



An asthma collaboration to reduce childhood asthma disparities on the Navajo Nation: Trial protocol for the Community Asthma Program

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ABSTRACT

Navajo children disproportionately experience poor asthma outcomes. Following a one-year community engagement period with key stakeholders from the Navajo Nation, the Community Asthma Program (CAP) was created using evidenced based programs with the goal of reducing asthma disparities among Navajo children. CAP is being evaluated with a six-year, multi-site step-wedge design in three Navajo communities: Tuba City, Chinle and Fort Defiance, Arizona. The primary outcome is asthma exacerbations defined as use of systemic oral corticosteroids, asthma hospitalizations, asthma related ED visits, and ICU admissions. Asthma exacerbations will be measured using data from the electronic medical records of the three community health care centers. Secondary outcomes include will changes in asthma-related events and asthma control. The RE-AIM (*Reach and representativeness*, 2) *Effectiveness*, 3) *Adoption*, 4) *Implementation*, and 5) *Maintenance*) framework is being used to guide the implementation evaluation which includes iterative collection and analysis of process data to identify facilitators and barriers, describe relevant organizational contexts, and inform strategies for dissemination. The CAP intervention requires community engagement and participation, building community capacity, incorporating evidenced-based guidelines and practices while ensuring program strategies actively involve Navajo community members during all steps of the intervention. The outcome of this trial will allow us to determine the effectiveness of a multi-component, community-focused intervention to improve asthma in a tribal community.

1. Introduction

The Centers for Disease Control and Prevention (CDC) estimated the prevalence of asthma among school-aged children in 2020 was approximately 8% [1]. Asthma is associated with frequent exacerbations that cause respiratory symptoms and difficulty breathing. These

symptoms typically result in poor health outcomes including chronic school absenteeism, parental work absenteeism, and increased emergency department (ED) visits, hospitalizations, and medical expenditure [2–7]. Socio-economic, environmental and genetic factors contribute to asthma prevalence and severity experienced by children. These disparities disproportionately impact low-income, minority children [8].

For children living on the Navajo Nation, the largest and most

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Abbreviations

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|------|------------------------------------|
| ACIP | Asthma Care Implementation Program |
| ALA | American Lung Association |
| ATP | Asthma Toolkit Program |
| CAC | Community Advisory Committee |
| CAP | Community Asthma Program |
| CHP | Center for Health Promotion |
| CHR | Community Health Representative |
| DSMB | Data Safety Monitoring Board |
| ED | Emergency Department |
| EMR | Electronic Medical Record |
| ICC | Intra-cluster Correlation |
| ICU | Intensive Care Unit |
| IHS | Indian Health Services |

| | |
|--------|---|
| IRB | Independent Review Board |
| MOU | Memorandum of Understanding |
| NIH | National Institutes of Health |
| NHLBI | National Institutes of Heart, Lung and Blood Institute |
| NNHRRB | Navajo Nation Human Research Review Board |
| PI | Principal Investigator |
| QoL | Quality of Life |
| RE-AIM | Reach, Effectiveness, Adoption, Implementation, Maintenance |
| REDCap | Research Electronic Data Capture |
| SD | Standard Deviation |
| SFTP | Secure File Transfer Program |
| US | United States |
| 95% CI | 95% confidence interval |

populous tribal reservation in the U.S., [9], the prevalence of childhood asthma (18%) is approximately twice as high as the U.S. national average (8.6%) [10]. Devastating poverty, multiple environmental pollutants and long travel distances to health care services fuel these disparities [11,12]. At this time, Indian Health Services (IHS) and Tribally-Operated 638 Programs on the Navajo Nation have 12 administrative units that provide health services to roughly 250,000 tribal members [13]. Evidenced-based asthma care has been inconsistent among Navajo children who use these health systems resulting from longstanding challenges such as underfunding, frequent employee turnover and limited access to specialists [14]. Guideline concordant care for pediatric asthma is an important component of improving asthma control, severity and decreasing disparities among pediatric patients and Navajo children [15]. To date, there have been no intervention studies directed specifically to pediatric asthma treatment on the Navajo Nation.

Supported by one year of funding from the National, Heart, Lung and Blood Institute (U34HL 130762), we engaged over 1500 people on the Navajo Nation through 66 face-to-face meetings to develop an Asthma Care Implementation Program (ACIP). These engagements resulted in widespread community support and commitment to partnerships from the President and Vice President of the Navajo Nation, governmental organizations, healthcare centers, schools, and communities in the three participating agencies (Chinle, Ft. Defiance, and Tuba City). Strategies to guide and facilitate implementation were discussed with key leaders, groups, and organizations and a plan for the “Community Asthma Program” (CAP) was established. Community Advisory Committees (CACs) were created to continue planning and monitoring the implementation of the ACIP. Strengths present on the Navajo Nation that will help assure success of this program include no- or low-cost healthcare and medications in IHS and 638 facilities, transportation resources, a large and well-trained community lay health worker program, and strong community and family commitment to child health. The overall objective of the current study, entitled, “An Asthma Collaboration to reduce Childhood Asthma Disparities on the Navajo Nation”, is to implement evidenced based asthma interventions and evaluate their impact on pediatric asthma outcomes. This work was supported by the National Institutes of Heart, Lung and Blood Institute (U01 HL138689). The primary objective of this clinical trial is to implement and evaluate an integrated and comprehensive evidence-based Asthma Care Implementation Program (ACIP) in three participating Navajo agencies (Tuba City, Chinle and Fort Defiance, Arizona). The intervention will bring together evidenced-based programs, tailored to address the needs and requests articulated by the Navajo community during the engagement year. We hypothesize Navajo children ages 7–17 will experience reduced asthma exacerbations as measured by systemic corticosteroid use, asthma hospitalizations, asthma Emergency Department (ED) visits

and Intensive Care Unit (ICU admissions for asthma after completion of the intervention.

2. Materials and methods

2.1. Study design and setting

This study will use a step-wedge, cluster randomization design [16] in which the three communities were randomized at study onset and will sequentially proceed from control status to intervention until all have received intervention exposure (Fig. 1). The three targeted Navajo Nation communities represent clusters within the randomization. Order of intervention was randomly determined to be Tuba City, followed by Chinle, and Fort Defiance. The study intervention will be conducted for one year in each respective community, preceded by a “baseline” observation period and followed by a “post” observation period. The intervention occurs with IHS and 638 facilities and pharmacies, schools, families, and communities. The study team will not provide direct services to Navajo children or families and will not enroll individuals in the intervention. Instead, the intervention goal is to build community capacity that provides high quality and sustainable asthma care, education, and support to all families of children with asthma. The study was approved by, and is proceeding under the regulatory oversight of the Navajo Nation Human Research Review Board (NNHRRB) and the National Jewish Health IRB.

2.2. Intervention components

The core of the intervention is educational and directed at health care providers, schools, Community Health Representatives (CHRs), and children with asthma.

2.3. Health care worker training (IHS and 638 facilities and pharmacies)

In each of the three target communities, health care workers will receive expert instruction in pediatric asthma care and management in the form of the Asthma Toolkit Program (ATP), based on the Colorado Asthma Toolkit Program [17,18]. Trainees encompass all practice staff, including doctors, pharmacists, mid-level providers, nurses, medical assistants, and front desk staff. The ATP has three components which occur in the following order: 1) self-directed online training with assessment via the ATP website, 2) a one-day in-person workshop, and 3) a follow up in-clinic visit. The online and in-person training covers seven major content areas: 1) overview of the pathogenesis and treatment of asthma, 2) steps to control asthma, 3) categorization of severity and appropriate treatments at each level, 4) pharmacology, 5) conduct of spirometry, 6) trigger avoidance, 7) provider communication tools to

| 2017 | 2018 | 2019 | 2020 | 2021 | 2022 |
|----------------------------------|---------------------------|------------------------|-------------------------------|----------------------------|------|
| Tuba City Baseline Period | Tuba City Intervention | Tuba City Follow-up | | | |
| Chinle Baseline Period | | Chinle Intervention | Chinle Follow-up | | |
| Fort Defiance Baseline Period | | | Fort Defiance Intervention | Fort Defiance Follow-up | |
| Data Collection Period | | | | Data Analysis Period | |

Fig. 1. “An Asthma Collaboration to reduce Childhood Asthma Disparities on the Navajo Nation” study timeline, 2017–2022.

improve asthma self-management, and 8) example case studies. Emphasis is placed on building sustainability within practices by engaging practice staff to actively brainstorm and develop the training implementation plan that will work for their practice. Some elements of the in-person training are only provided to those for whom they are pertinent. For example, front desk staff do not review medication prescription guidelines. After the training ends, all participating clinics continue to have access to additional digital resources via the Asthma Toolkit website, including refresher videos, and documents such as asthma action plan templates [17–19]. Physicians and pharmacists will also be educated about the Stock Inhaler for Schools Program (see below).

2.4. Community health representative/school staff training

Training for CHRs, school personnel and community members consists of two primary components: the American Lung Association’s (ALA) Asthma 101 and Open Airways for Schools® (OAS) facilitator training. The first component, Asthma 101, was developed by the ALA to train teachers and school personnel about asthma and how to help children who experience asthma symptoms at school [20]. The curriculum is taught during a 1-h in-person session with a registered nurse who is also a certified asthma educator (AE-C).

CHR and interested community members will complete facilitator training for implementing the ALA’s award-winning curriculum, Open Airways for Schools®. OAS® consists of six, 1-h classes aimed at empowering children regarding their asthma and is typically taught during school hours [21]. The program uses a “train-the-trainer” model, where CHR or community members are trained as both an instructor and facilitator which enables them to teach additional OAS® facilitators, but also implement the program with asthmatic children; thus ensuring program sustainability. All children with asthma, ages 8–11 years and enrolled in schools located in one of the three sites, are eligible to receive the OAS® course. The CAP program will work with individuals who were trained to facilitate (OAS) to assist them in connecting with schools and scheduling the OAS® classes during the intervention year. Materials for conducting OAS® including poster boards, facilitator handbooks, child and parent worksheets, and small incentives for children will be provided in kits to each facilitator by the CAP. Extra kits will be distributed to the health care centers and the CHRs for future use.

2.5. School stock inhaler program

The third component of the school-based program consists of a Stock Inhaler for Schools Program. A stock inhaler is a single, albuterol inhaler (i.e., short-acting beta agonist) with a supply of valved-holding chambers that can be used by multiple individuals at the school [22]. Such programs have been shown to reduce 9-1-1 calls and EMS transports for respiratory distress from schools [23]. A stock inhaler’s primary function is to relieve the symptoms of respiratory distress during any event

where the individual does not have immediate access to their personal rescue inhaler. Investigators will work with IHS and 638 facilities to train physicians and pharmacists about Arizona state law regarding stock inhalers (since the involved Navajo communities are in Arizona). A pediatrician in each community will be the designated provider who will sign the standing medical orders and prescriptions for each school. The pharmacists will serve as the point of contact for refills for each school. All program supplies (including standing medical orders, albuterol and spacers) will be provided by the health care facilities at no charge to the school. The CAP program will provide a hands-on, 1-h training conducted by an RN and AE-C for employees at each school on how and when to use the stock inhaler. The training curriculum is also available online for school personnel [24]. Investigators are currently working with the Health and Human Services Committee of the Navajo Council to draft and pass a stock inhaler law by the Navajo council that will apply to all Diné schools.

2.6. Outcome measures

2.6.1. Primary outcome measure

The primary outcome measure, asthma exacerbations, is defined using the National Institutes of Health outcomes workshop [25,26] and measured in the health care systems’ EMR databases from the three participating agencies. The definition includes systemic oral corticosteroids, asthma hospital admissions, asthma ED visits, and ICU admissions/intubation.

2.6.2. Secondary outcome measures

Several secondary outcomes (family reports of asthma-related events and asthma symptom control) will also be measured in a sample of children (up to 100 at each site). The secondary quantitative outcomes will be gathered from family interviews (see below for more information).

2.6.3. RE-AIM

The RE-AIM framework will be used to conduct an implementation evaluation that includes iterative collection and analysis of process data. RE-AIM conceptualizes the public health impact of an intervention as a function of five factors: 1) *Reach and representativeness*, 2) *Effectiveness*, 3) *Adoption*, 4) *Implementation*, and 5) *Maintenance* [27,28]. We will: 1) identify facilitators and barriers; 2) identify relevant organizational contexts including diverse stakeholder impressions; and 3) inform strategies for dissemination and establishing sustainability. In the final year of sustainability assessment (i.e., “Maintenance”), the Investigators, Navajo Nation governmental leadership, and other stakeholders will determine how the ACIP can be expanded to other Navajo agencies, Native American groups, and high asthma-burden populations. Table 1 describes our iterative data collection approach.

Table 1
Iterative data collection using the RE-AIM framework, 2017–2023.

| RE-AIM Domain | Data Source |
|--|--|
| REACH (% and representativeness of children receiving intervention) | |
| A. <u>Denominators</u> : (i) # children eligible for asthma services; (ii) # seen at clinic; (iii) # eligible for school asthma programs | IHS/schools |
| B. <u>Numerators</u> : (i) and (ii) # of eligible children seen at clinic with documented evidence of guidelines-based care; (iii) # participating in school programs | IHS/ Guidelines-based care checklist |
| C. <u>Representativeness</u> : Compare characteristics of participating and non-participating children | IHS/schools |
| EFFECTIVENESS (Outcome Measures) | |
| A.Oral corticosteroids, hospital admissions, ED visits, and ICU admissions/intubation | IHS |
| B.Family reports of asthma events, symptom control, satisfaction and quality of care | Parent/child interview and questionnaires |
| ADOPTION (% and representativeness of clinics, schools, and staff) | |
| A. <u>Denominators</u> : (i) # of clinics (ii) # of schools invited | IHS |
| B. <u>Numerators</u> : # clinics implementing guidelines-based care; (ii) # of schools participating | IHS/ Guidelines-based care checklist |
| C. <u>Representativeness</u> : Compare participating and non-participating clinics and schools (e.g., size, staffing, credentials) | HIS/census data |
| IMPLEMENTATION (fidelity to interventions; adaptations to enhance feasibility) | |
| A.Proportion of children's' asthma visits with documented guidelines-based care (child-level impact); comprehensiveness/promotion of school asthma programs (setting-level impact) | HIS chart reviews/interviews with staff |
| B.Identification of implementation barriers and facilitators to delivering guidelines-based care at clinic and asthma programming at schools | KI interviews with healthcare and school leaders and staff |
| MAINTENANCE (Child and Setting-level Outcomes, sustained through Year 6) | |
| A. <u>Child/family-level</u> : Urgent care visits, hospitalizations, oral steroids in Years 5 and 6; medication adherence; satisfaction | IHS Parent/child interviews |
| B. <u>Setting-level</u> : Continued commitment to guidelines-based care; assessment of facilitators (e.g., policies) and barriers (e.g., staffing and funding) to maintenance | KI interviews with healthcare and school leaders and staff |
| C. <u>Community-level</u> : Report results, discuss feedback and recommendations for long-term maintenance and dissemination of guidelines-based care/school programs | Meetings with school and health boards, councils, chapter houses |

2.6.4. Study recruitment of communities and families

Our team obtained both letters of support for the project and memoranda of understanding (MOUs) from relevant Navajo stakeholders including but not limited to school district Superintendents, the hospital Board of Directors and Navajo chapter houses. Collectively, the three agencies within which we are working represent 43% of the Navajo Nation population and based on IHS data, are home to an estimated 8443 children with asthma, Notably, our community-based step wedge study design will not recruit individual children who will be randomized to any treatment condition. While we will not recruit individual participants for the intervention, we will recruit and interview up to 300 parents or guardians of a child with asthma in annual interviews assessing the secondary outcomes of asthma symptoms, asthma control, and satisfaction with asthma care. Recruitment of families of children with asthma will occur through community-based events such as large social gatherings and flea markets, as well as at IHS clinics and schools. These differing methods of recruitment are likely to result in different types of families (i.e., those who are well connected to the health care system, likely to be recruited at the clinic; and those less

connected to the health care systems, likely to be recruited at community events) and we want to represent all types of families in our interviews.

2.6.5. Inclusion & exclusion criteria of families for interviews

To be eligible participants must meet the following criteria: 1) residents of the Navajo Nation over age 18-years, 2) the parent or guardian of a Navajo child between ages 7- and 17-years-old, and 3) the child must have physician diagnosed asthma. Exclusion criteria include 1) inability to consent, and 2) inability to understand written and spoken English. Interviews will include both quantitative and qualitative questions and the Asthma Control Test (ACT) and Childhood Asthma Control Test (C-ACT) depending on the child's age at time of interview [29,30]. Children will be consented if administered the C-ACT.

2.6.6. Power

Because step-wedge designs include a one-way crossover component (control to intervention), the data analysis will include between- and within-cluster comparisons over time and account for temporal variations. We used a conservative sample size estimate based on our primary outcome (percentage of all children with asthma in the IHS who have had an exacerbation in the past 12 months). In 100 randomly selected patient charts from the Chinle IHS, 52% of the children had required oral corticosteroids the previous year. Based on our prior research, we expect our intervention to cut this number in half to 26%, with similar reductions in the other health care events considered as representing asthma exacerbations. A sample size of 125 has 83% power to detect a decrease of half that amount: 52 to 39%. If we employ a sample size for a stepped-wedge design using the sample size estimate of 375 (125 x 3), three clusters (i.e., communities), one measurement pre-intervention, one measurement post-intervention, and an intra-cluster correlation (ICC) of 0.1, we estimate 125 subjects per community will allow sufficient power to test for differences in healthcare outcomes. Based on discussions with included health care centers preparatory to this project, we anticipate a final sample size greater than 125 per cluster [31].

2.6.7. Quality assurance and control plan

Using guidelines specified by the National Institutes of Health (NIH) for the quality management of intervention studies [32], a Clinical Quality Management Plan will be used as a template to guide the study's quality assurance and control. Specifically, a checklist will be created to monitor participant data on a monthly, quarterly and annual basis. Essential study documents including questionnaires will be monitored on a quarterly and annual basis including NNHRRB-specific documents. Study-wide training materials will be reviewed on an annual basis to ensure updates to educational materials are included. Of notable mention is that all study materials are reviewed and must obtain annual permission from the NNHRRB.

2.6.8. Data management plan

The University of Arizona Asthma & Airway Disease Research Center (A₂DRC) and the National Jewish Health Center for Health Promotion (CHP) will oversee management of study databases and electronic forms, and will manage the databases throughout the duration of the project. Medical record outcome data will be provided to study personnel in a de-identified database file via Secure File Transfer Protocol (SFTP), and will be stored on a HIPAA-compliant University of Arizona server. Other outcome data will be collected using direct data entry into a Research Electronic Data Capture (REDCap) database. Qualitative interview data will be collected via electronic data capture and input directly into a REDCap database. Due to limited internet accessibility on the Navajo Nation, paper forms will be occasionally used to collect data. When used, their information will be hand-entered into the appropriate study database by study personnel. Then, paper forms will be scanned and stored on HIPAA-compliant servers, and paper copies will be stored in locked filing systems. Study data analysts will

monitor data integrity weekly during periods of data collection. Data will be encrypted via SFTP whenever it is transferred electronically between sites. Protection of confidentiality of interviewees' personal data will be accomplished by assigning each interviewee a distinct subject number and using this number rather than the person's name or other protected health information wherever possible on all documents and electronic data acquired from that individual. When data are used in planned analyses, data sets include only participants' research numbers as identifiers. All data files are password-protected, and only project investigators and select project staff have knowledge of the passwords for data access.

2.7. Data analyses plans

2.7.1. Primary and secondary data analysis plan

We will analyze primary and secondary outcomes using individual-level data modeled statistically using generalized linear mixed models. This type of statistical model for a step-wedge design [16] includes a random effect for cluster (community), a fixed effect that corresponds to the time interval of measurement (before or after the intervention), and an indicator of whether the measurement was made at baseline or after the intervention. This modeling approach will permit us to control for potential confounding variables, and the inclusion of interaction terms in our modeling will permit us to parse the relationships between the treatment, community, and asthma exacerbations.

2.7.2. Implementation data analysis plan

The Implementation process analysis (Reach, Adoption, Implementation, and Maintenance) plan includes a series of analyses. Data from a guideline-based care checklist, IHS patient records, and school-level fidelity checklists and student health records will be used to assess availability, promotion, and use of recommended asthma interventions (e.g., spirometry in clinics; Open Airways in Schools). The extent that children are seen in participating clinics and/or schools who receive guideline-based care and reduced asthma exacerbations and the consistency of intervention delivery across participating settings will be used to calculate two impact metrics [33,34]. *Child-level impact*: program reach includes change in quantitative outcomes (i.e., median effect size, or % experiencing decreased asthma exacerbations compared to control phase); *Setting-level impact*: adoption rate using the mean proportion of recommended asthma care components delivered [33]. *Setting-level maintenance potential* will be calculated, based on percentage of adopting clinics and schools instituting policies, training, performance measures and sufficient funding to continue the clinic and school programs beyond the study period. Calculation of the two impact metrics, plus setting-level maintenance, provides a means of quantifying and comparing different types of programs with each other, and across different settings, which is useful for making dissemination decisions [35].

Two types of qualitative data will be collected: 1) qualitative data from the family interviews (e.g., perceptions about home, school, healthcare, and environment that impact the child's health), and 2) discussions with community members (health and school boards, agency councils and chapter houses). For qualitative data capture, the number of families to be interviewed will be based on achieving concept saturation. Questions cover the key concepts of facilitators and barriers to implementation of the program, program satisfaction, and perception of quality of care across implementation sites.

2.7.3. Covid-19 pandemic

The COVID-19 pandemic brought forth several challenges to this study and several amendments to the original study protocol were proposed and subsequently approved by the Navajo Nation, IRB and NHLBI. When the Navajo Nation was placed on lock down in March 2020, barriers to completing the study tasks were experienced by our team. In order to complete the proposed tasks, our team amended the

study protocol to allow for training and data collection activities to continue remotely. First, we completed remote training for IHS clinicians located in Chinle, Arizona (e.g., the second study location). Second, we delayed training in the third community Ft. Defiance/Window Rock, until the COVID-19 pandemic was under control. This delay resulted in a request to NHLBI for a one-year no-cost extension. Third, we worked with our Navajo staff to change the family interviews from in-person data collection to remote data capture using telephone interviews. Study staff contacted enrolled families via telephone using the phone number on file in REDCap. Finally, we also conducted interviews to determine the impact of the COVID-19 pandemic on the families in our study. The findings of these family interviews have been previously published [36]. In order to maintain the relationships with families enrolled in the study, our staff offered supported and information from the health care facilities on how to take care of their child with asthma during the pandemic.

3. Discussion

Reducing childhood asthma disparities on the Navajo Nation remains an important public health priority. However, leveraging the expertise of the community remains integral to reducing asthma disparities historically and disproportionately experienced by Navajo children. To date, no partnership with researchers and the Navajo community has aimed at decreasing asthma disparities among Navajo children. A core tenant of the CAP focuses on community engagement and participation, building community capacity, incorporating evidenced-based guidelines and practices (or eliciting a westernized medicine approach) while ensuring intervention strategies actively involve Navajo community members during all steps of the intervention. The project's foundation and our team's approach was built from a year-long engagement strategy that allowed us to meet face-to-face with community members and leaders of the Navajo Nation, and to listen to the needs of each community and their concerns with childhood asthma. In an effort to better understand the unique needs of each community, while identifying and leveraging our partnerships with the community, our team focused on building upon existing community knowledge and resources. While these actions remain necessary with any intervention, approval from the NNHRRB would not have been feasible during the first grant year if we had not engaged with the community for an entire year prior to the funding cycle.

4. Additional limitations

One limitation with conducting implementation research in partnership with health care organizations and schools is the potential for individuals from within an organization to not adopt the program or intervention. Therefore, intervention activities must be supported and facilitated by leadership and those individuals who are involved with implementing the program. For example, healthcare workers (i.e., hospital administration, clinicians, nurses and respiratory therapists) may not be interested or have the adequate time to complete intervention activities in addition to their current job tasks. The same is held true for school personnel (i.e., school administrators, teachers and nurses) who were asked to complete additional trainings during the intervention year. To overcome these limitations, our study team focused on engaging with leadership teams at each health care facility and school to ensure staff were supported and given the appropriate time for completing intervention activities.

The step-wedge design inevitably allows for the CAP program to be received by all participating communities and not just those randomized to the intervention. Classical clinical trial designs do not always allow for the intervention to be received by all participants, but rather only allow participants randomized to the intervention to receive the full benefits of the intervention. Within the Navajo community, evidence-based guidelines that significantly improve asthma outcomes should

be received by all children impacted by the disease. A step wedge design motivates both community partners, research participants and clinicians to become involved in the study as to receive the full benefits of the intervention.

The ACIP being tested in this intervention builds strong evidence for improving asthma control and decreasing asthma disparities among Navajo children. Furthermore, the CAP program is the first randomized intervention to incorporate evidenced-based practices in partnership with the Navajo Nation. These interventions are highly scalable and the widespread expansion to other Navajo Nation agencies, and other First Nations tribes, and high asthma-burden populations remains feasible.

Significance for public health

The Community Asthma Program intervention leverages community engagement and participation, builds community capacity, incorporates evidenced-based guidelines and practices while ensuring program strategies actively involve Navajo community members during all steps of the intervention. To date, there have been no intervention studies directed specifically to pediatric asthma treatment on the Navajo Nation. This protocol describes the step-wedge trial design to ensure all communities involved receive the intervention. The outcome of this NHLBI-funded trial will allow us to determine the effectiveness of a multi-component, community-focused intervention to improve asthma disparities in a tribal community.

Author contribution statement

Study design and protocol: AAL, BS, PN, EB, AL, DK, JKG, HP, WM, BB, LBG. Wrote and or edited portions of this manuscript: AAL, BS, DK, BB, LBG. Provided critical feedback and revisions of final manuscript: AAL, BS, PN, EB, AL, DK, AK, TS, JKG, HP, WM, BB, LBG.

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Ethical approval

The study was approved by, and is proceeding under the regulatory oversight of the Navajo Nation Human Research Review Board (NNHRRB) and the National Jewish Health IRB.

ClinicalTrials.gov identifier

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Declaration of competing interest

All authors report no competing interests.

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