtration units were not used in the Alaska study homes, but the Tx3 arm still served as a control group (i.e., no treatment).

2.6 Health outcomes assessment

The primary health outcome was occurrence of LRTI among children, and was assessed using active surveillance within the home. Identification of LRTI episodes occurred through a three step process: (1) parent reporting of symptoms; (2) Community Coordinator collection of confirmatory and severity data; and (3) physician classification of case status based on data collected by the Community Coordinator, and when available, data collected from a clinic or hospital.

To facilitate parent reporting, Community Coordinators trained parents in the identification of symptoms consistent with LRTI (cough, difficulty breathing, fast breathing, noisy breathing, nasal discharge, loss of appetite and fever). Parents were asked to contact their Community Coordinator when such symptoms were present in household children less than five years old (Step 1). Home visits occurred within 48 hours of parent notification of signs and symptoms of LRTI. At this visit, the Community Coordinator interviewed the parent about the child’s symptoms using a Child Symptom Questionnaire (CSQ). The Community Coordinator then measured temperature, respiratory rate, and saturated oxygen, and evaluated the child for the presence of chest indrawing (retractions), wheeze and cough (Step 2). For any study participant experiencing symptoms, the Community Coordinator documented the presence of symptoms and date of onset with the parent. During the regular communication with the parent and subsequent home visits, the Community Coordinator continued to track this child’s symptoms. Per approaches used internationally, if symptoms recurred within a period of less than 14 days, these symptom days were considered part of the immediately preceding episode rather than a separate episode. Days with cough as the only symptom were not included as symptom days for the given LRTI episode.[38] The Community Coordinator also determined if the child was observed by a health care provider, clinic, or hospital during this episode. If available, health records from such visits were collected from the health provider with the corresponding parent-signed medical release forms. Data collected from medical records included health care provider diagnosis, auscultatory findings, and laboratory/radiological findings.

The Step 1 strategy may have been adversely impacted by lack of follow-up by the parent or communication barriers that varied by community. To address this, the Community Coordinator engaged in active and frequent surveillance of homes (Step 2), interviewing the parent a minimum of once every two weeks regarding symptoms among study participants. This communication occurred via telephone, email, or a home visit depending upon the community setting and the preferred method of communication. The Community Coordinator also visited the home a minimum of once per month to assess lung sounds, and measure temperature, respiratory rate, heart rate, and saturated oxygen. This monthly visit occurred regardless of whether the parent had reported child symptoms consistent with LRTI. When indicated, the Community Coordinator collected objective measures and prospectively tracked symptoms according to the Step 1 procedures indicated above.

For primary analysis, the final case determination was made by our team pediatric pulmonologist (Step 3). Case determination was based on health measures collected in the field and medical records, when available. To improve specificity for LRTI, the pediatric pulmonologist further distinguished between moderate and severe LRTI (i.e., secondary case status determination) according to the presence of fever, chest indrawing, wheeze and saturated oxygen readings as documented from direct field observation or from clinical records. Start and end dates for each LRTI were determined through review of the CSQs, health measures from Community Coordinator visits, and medical record history.

2.7 Exposure assessment

$PM_{2.5}$ exposure measurements were conducted within the common room of each participating household during one, six-day sampling event in the first winter. During each sampling event, a DustTrak (8530, TSI, Shoreview, MN) was used to continuously measure $PM_{2.5}$ mass concentration with 60-second time intervals. The local Community Coordinator was instructed to place the DustTrak 3–5 feet above the ground in the same room that the wood stove was located, usually in the common area (living room). Following the sampling period, the Community Coordinator downloaded the electronic data file from the DustTrak to a computer, and then uploaded the data files to a database created by the University of Montana team. In addition to measuring indoor $PM_{2.5}$, we monitored stove use throughout the winter assessment periods with stove use monitors (i.e., temperature logging devices such as Thermochron iButton® and LogTags®). These units were placed next to the back left leg of the stove (either by hook or magnet), with the data downloaded from the units monthly during both winter assessment periods. Photos of the wood stove, stovepipe, wood storage, and chimney were taken and provided to a wood stove consultant working with our team to assess the overall quality of each wood stove. DustTraks were calibrated annually, and cleaned and zero-calibrated prior to each sampling run.

2.8 Other measures

In order to accurately interpret the air sampling results within each of the homes, it was important to consider the many variables that might contribute to $PM_{2.5}$ exposures. Using home activity logs, the Community Coordinators worked with the household contacts to ascertain activities that occurred within the home during the sampling period. Specifically, activities recorded in the logs included cooking, any in-home smoking (cigarette, pipe, or other), cleaning, and other activities that may have contributed to increased PM levels (e.g., burning incense or candles). A record of wood burning activity was also utilized to track the frequency/amount of burning during each 6-day sampling episode. Wood fuel moisture was also measured during the sampling period to monitor both the quality of burned materials and the educational intervention effectiveness.

We captured additional data that may be relevant to either risk of LRTI or $PM_{2.5}$ exposures. Recorded household-level characteristics included total number of residents, home age and square footage, presence of mold, household pets, parent education level, household income, and household smoking. Additional home heating questions including the primary and secondary sources of heat, as well as the woodstove age, model, EPA certification, and time since the chimney was last cleaned. To further assess tobacco smoking within homes, wipe samples were also collected with the intent of analyzing for nicotine.

Finally, a short assessment (Knowledge, Attitudes, and Behaviors (KAB) survey) was utilized at the beginning and end of the heating season to measure knowledge gained and retention of education messages for Tx1 homes and post only knowledge for Tx2 and Tx3 homes. Post winter questionnaires were additionally utilized to assess compliance and use of the provided tools (i.e., moisture meters, fire starters, and stove thermometers for Tx1; and filters for Tx2 and Tx3 homes).

2.9 Interim and planned analyses

Interim analyses were conducted as described in the study Data and Safety Monitoring Plan (DSMP), which was established to guide the oversight of this study in order to ensure the safety of participants and the validity and integrity of the data. We reviewed interim findings on the primary aim, risk of LRTIs, for indications of clear or extreme benefit or harm. Specifically, an external biostatistician, blinded to treatment coding, evaluated the efficacy, relative to control, of both the Education (Tx1) and Air Filtration Unit (Tx2) in reducing LRTIs in children. If either was significantly more efficacious than the control condition, then we would have recommended that the control arm be eliminated and subsequently enrolled participants be randomized to either Tx1 or Tx2. A more conservative significance level of 0.01 was utilized to account for the multiple testing occurring when data were examined more than once. The planned interim analysis occurred after data collection in Year 3. The choice of timing for the interim analysis reflected a balance between maximizing the ability to 1) detect true efficacy of the interventions and 2) implement changes in study protocol, if necessary, to benefit as many subjects as possible and uphold our ethical obligations to study participants. Evidence of extreme benefit or harm was not observed, and the study proceeded as planned.

Following completion of data collection, planned statistical analyses will be conducted using SAS v9.2 (Cary, NC). A descriptive analysis will also be conducted to describe the treatment groups with relation to pertinent demographic variables and home characteristics at baseline to assess the effectiveness of the randomization strategy. T-tests, or chi-square tests as appropriate, will be used to compare differences between groups and identify variables that were unequally distributed despite the randomization strategy. Following this comparison, any differences related to those characteristics on the primary outcome of incidence of LRTI among children < 5 years in the three treatment arms will be assessed. Incidence will be calculated as the number of new LRTI events per child-weeks of observation. Intention to treat analyses will be performed, assuming no change in the presence or absence of LRTI symptoms during missing time periods of follow-up for a given child. Each child could contribute multiple LRTI events to the numerator. A new episode of LRTI will be one following an observed two-week interval without LRTI.[99] Generalized Linear Mixed Models,[39, 40] more specifically random intercept Poisson regression, will be used to estimate and compare incidence rates of LRTI in the intervention arms. A Type I error was set at alpha = 0.04 to account for prior interim analysis. Inclusion of nested random effects will be used to account for the within household, community and cohort clustering effects. Primary analyses will examine the impact of Tx assignment in unadjusted models, but we will also test sensitivity of results to adjust for individual as well as household covariates at baseline. Individual-level covariates to be considered include vaccination history, occurrence and duration of breast-feeding, birth weight and mother's age at birth. Household-level covariates to be considered include crowding, household smoking, presence of mold, and parents' education level. Each variable's strength of association with the outcome as well as stepwise variable selection strategies will be used to achieve a parsimonious model. For all aims, we will initially assume that data were missing completely at random. If missing data occur more frequently within a particular study arm or study site, we will employ multiple imputation methods to reduce bias attributable to these factors. In secondary analyses we will also evaluate treatment efficacy separately for each study site. Although we anticipate that factors such as meteorological and ambient air pollution will be accounted for with the nested random effects model, we will also evaluate the influence of these factors in secondary analyses.

2.10 Expected results and power calculations

As described above our target recruitment was 108 households per intervention arm across the study sites (n=324 total). We expected 1.5 children < 5 years among households with at least one child in this age group (child n=486 total). We anticipated limited design effect due to this clustering by household. A review of intervention studies for diarrheal disease described design effects of only 1.0 to 1.4 due to randomization at the household level for small cluster sizes of 1.3 to 1.7 persons.[41] Thus, we assumed a sample size of ~162 children per intervention arm with limited impact on power after accounting for within-home observations. We estimated 31% occurrence of LRTI during the two, six-month health assessment periods. This overall estimate was based on averaging data for LRTI outpatient visits and hospitalizations (44% among AN children < 5 years of age; 34% among AI children in the Southwest region; and 16% among general population US children).[3] We anticipated that our procedures for active surveillance were more sensitive for detection of LRTI without sacrificing specificity. For example, some of our AN populations have limited access to regional health centers when secondary and/or tertiary care is required, so LRTI rates based on outpatient visits and hospitalizations likely underestimate LRTI disease burden in these communities. We also expected that LRTI disease burden in the rural and frontier communities of western Montana (Study Area #1) would be higher than the general population estimates above.[42] At the 95% confidence level, we would have 80% power to detect a relative risk (RR) of 1.5 for the control group relative to one of the treatment groups. Given previous work, this is a reasonable detectable RR. A pooled analysis of 24 studies evaluating exposure to biomass smoke and risk of child pneumonia found a summary odds ratio (and 95% CI) of 1.78 (1.45, 2.18).[43] All 24 studies considered evaluated exposures to cookstove smoke in developing country settings, and only one of the 24 studies was an intervention randomized trial design.[27] The randomized trial in a Guatemalan population utilizing open wood fires for cooking observed a 50% reduction in indoor wood smoke exposures in intervention-assigned homes (similar to the 60% reduction observed in our previous study employing filtration units) and a 30% increased risk (i.e. RR=1.3) of physician-diagnosed pneumonia in children associated with the control arm. We anticipate an even greater exposure-response at the lower baseline $PM_{2.5}$ concentrations in our study settings.

3. Discussion

Global burden of disease assessments have pointed to household air pollution (HAP) as one of the leading causes of early mortality, primarily driven by the impact on childhood pneumonia.[2] Combustion of biomass fuels for heating and cooking is a significant source of $PM_{2.5}$ throughout the world, and an important contributor to childhood LRTI. It has been estimated that one-half of the world’s households continue to cook with solid fuels, approximately 95% of which consists of wood fuel or burning of agricultural residues.[44] Incomplete combustion and poor ventilation can result in extremely high $PM_{2.5}$ exposures within these developing country settings,[45, 46] corresponding to an elevated risk of LRTI among children.[47–51] According to the World Health Organization, 8% of mortality in children under five years of age is attributed to indoor smoke from solid fuels, primarily due to increased risk of LRTI.[52] In these global settings, improved cookstove interventions have shown conflicting results with respect to children’s risk of pneumonia.[26, 27] Numerous challenges with these and similar studies have been identified, including limited adoption of new appliances and difficulty in translating laboratory-based testing of new technologies to real world settings.[53]

Relatively few studies in developed countries have evaluated the relationships between residential wood stove smoke and risk of childhood respiratory infections. In British Columbia, residential exposures to wood smoke were associated with increased outpatient and hospital visits for infant bronchiolitis (8% increase per interquartile increase in wood smoke exposure days) despite the absence of an association between ambient $PM_{2.5}$ and bronchiolitis.[54] Hypothesized biological pathways for this biomass smoke and LRTI association include compromised immunity in the lungs and immune suppression, resulting in increased susceptibility to infections.[55] Our team has previously evaluated childhood respiratory disease in a rural western Montana community that initiated a wood stove intervention program (replacing 1,100 old wood stoves with high efficiency wood stoves).[22] In addition to reductions in winter ambient PM2.5 (~27%), we observed reductions in parent reporting of child bronchitis (54.6% reduction per 5 μg/m3 decrease in average winter PM2.5), influenza (52.3%), cold (25.4%), throat infection (45.1%) and wheeze (26.7%).[22] Association between wood smoke exposure and LRTI risk have also been observed in AI/AN communities.[24, 32, 56, 57] A case-control study among children < 3 years old from wood burning homes in the YK region of Alaska showed a robust association with LRTI hospitalization (odds ratio, OR (95% CI) = 2.2 (1.2, 4.1)) after accounting for other factors such as number of sinks in the homes, crowding, and children with a history of prematurity, congenital heart disease, or chronic lung disease.[56] In addition, our team recently conducted door-to-door surveys in three YK Delta communities (i.e., communities similar to those that participated in this study), with more than half of all homes having wood stoves.[57] Child health surveys indicated an association between reporting of LRTI among children and household use of wood for heating. Importantly, after adjusting for household smoking we observed higher, though imprecise, ORs for LRTI (child pneumonia and bronchitis) among children living in wood stove homes (compared to fuel oil homes). Reporting bias was a concern in this study, but we observed no so such association for influenza-associated illness across the study sites.

In the U.S., wood stoves are the most intensively utilized type of space heater, with over 11 million homes currently using wood as either a primary or secondary heating source.[58, 59] With an average annual usage of 2,100 hours per device, more than 80% of existing wood stoves are old and inefficient models.[60] In many rural areas of the US, limited alternatives to burning wood for home heating are available due to the lack of existing natural gas pipelines and the elevated costs of heating oil and other fossil fuels. In addition to being a significant source of ambient $PM_{2.5}$,[29, 46, 61, 62] wood stove use can result in elevated, sustained $PM_{2.5}$ exposures *within* homes.[63–65] Median $PM_{2.5}$ concentrations within wood stoves homes have been reported from 12.8 to 54.0 $\mu g/m^3$.[23, 64, 66] Notably, two of our research studies conducted in rural western Montana found that half of the homes investigated had 24-hour $PM_{2.5}$ average concentrations that exceeded the current daily Environmental Protection Agency's (EPA) National Ambient Air Quality Standard of 35 $\mu g/m^3$.[23, 65] Although currently no indoor $PM_{2.5}$ standards exist, these indoor exposures are concerning, as individuals, on average, spend ~87% of their time indoors.[67]

To address the problem of high-emission heating appliances many public health and environmental agencies have promoted community-targeted programs to turn over the stock of old, inefficient stoves and replace them with newer stoves that have higher combustion efficiencies and lower emissions (i.e. wood stove changeouts). To our knowledge, only four studies have been conducted in North America that have comprehensively evaluated the efficacy of this type of intervention on improving indoor air quality.[64–66, 68] Results from these studies showed highly variable outcomes, with 33 to 45% of homes demonstrating no reduction in indoor $PM_{2.5}$ following the introduction of EPA-certified wood stoves. Two of the studies demonstrated highly variable effects, with overall average reductions in indoor

$PM_{2.5}$ after accounting for repeated measures and ambient factors.[64, 65] Only one of the studies occurred within the context of a randomized trial, and it showed no average reduction in indoor $PM_{2.5}$ relative to control homes (mean percent reduction = 1; 95% CI: −31, 34).[68] The cost of wood stove change-out interventions ($2,500-$4,500 per home) also precludes this intervention from being broadly implemented in rural, economically challenged communities.

4. Summary

In this study, we will evaluate the efficacy of an education intervention to promote best burn practices, as improper stove use and behavioral factors can lead to elevated indoor wood smoke exposures. A recent survey of wood stove homes in Washington found that only 61% of homes seasoned firewood for the recommended six months, and less than half of the homes complied with recommended wood storage practices.[69] Burning of wet wood and improper stove use have also been noted on the Nez Perce Reservation.[70] Our team was involved with a wood stove change-out study on the Nez Perce Reservation, where 16 older model wood stoves were replaced with new EPA-certified stoves. Following the installation of the new wood stoves, some homes had higher indoor $PM_{2.5}$ concentrations compared to prechange-out levels. After communicating with the homeowners, it was discovered that many were not following best-burn practices (inefficient burn temperatures and improper maintenance) with their new stoves. Following additional training on proper stove use, $PM_{2.5}$ concentrations were lowered within the homes.[64] Despite the promotion of best-burn practices by various tribal, local, state, and federal agencies,[35–37] such strategies have rarely been formally and rigorously tested in regionally and culturally distinct settings.

The second intervention arm involves the placement of air filtration units in homes that burn wood for heat. Air filtration unit interventions have consistently demonstrated substantial $PM_{2.5}$ reductions in wood burning homes.[68, 71–73] Our team has evaluated the efficacy of the 3M Filtrete (Ultra Clean Air Purifiers, 3M, St. Paul, MN) in reducing indoor $PM_{2.5}$ in wood burning homes located in rural areas throughout Montana, Idaho, and Alaska. This intervention has consistently resulted in a ~60% exposure reduction in indoor $PM_{2.5}$ concentrations [95% CI: 26, 90] relative to placebo homes, as well as reduced particle count concentrations (in several PM size fractions) by 61–85%.[68, 72] Although these filtration units consistently work well in improving indoor air quality, we have learned that economic considerations (costs of the unit (~$200), yearly filter replacement (~$100), and energy usage (~$100-$200/year), size, and long-term compliance issues prevent these interventions from becoming sustainable and easily disseminated - especially in rural, low income, and underserved areas.[68, 74]

These two treatment arms, education intervention and air filters, will be compared against a control arm to evaluate the impact on reduced lower respiratory tract infection among children under five years. We have recently demonstrated efficacy of exposure reduction strategies in lowering peak flow variability among children with asthma, but changes to quality of life and other measures of lung function were not evident.[75] Rural children less than five years old and exposed to household air pollution represent a population that is particularly vulnerable to respiratory infection. The goal of this randomized trial was to provide evidence for simple, cost-effective strategies that can be deployed in similar rural settings to protect children's health.

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Table 1.

Best-burn messages communicated as part of the Education Intervention (Tx1).

How to treat your firewood before burning:

- Properly split your firewood (6 inches or less in diameter).
- Properly cover and store your firewood.
- Dry firewood for 6–12 months before burning.
- Use a ***moisture meter*** to test your wood.
- Only burn dry, seasoned wood (moisture content <20%).
- Wood can be conditioned inside for 2 days before burning.

How to optimally burn your firewood:

- Maintain a bed of ash just below the vent holes of the wood stove.
- Dry kindling, air movement, and ***fire starter*** can help you start a hot fire quickly.
- Small hot fires that burn for 20 to 30 minutes are key to reaching optimal burn temperatures
- Use a ***wood stove thermometer*** to help you burn at optimal temperatures.
- Before reloading, it is important to allow the fire to burn for 20–30 minutes or until optimal temperatures are reached.
- Do not burn items other than wood (e.g., trash, cardboard, etc.).

Additional tips:

- Crack a window/door on the same level when starting a fire.
- Check your chimney 20–30 minutes after starting a fire to verify that minimal smoke is emitted.
- It is important to clean your flue and chimney frequently!