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ABBREVIATIONS AND DEFINITIONS OF TERMS

CAPP	Community Asthma Prevention Program
ED	Emergency Department (Admission)
IP	Inpatient Admission
CHW	Community Health Worker
EHR	Electronic Health Record
SC	Study Coordinator
PCP	Primary Care Provider
RA	Research Assistant
SBAT	School Based Asthma Therapy
EBI	Evidence Based Intervention
CBM	Center for Biomedical Informatics
HV	Home Visit
REDCap	Research Electronic Data Capture (Web-based Survey Platform)
NHLBI	The National Heart, Lung, and Blood Institute
DSMB	Data Safety Monitoring Board
DSMP	Data and Safety Monitoring Plan
FQHC	Federally Qualified Health Center
NIH	National Institutes of Health
PAMCOP	Pediatric and Adolescent Medicine Centers of Philadelphia

ABSTRACT

Context:

Childhood asthma is characterized by prominent, persistent and pervasive disparities. For instance, in addition to often cited disparities in specific health outcomes and global quality of life, students with asthma miss three times more school days than students without asthma with the highest proportion of missed days in low-income communities. To address asthma disparities in a patient-centered, sustainable manner, and consistent with a social ecological framework, one must intervene in all environmental contexts (i.e., home, school, healthcare system, community) of children with asthma. As a result of an assessment of local needs, resource mapping, and months of planning, an asthma care implementation program has been developed with the broad objective of integrating home, school, healthcare system, and community for school-aged asthmatic children in West Philadelphia.

Objective: To determine if the utilization of CHWs in a comprehensive community-based intervention to connect home, school, healthcare system and community for low-income minority school-aged asthmatic children and their caregivers improves asthma control and thereby reduces asthma disparities for this community.

Study Design: Randomized controlled trial

Setting/Participants:

640 asthmatic children (ages 5-13 years) will be recruited from CHOP Care Network sites (Cobbs Creek, Karabots, and South Philadelphia), CHOP ED, The Pediatric and Adolescent Medicine Centers of Philadelphia, Federally Qualified Health Centers and by community referral.

Other sites of intervention include: All School District of Philadelphia public elementary schools located in West Philadelphia will be invited to participate. Several public charter elementary schools in West Philadelphia some of which are served by school-based health centers managed by Education Plus, Inc. d/b/a Education Plus Health will also be invited to participate for a total of no greater than 40 elementary schools.

Study Interventions and Measures:

Interventions taking place at school, home and in the primary care setting to improve asthma control and reduce symptom days evaluated using main and simple effects from the factorial design.

PROTOCOL SYNOPSIS

Study Title	West Philadelphia Asthma Care Implementation Plan
Funder	NIH
Clinical Phase	Implementation Phase
Study Rationale	<p>The overall purpose of care coordination is to identify and engage families in development of a care plan that links clinical, psychosocial and other services in order to provide best care to the child with asthma. It is essential that care coordination emphasizes the central role of the health of the child while recognizing family concerns and identifying strengths and gaps in care. In care coordination, it is important to establish and support a continuous relationship with clinical caregivers as well as empower families to advocate for their needs and satisfaction.</p> <p>Through a combination of asthma management interventions for children including, Yes We Can™ Children's Asthma Program, School Based Asthma Therapy, and the American Lung Association's Open Airways For Schools®, utilizing CHWs as the connectors, families of children with asthma will receive services of a trained and knowledgeable liaison to proactively support the delivery of evidence based care and follow-up in the primary care office, school and at home.</p>
Study Objective(s)	<p>Primary</p> <p>To improve asthma control through the use of Community Health Workers that provide a network of education and care coordination support, and to facilitate communication for families of children with asthma in West Philadelphia by integrating home, school, healthcare system, and community for school-aged asthmatic children in West Philadelphia.</p> <p>Secondary</p> <p>To reduce asthma symptom days and school absences through the use of CHWs, evaluate cost-effectiveness of study interventions, and to investigate moderators of intervention effectiveness to identify subgroups of children that may be more likely to benefit from the study interventions.</p>
Test Article(s) <i>(If Applicable)</i>	N/A
Study Design	Randomized controlled trial

Subject Population key criteria for Inclusion and Exclusion:	<p>Inclusion Criteria</p> <ol style="list-style-type: none"> 1. Parents (guardians) and their children ages 5-13 years 2. Children with diagnosis of asthma 3. Uncontrolled Asthma (as evidenced by one or more asthma exacerbations requiring oral steroids within the past year, two ED visits for asthma or one inpatient admission for asthma within the past year) 4. Reside in one of the seven West Philadelphia zip codes: 19104, 19131, 19139, 19142, 19143, 19151, 19153 5. Enrolled in elementary school 6. Receive primary care at CHOP Care Network sites (Cobbs Creek, Karabots, and South Philadelphia), The Pediatric and Adolescent Medicine Centers of Philadelphia (PAMCOP) or a Federally Qualified Health Center (FQHC) in West Philadelphia 7. Parental/guardian permission (informed consent and if appropriate, child assent) 8. English speaker <p>Exclusion Criteria</p> <ol style="list-style-type: none"> 1. Children with other chronic respiratory illnesses such as cystic fibrosis 2. Cyanotic congenital heart disease 3. MRCP-Mental retardation and/or cerebral palsy 4. Severe Neurological Disorder 5. Parents/guardians or children who, in the opinion of the Investigator, is likely to be non-compliant with study schedules or procedures. 6. Children who do not live in West Philadelphia (zip codes: 19104, 19131, 19139, 19142, 19143, 19151, 19153)
Number Of Subjects	<p>640 patients will be recruited from CHOP Care Network sites, a private pediatrician office, Federally Qualified Health Centers (FQHCs), CHOP ED and by community referral.</p> <p>Sites Include:</p> <ul style="list-style-type: none"> • CHOP Care Network sites: Cobbs Creek, Karabots and South Philadelphia • CHOP Emergency Department • Federally Qualified Health Centers (FQHCs) serving West Philadelphia residents • The Pediatric and Adolescent Medicine Centers of Philadelphia (PAMCOP) serving West Philadelphia residents

	<ul style="list-style-type: none"> • School District of Philadelphia Public Elementary Schools located in West Philadelphia (including Southwest Philadelphia) who agree to participate • Public Charter Schools located in West Philadelphia (including Southwest Philadelphia) who agree to participate
Study Duration	Active subject participation will last up to 24 months; Medical record review will continue for up to two years from the 12-month follow-up visit or until the data collection period for the study has ended, whichever occurs first. This study is expected to be conducted over six years.
Study Phases	Screening Study Intervention Study Follow-up
Efficacy Evaluations	Obtain baseline and follow-up measurements of asthma control, symptoms, patient and caregiver asthma knowledge, presence of environmental triggers, school and work day absenteeism, and healthcare utilization
Safety Evaluations	Adverse event reports will be collected at each visit. These reports will be reviewed at weekly meetings by the PI to determine if they are a result of the study. A DSMB has been appointed by the funding sponsor to oversee safety of the interventions.
Statistical And Analytic Plan	Analysis to be conducted by biostatisticians at the University of Pennsylvania and data managers at the Biostatistics and Data Management Core at CHOP
DATA AND SAFETY MONITORING PLAN	The PI will be responsible for the study's Data and Safety Monitoring Plan with oversight provided by a DSMB appointed by the NIH.

TABLE 1: SCHEDULE OF STUDY PROCEDURES[illegible]

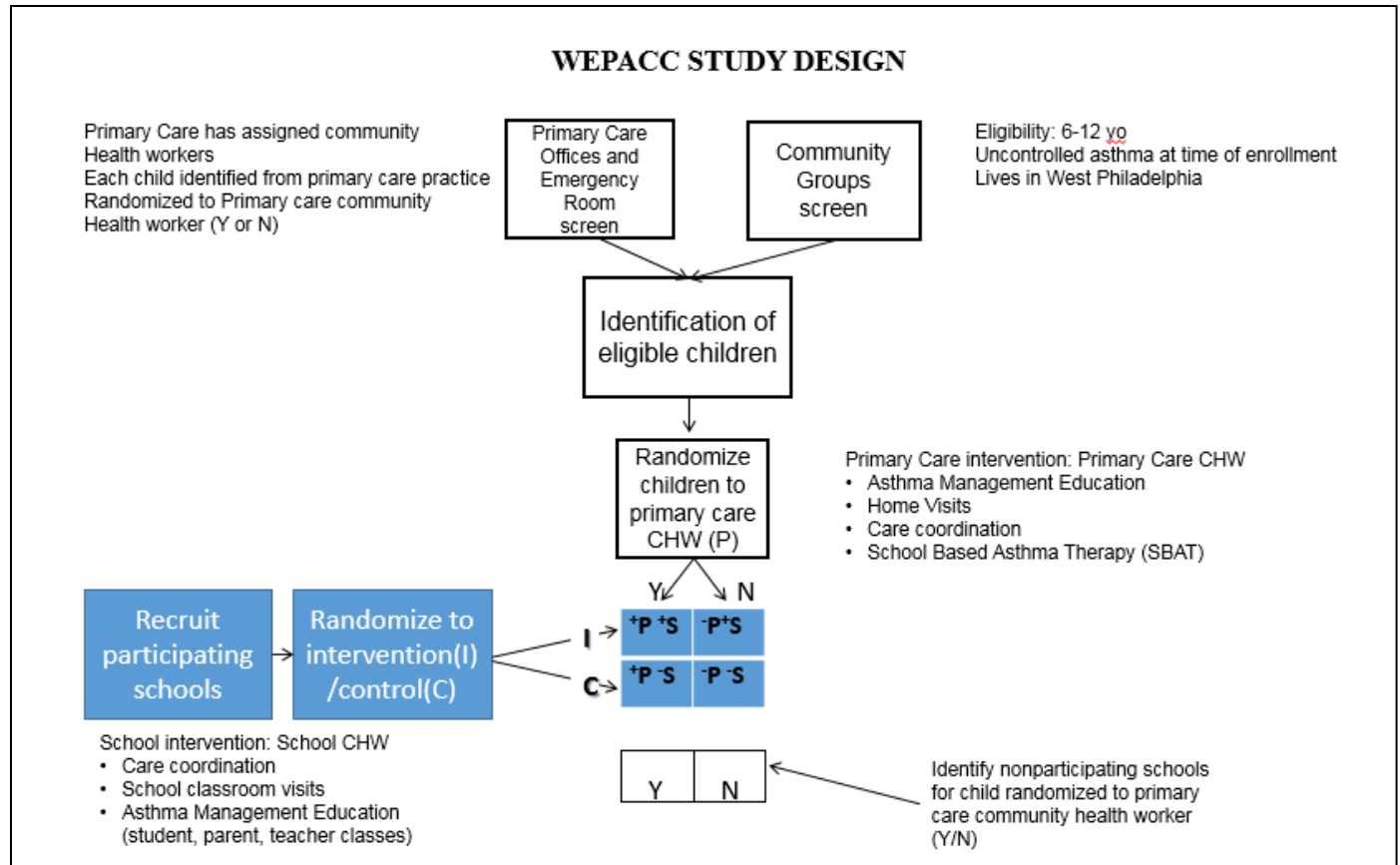
FIGURE 1: WEPACC MODEL STUDY DESIGN

FIGURE 2: LOGIC MODEL FOR STUDY DESIGN

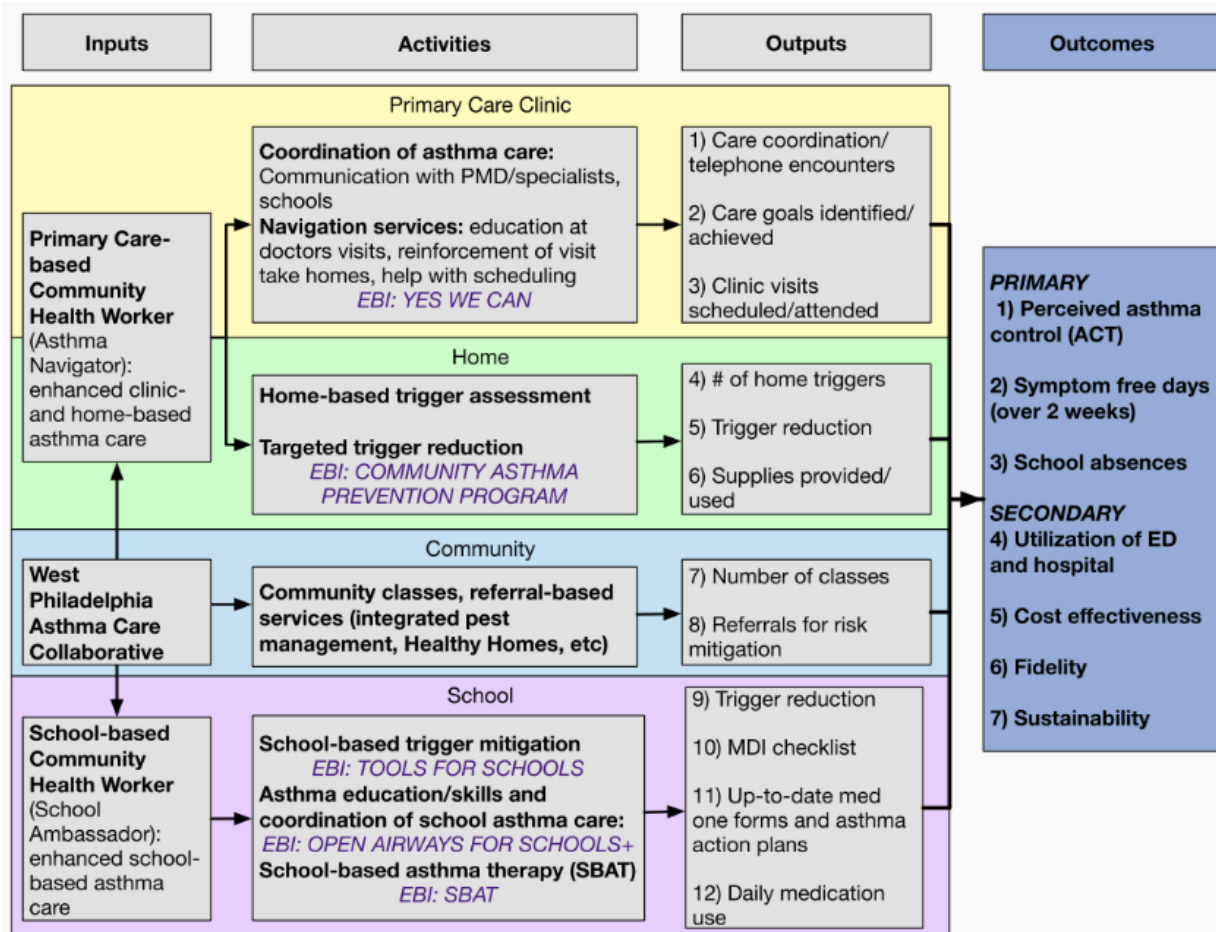
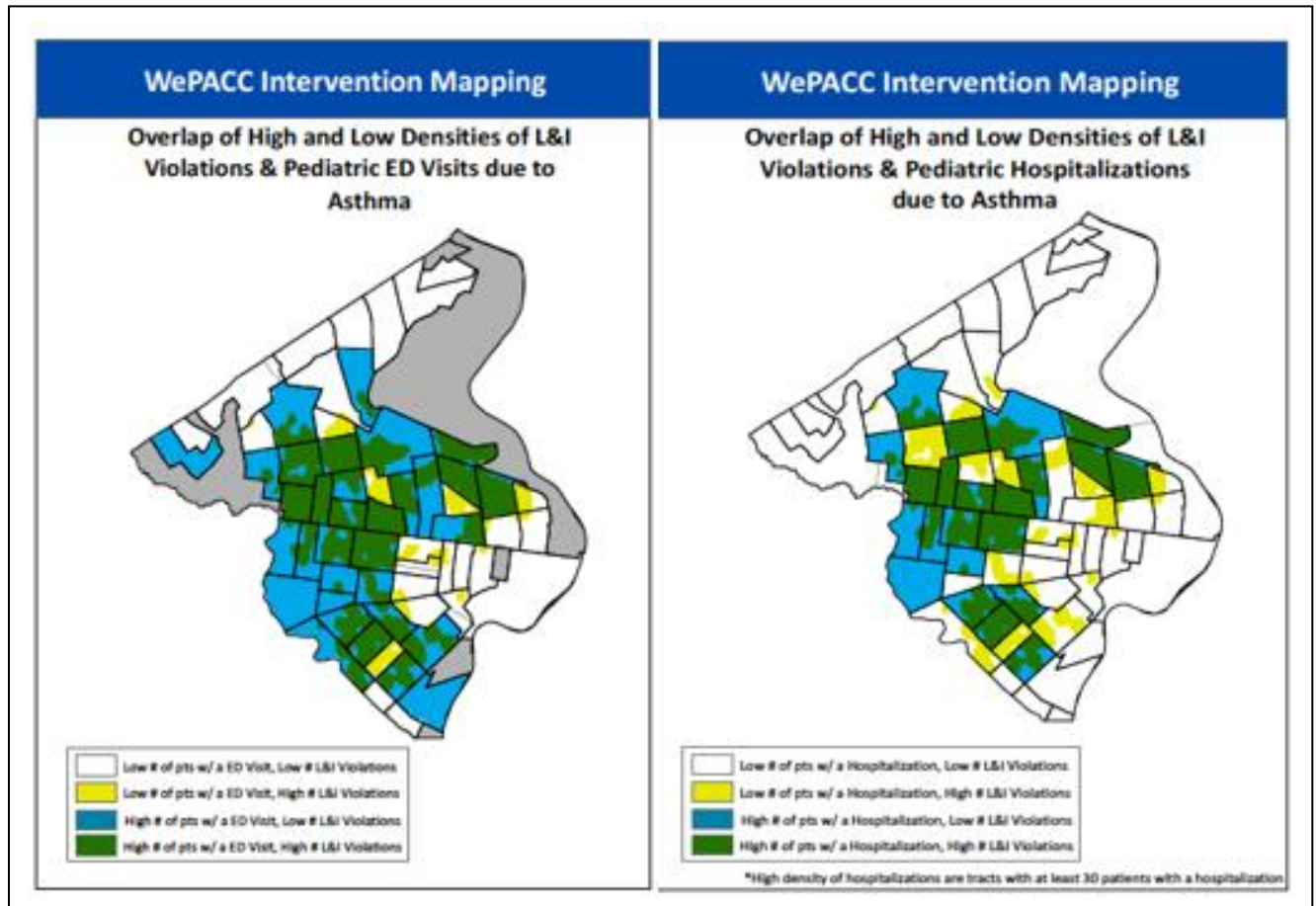


FIGURE 3: RISK MAPPING

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Childhood asthma is characterized by prominent, persistent and pervasive disparities. For instance, in addition to often cited disparities in specific health outcomes and global quality of life¹⁻⁴, students with asthma miss three times more school days than students without asthma, with the highest proportion of missed school days in low-income communities⁵. To address asthma disparities in a patient-centered, sustainable manner, and consistent with an ecological framework, one must intervene in all environmental contexts (i.e., home, school, healthcare system, community) of children with asthma. Previous studies demonstrate that community health workers (CHWs) can effectively deliver evidence-based care coordination, environmental mitigation, and asthma education interventions in specific settings⁶⁻⁸. However, this work has not been delivered in an integrative manner to connect settings. Utilization of CHWs in a comprehensive community-based intervention to connect home, school, healthcare system and community for school-aged asthmatic children and their caregivers may eliminate asthma disparities.

The Community Asthma Prevention Program (CAPP) has a two decade history of utilizing CHWs to improve asthma outcomes of children in Philadelphia^{9,10}. Over ten members of inner-city Philadelphia have been trained and employed as CHWs to effectively provide home asthma education and environmental mitigation for children who have asthma-related ED or hospital visits. Building on this foundation, we established a network of stakeholders, The West Philadelphia Asthma Care Collaborative (WEPACC), with representation from public housing, healthcare, community, and schools. As a result of local needs assessment, resource mapping, and months of planning, we designed an asthma care implementation program with the broad objective of integrating home, school, healthcare system, and community for school-aged asthmatic children in West Philadelphia. We will accomplish this goal using CHWs to deliver sustainable patient-centered evidence-based interventions. The evidence-based interventions include (1) a primary care-based Yes We Can™ Children's Asthma Program with home visitation and (2) a comprehensive and rigorously evaluated school-based intervention, Open Airways For Schools® and (3) School Based Asthma Therapy¹¹⁻¹³. CHWs will function as the hub of each intervention, serving either as primary care CHWs or school CHWs to provide a network of education, care coordination support, and to facilitate communication for families of children with asthma between the four sectors. If proven effective, this care coordination program will assist caregivers in assessing resources, improving self-management skills and ultimately reducing asthma-related ED visits and hospitalizations.

In the face of best asthma practices, quality of care is also affected by communication between patients and providers, particularly across cultures. When people of color access routine care, physicians are often unknowingly biased in their care. This may partially be explained by different styles of communicating between providers and patients, different belief systems and unfamiliarity with the patient/caregivers social stressors which affect their ability to be adherent with treatment. Giving the caregiver a central health liaison who is also a resident in the community such as the CHW, will help to bridge communication gaps between caregiver and clinician, identify belief systems and enable caregivers to deal with social stressors.

Another example of current system limitations is that of our own CAPP program. Although many have benefited from these programs, high risk families need a higher intensity of service beyond the type of home visiting program CAPP provides which is focused on health education and environmental mitigation in the home without making a formal connection to health care and schools.

Strunk and colleagues found that diverse ethnic and racial minorities experienced disparities in access to asthma care that lead to greater morbidity and mortality¹⁴. Absence of regular care for urban African American children results in increased morbidity for chronic diseases like asthma. Urban children have more difficulty with self-management of their asthma for various reasons, which include poverty, stresses related to living in an urban environment, lack of knowledge about asthma and lack of family and community support. Many studies reveal that asthma education is effective in reducing emergency department visits, hospitalizations and lost days of work. Improving access to care not only involves changing the structure of health care delivery, but also involves addressing educational needs, psychological issues, and cultural beliefs and practices in developing interventions to improve access to care.

Community Needs Assessment. In order to understand the impact of asthma in West Philadelphia, our needs assessment included both qualitative inquiry (i.e., focus groups and interviews) as well as identification of key local, regional and national data sources for secondary data analysis conducted by Philadelphia Health Management Corporation (PHMC) under the guidance of WEPACC. Knowledge of the neighborhoods relevant to WEPACC informed our intervention planning and implementation.

Results from secondary analysis of data. Population. West Philadelphia (zip codes 19104, 19131, 19139, 19143, and 19151) has 233,000 residents, including 49,000 ages 0-17. Seventy-four percent of West Philadelphia residents identify as Black/African American. Thirty-two percent of children live below the federal poverty level, 98% of children have health insurance, and 100% of parents reported their child receives regular healthcare¹⁵. This high access to healthcare suggests that an intervention involving partnerships with healthcare providers has the potential to reduce the impact of asthma in West Philadelphia. Twenty-five percent of the children in these zip codes have asthma¹⁶. CHOP is the primary source of pediatric emergency and hospital care for West Philadelphia and provides primary care for over 40,000 children in West Philadelphia.

Utilization. 1,353 children residing in West Philadelphia were hospitalized for asthma, and 3,186 children were admitted to CHOP's emergency room for asthma in 2014-2015¹⁷. The concentration of hospitalizations and emergency room discharges is relatively consistent across West Philadelphia. Notably, the WEPACC pilot zone, outlined on both maps, is interior to the overall WEPACC ZIP codes, and contains census tracts with both high numbers of asthma hospitalizations and ED discharges.

Community Resources. Community assets were mapped to inform the design of the intervention with input from WEPACC stakeholders.

Risk Factors. Since poor housing conditions are associated with asthma morbidity, we mapped housing code violations and overlapped them with CHOP

hospitalization/emergency room data to determine areas of highest risk. The resulting map revealed that the highest risk areas centered around three primary care centers which are the sites of enrollment for our study (Figure 3).

Qualitative Assessment. Under the guidance of the West Philadelphia Asthma Care Collaborative (WEPACC), Philadelphia Health Management Corporation (PHMC) collected qualitative data from focus groups and key informant interviews in order to assess the needs of children with asthma in West Philadelphia. A total of five focus groups were convened between November 2015 and April 2016. Three groups consisted of parents of children with asthma (n=24), one group with children with asthma (n=7), and one group with school nurses (n= 7). A total of seven key informant (KI) interviews were conducted between May 2016 and July 2016. Participants included parents of children with asthma, health care providers, and an insurance company representative. Needs and concerns were identified from all environmental contexts, home, school, healthcare system, and community. Home concerns included landlord unresponsiveness, difficulty with controlling triggers such as second hand smoke exposure and mold, parental mental health issues, children living in multiple homes, and difficulty using medication. School nurse concerns included the lack of full time nurses, lack of asthma education, poor communication, indoor triggers in the school, missed school days due to asthma, and incomplete med-1 forms. Healthcare concerns were of lack of understanding about asthma, poor communication between parent and provider, missed appointments, medication use and controlling child's asthma. Lastly, lack of awareness about asthma, uncontrollable outdoor triggers like air pollution and secondhand smoke were identified as major concerns in the community setting.

Piloting the school intervention. As we conducted the needs assessment, we also began developing our plan for implementation strategies, or the “how” of implementation (i.e., the active methods to increase adoption, implementation and sustainment of evidence-based intervention)¹⁸. Intervention mapping is a systematic process for developing interventions to inform implementation strategies that comes out of a participatory design approach¹⁹. Mapping has been used to develop a number of effective health-related programs, including those addressing sex education, obesity, and cancer prevention²⁰⁻²². We applied mapping to the development of the implementation strategies to be used to implement school-based asthma care.

CHOP Care Network Cobbs Creek, Karabots and South Philadelphia locations each employ a CHW who conduct care coordination and home visits. However, these three CHWs are not able to serve all persistent asthmatics in the practice and do not connect directly with schools to coordinate care for children with asthma. Since our needs assessment revealed caregiver and school nurse concerns regarding asthma management in schools, we focused our pilot on enhancing the connection of CHWs to a local elementary school in order to explore challenges and opportunities for CHWs in elementary school. Thus we piloted the feasibility of a CHW coordinating school asthma care for seven students receiving primary care through CHOP CN Cobbs Creek. After obtaining consent from the parents, the CHW worked directly with the school nurse, principal, and teacher in order to implement elements of the school intervention to improve communication between caregiver, clinical team and school. The CHW enrolled patients at CHOP CN Cobbs Creek and then coordinated with the primary care physician completion of all necessary forms and appropriate

medication/device orders. Despite initial challenges, such as incomplete forms, poor communication between caregiver and nurse, no medications on site, our CHW was able to complete the initial intervention for all 7 children within three weeks of enrollment. Subsequent key informant interviews with the caregivers, school nurse and CHW were overall positive with caregivers and school nurses appreciative of the role of the CHW who coordinated with caregiver and school nurse to make sure that the school had forms, medication and devices needed to provide asthma care for enrolled students. With this success we believe our study design to put CHWs in each of the intervention schools is feasible and the best option for closing gaps and connecting asthma care for school-aged children.

1.2 Relevant Literature and Data

CHWs can improve outcomes for chronic diseases including asthma. Community Health Workers integrated into the health team is supported by the Affordable Care Act²³. As community residents they are uniquely situated in the community and public health and can serve as the connectors between the two²⁴. In the primary care setting, community health workers (CHWs) can enhance the three principles of the medical home: whole person orientation, care coordination, and quality and safety by (1) ensuring that the caregiver's voice is heard regarding asthma, medications, and stressors,^{25–27} 2) creating opportunities for the caregiver to “teach back” 3) facilitating communication between the caregiver and primary care provider/specialist, and 4) helping caregivers make and reach goals for asthma management^{28–30}. Primary care-based CHWs can promote adherence to asthma guidelines for asthma control, care plan completion and spirometry. CHWs can also facilitate communications when caregivers encounter barriers to scheduling and obtaining medications and devices, or need advocacy for psychosocial issues^{31–33}. In addition CHWs delivering multi-component trigger reduction interventions effectively improve asthma symptoms³⁴. CHW delivered asthma classes in schools have resulted in improved asthma knowledge and self-management skills^{35,36}.

There is great potential for CHWs to connect the four sectors where children live. The potential synergistic strength of integrating interventions across multiple sectors (home, school, community, healthcare system) has not been fully leveraged despite knowledge that multi-level interventions are most effective³⁴. Currently asthma evidence-based interventions (EBI) are routinely implemented in either the home, school, or primary care setting. Even when caregivers of poor children are engaged in asthma interventions in one setting, they often have to navigate challenges in another setting, such as an under-resourced home, non-supportive school, or disengaged health care provider. In one study a comprehensive school management program to promote care coordination and better asthma management conducted by school nurses did not succeed because it placed additional responsibilities on the school nurse and there was no buy in from the primary care practice³⁷. CHWs providing the connection between the home, school and primary care practice may reduce the burden on caregivers and facilitate asthma management for school-aged children. Further, CHWs, as community residents, are knowledgeable about the public school system and can help parents connect to local resources. CHWs potentially provide the missing link to coordinate between multiple sectors to optimize interventions³⁶.

Asthma-trained community health workers have the potential to ensure that caregivers make and keep follow-up appointments post ED visits by conducting periodic telephone assessments. They are invariably equipped with asthma educational knowledge and resources that would be an invaluable asset to patients and their families. Not only are they trained in the nature of the disease, but they are often members of the same communities as patients and families, giving them an advantage on building bridges and establishing relationships between the family and primary care office.

1.3 Compliance Statement

This study will be conducted in full accordance all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

2.1 Primary Aim

The primary aim of this study is to compare effectiveness of the primary care and school interventions to improve asthma control using main and simple effects from the factorial design.

- *Specific Aim 1a.* Compare the main effects of primary care CHW and school CHW intervention to control group.
- *Specific Aim 1b.* Compare the differences between children outcomes who receive both interventions (primary care AND school) to only one intervention (primary care OR school).
- *Specific Aim 1c.* Compare each of the active interventions groups (primary care, school, combination) to control.

2.2 Secondary Aims

The secondary aim of this study is to explore moderators and mechanisms of effectiveness of the interventions.

- *Specific Aim 2a.* Investigate moderators of intervention effectiveness outcomes to identify subgroups of children that may be more likely to benefit from the study interventions.
 - *Specific Aim 2b.* Investigate mechanisms of the effect of the intervention, i.e. linkage of communications between school and primary care CHWs and daily participation in school-based asthma therapy, on asthma control, reduced symptom days, and decreased school absences.
-

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

A factorial design will be used to understand the effectiveness of primary care and school CHWs in the implementation of Evidence Based Interventions (EBI) Yes We Can™ Children's Asthma Program in the primary care setting, and Open Airways For Schools® and school-based asthma therapy in the school setting. West Philadelphia children with uncontrolled asthma will be recruited in the Emergency Department or primary care clinic and randomized to a primary care CHW (P+) or usual care (P-), and identified as being in a participating school that has been randomized to a CHW-led school intervention (S+) or none (S-). This study design demonstrates how each sector will be involved in this comprehensive implementation plan. The primary outcomes is asthma control. Secondary outcomes include symptom free days, school absences, hospital and emergency room utilization and cost savings.

This will be a randomized controlled clinical trial of children diagnosed with asthma, ages 5-13 years old randomized after consenting to primary care CHW (P+) or no primary care CHW (P). In the Primary Care Based CHW arm (P+) the CHW will provide one-on-one asthma education in the office and home, environmental trigger mitigation in the home, assistance in identifying care coordination goals with linkages to resources to address barriers and will facilitate communication between the health care provider and the family. The intervention group (P+) will have a total of four visits to the primary care office where they will receive asthma self-management education in the office, review of medications, asthma control assessment, pulmonary function assessment and care coordination. They will receive three intervention home visits where the CHW will reinforce asthma self-management skills, assess the home environment for asthma triggers, provide supplies for environmental remediation and educate caregiver regarding asthma trigger avoidance techniques. This arm will also be eligible for school based direct observed asthma treatment called school-based asthma therapy (SBAT). At twelve months the intervention group will receive an end of study assessment in the primary care office and in the home. The control group will not receive any of the aforementioned services for one year after enrollment. They will be referred to community asthma classes administered by CAPP. After one year the control group will receive one home visit at which time they will receive an environmental home assessment and environmental remediation supplies.

Children in both arms (P+ and P-) may attend an intervention school. Roughly 30 elementary schools have been identified by the School District of Philadelphia to participate in this project. Several public charter schools including three public charter schools served by school-based health centers managed by Education Plus Health have been identified to participate in this study. One half of the schools (S+) will be randomized to receive **Open Airways for Schools Plus** designed by Clark, et. al., an EBI asthma education and care coordination model for schools, and School Based Asthma Therapy (directly observed controller medication use).¹¹ The remaining half of the identified schools (S-) will be offered training on how to implement the two evidence-based programs in years 4 and 5 of the project.

3.1.1 Screening Phase

We will screen electronic health records to recruit 640 children ages 5-13 years old with uncontrolled asthma (evidenced by one or more asthma exacerbations requiring oral steroids within the past year -OR- two ED visits for asthma within the past year -OR- one hospitalization for asthma within the past year) from several primary care centers (CHOP Care Network – Cobbs Creek, CHOP Care Network - Karabots, CHOP Care Network – South Philadelphia, The Pediatric and Adolescent Medicine Centers of Philadelphia (PAMCOP) and Federally Qualified Health Centers) who live in seven West Philadelphia ZIP codes (19104, 19131, 19139, 19142, 19143, 19151, 19153). In addition, CHOP Emergency Department (ED) will screen and refer children for enrollment when they are seen in the ED. Community partners will also refer children at community events. All screening surveys will be faxed to a confidential fax line and caregivers of all referred patients will be asked if they would like to be screened for study eligibility and participation.

Participants that both meet eligibility criteria and are interested in participation, will be consented/assented using a CHOP IRB reviewed consent form prior to participation in the study. The parent/guardian and the child will have 10 minutes or greater to review the consent form and ask any questions about participation.

3.1.2 Primary Care Based Intervention

Children who are randomized to the primary care arm will be assigned a primary care community health worker (CHW). We will implement the *Yes We Can*TM Children's Asthma Program¹² intervention which is a medical-social model based on a chronic care approach, including risk stratification, clinical care management, social care coordination by a community health worker, and primary care asthma champions. This intervention includes asthma education and trigger reduction visits and care coordination. There will be five clinic visits and four home visits over 12 months implemented by the *primary care CHW* who is integrated into the practice.

Study Visit 1 (primary care office): Once consented and randomized, the CHW will collect baseline data (study questionnaires, weight, height, spirometry), administer a caregiver needs assessment and assist caregiver in choosing 2-3 care coordination goals such as keeping appointments, reduce secondhand smoke exposure or using medications correctly. The CHW will conduct in-office asthma teaching (medications/devices/asthma care plan), coordinate specialist visits and assist caregivers in voicing questions/concerns about medications or treatment plans to the primary care provider. They will personally schedule patients for follow-up visits with the primary care provider. Home Visits 1, 2 and 3: The first three home visits will occur within 2, 4 and 6 weeks after enrollment. At the first visit the CHW will conduct an environmental assessment of the living area and bedroom for common asthma triggers. Based on those findings the CHW will educate regarding asthma trigger avoidance and give supplies to reduce those triggers (mattress and pillow covers, roach bait, mice traps, tiles for carpeted floors) at the second visit. The CHW will also review medications available for the child at home and whether forms/prescriptions have been completed for school. They will coordinate with the primary care team as needed. Video conferencing through a HIPAA-compliant application licensed by CHOP, including but not limited to Vidyo telehealth visits in MyCHOP, may be used for home

visits that cannot be conducted in person due to health or safety concerns. For telehealth home visits, supplies will be provided to families via U.S. postal mail with caregivers providing confirmation of receipt. Study Visits 2, 3, and 4 (primary care) will occur at 3, 6, and 9 months post-randomization. At these visits, the participants will receive asthma maintenance care by the provider/clinician and pulmonary function testing (spirometry) in addition to the education and care coordination activities by the CHW as described in the first visit. A member of the research team other than the assigned CHW (Home Visitor) will administer study questionnaires at these visits. At Home Visit 4 at 12 months post-randomization the CHW will conduct an environmental assessment to document trigger reduction techniques in the home and review medications. At Study Visit 5 at 12 months post-randomization, the asthma control questionnaire (ACQ)³⁸, additional study questionnaires, pulmonary function testing (spirometry) and care coordination goals will be completed. Study staff will administer a CHW satisfaction survey via telephone between 13 and 24 months post-randomization once all primary care and school interventions have been completed.

3.1.3 School Based Intervention

West Philadelphia elementary schools who have agreed to participate will be randomized to either receive the school intervention facilitated by a school CHW or usual school care (no intervention). Intervention schools will receive **Open Airways for Schools *Plus*** designed by Clark, et. al. to improve the disease management skills of children with asthma and enhance control of asthma in the school¹¹. It contains four “essential components” of the recently published School-based Asthma Management Program (SAMPRO) summit guidelines and has been found to decrease both asthma symptom days and school absences³⁹⁻⁴¹. The school intervention includes: (1) **Open Airways for Schools®** curriculum for all children with asthma. One class series will be conducted by the school CHW each semester. (2) Orientation to asthma and control strategies for principals and school personnel at the start of each school year led by the study team along with the school CHW, (3) For School District of Philadelphia public schools, walk-throughs for custodial personnel to address potential environmental asthma triggers. This will be managed and conducted by school district personnel, and (4) Assistance with obtaining asthma care plans and medication administration forms from primary care provider offices facilitated by the school CHW.

For participants assigned to both interventions, the school and primary care CHWs will collaborate to coordinate care across the school nurse and primary care offices. In addition to the primary care and school interventions above, this treatment group will receive enhanced coordination with **School-Based Asthma Therapy** for prescribed daily controller medication⁴². The primary care CHW will obtain a copy of the current asthma care plan, school medication administration form, a rescue inhaler prescription for school, and an asthma controller medication prescription to conduct school based asthma therapy. Prescriptions for rescue inhalers and asthma controller medications will be dispensed before the child leaves the primary care office. Depending on the participant’s health insurance coverage the prescriptions may be filled using an automated medication dispensing system (mobile pharmacy) at Cobbs Creek, Karabots, and South Philadelphia CHOP primary care practices or through an internal pharmacy at a Federally Qualified Health Center. Primary care CHWs will deliver current asthma care plans, medication administration forms, rescue

inhalers (if applicable), and asthma controller medications (if applicable) directly to School CHWs at weekly team meetings. School CHWs will deliver these items to the school nurse to file/store in a designated location in the school nurse's office. The school nurse and/or School CHW will coordinate with teachers to schedule an intake appointment for children receiving school based asthma therapy at which the nurse will complete a metered dose inhaler (MDI) checklist with the child to assess ability to self-administer medications and to schedule a time for the child to return to the office for daily medication administration. Medication use (both rescue and controller) will be recorded by the school nurse or school CHW⁴². If nurse is not present, as per usual school protocol, the principal will be responsible for assigning this task. For this treatment group, asthma management skills will be reinforced at home, school and in the primary care office.

Families of children who are not randomized to the primary care intervention will be offered Community Asthma Prevention Program (CAPP) asthma classes, conducted at community sites, which are available to the general public. Data will be collected from the control arm at 3, 6, 9 months by phone or in person. At 12 months an office visit will be scheduled, pulmonary function testing (spirometry) performed and end-of-study data collected. After completing the study these patients will receive one home visit from a primary care CHW to complete an asthma trigger assessment and distribute asthma trigger reduction supplies.

Schools who are not randomized to intervention arm will be offered training after the study data collection period has ended and during the last year of grant funding in how to implement the school asthma interventions and will be provided with information on how to sustain these interventions by obtaining reimbursement from health insurance companies for school CHW services.

During the COVID-19 pandemic, the study activities detailed above will be modified as follows to preserve the health and safety of participants, healthcare professionals, study staff and the West Philadelphia community. Data collection for study visits may take place remotely by telephone or video conference using a HIPAA-compliant application licensed by CHOP. In person clinic visits solely for study purposes will take place as permitted by CHOP Research Institute Policy and Guidelines. Study activities designed to take place in a school setting may take place remotely by telephone or video conference using a HIPAA-compliant application licensed by CHOP.

Asthma control is the primary outcome of this study. Symptom-free days, and school absences are secondary outcomes in this study. Asthma control has been cited by the NAEPP guidelines and asthma outcomes workshop as an important goal for prevention of asthma morbidity. In several studies, poor asthma control, whether defined by the patient (using self-reported, validated instruments) or by national asthma guideline classifications, has been strongly associated with an increased risk of asthma exacerbations which may lead to emergency room visits, hospitalizations and even death^{43,44}. Asthma control will be measured using Juniper's Asthma Control Questionnaire, a validated instrument for children and adults³⁸. Symptom-free days will be based on parental report recall of the last two weeks, consistent with previous studies^{45,46}. School absences will be measured by school and parental report. Additional secondary outcomes will include asthma-related emergency

visits and hospital visits (obtained from CHOP EHR), and cost-savings. Moderator variables will be measured using the CARAT survey which is a **Child Asthma Risk Assessment Tool** designed to help clinicians, asthma counselors and parents determine potential risks for children with asthma^{47,48}.

Data will be collected for all individually randomized participants at baseline, 3, 6, 9 and 12 months by a member of the research team in person or by phone. Participants will be compensated \$25 for each visit with data collection at baseline, 3, 6, and 9 months and \$45 for the end of study visit at 12 months.

3.2 Allocation to Treatment Groups and Blinding

The overall design will randomize participating schools to the school intervention (S+) or usual care (S-) based on predefined strata (defined by size, location, public school or public charter school status, etc.) to enhance balance. When children with uncontrolled asthma and their caregivers present in the primary care offices and provide consent to participate, these patients will be randomized either to a primary care CHW (child-level intervention) (P+) or usual care (P-), and this randomization will be stratified by the child's current elementary school and clinic of recruitment to ensure balanced assignment in the factorial design.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

The study duration per subject will be up to 24 months, if participant has not completed the assigned study interventions within the first 12 months of participation.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted at approximately six healthcare sites, including CHOP primary care sites (Cobbs Creek, Karabots and South Philadelphia), CHOP ED and approximately two Federally Qualified Health Centers serving West Philadelphia, and no greater than 40 elementary schools according to the number of schools agreeing to participate. This includes as many as 30 public schools and as many as ten public charter schools located in the West Philadelphia area.

Recruitment will stop when 640 subjects are enrolled. It is expected that at least 600 children will be evaluable subjects.

3.4 Study Population.

3.4.1 Inclusion Criteria

1) Parents (guardians) and their children ages 5-13 years

- Children will include those who:

- a) Have a diagnosis of asthma
 - b) Have uncontrolled Asthma (as evidenced by one or more asthma exacerbations requiring oral steroids within the past year -OR- 2 ED visits for
-

asthma within the past year -OR- 1 inpatient admission for asthma within the past year).

- c) Reside in one of seven West Philadelphia zip codes:(19104, 19131, 19139, 19142, 19143, 19151, 19153)
- d) Are enrolled in elementary school
- e) Are patients at primary care provider practices at CHOP CN Cobbs Creek, CHOP CN Karabots, CHOP CN South Philadelphia, PAMCOP or a Federally Qualified Health Center serving West Philadelphia residents.

2) Parental/guardian permission (informed consent) and if appropriate, child assent.

3) English Speaker

3.4.2 Exclusion Criteria

- 1) Subjects with other chronic respiratory illnesses such as cystic fibrosis
- 2) Cyanotic congenital heart disease
- 3) MRCP-Mental retardation and/or cerebral palsy
- 4) Severe Neurological Disorder
- 5) Cyanotic congenital heart disease
- 6) Parents/guardians or subjects who, in the opinion of the Investigator, may be non-compliant with study schedules or procedures.
- 7) Those who do not live in West Philadelphia (zip codes: 19104, 19131, 19139, 19142, 19143, 19151, 19153)

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Screening Visit

- Medical Record Review of the child
- Verbal consent/complete eligibility screening
- Identify child's elementary school
- Schedule first visit

4.2 Study Treatment Phase

4.2.1 Study Visit 1 (Enrollment)

All study participants will complete the following:

- Consent/Assent
- Baseline Questionnaire
- Clinical and vital sign measurements of child [weight, height, BMI, blood pressure, pulse, temperature, pulse oximetry (SpO2)]
- Pulmonary function test (spirometry) with child if not obtained from medical record
- 2-week parental recall of symptoms, school absences, and work days missed
- Asthma Control Questionnaire
- Child Asthma Risk Assessment Tool (CARAT)
- Caregiver's Quality of Life Questionnaire
- Caregiver Needs Assessment
- Cost Analysis Parent Questionnaire
- Observe MDI technique and complete MDI Checklist
- Assess possible adverse events from date of enrollment

4.2.2 Study Visits 2, 3, and 4 (Primary Care Office Visits)

Primary Care office visits will be scheduled for 3, 6 and 9 months post study enrollment. All study participants will complete the following:

- Asthma Control Questionnaire
- Clinical and vital sign measurements of child [weight, height, BMI, blood pressure, pulse, temperature, pulse oximetry (SpO2)]
- Pulmonary function test (spirometry) with child if not obtained from medical record.
- 2-week parental recall of symptoms, school absences, and work days missed
- Cost Analysis Parent Questionnaire
- Assess possible adverse events
- Review child's medical record for utilization of healthcare services
- Review care coordination goals and direct to community resources

4.2.3 Study Visit 5 (12-Month Follow-Up)

All study participants will complete the following:

- Pulmonary function test (spirometry) with child if not obtained from medical record.
- Clinical and vital sign measurements of child [weight, height, BMI, blood pressure, pulse, temperature, pulse oximetry (SpO2)]
- 2-week parental recall of symptoms, school absences, and work days missed
- Asthma Control Questionnaire
- Caregiver's Quality of Life Questionnaire
- Cost Analysis Parent Questionnaire
- Child Asthma Risk Assessment Tool (CARAT)
- Administer Asthma Knowledge Quiz
- Observe MDI technique and complete MDI Checklist

4.3 Primary Care Based Intervention:

4.3.1 Study Visit 1 (Baseline)

Additional components of Visit 1 will include:

- Care coordination goals developed with the parent/caregiver
- Coordinate school forms, medications and devices

4.3.2 Home Visit 1

Initial home visit scheduled within 2 weeks of enrollment. Primary care CHW will do the following with the child and parent/caregiver:

- Administer home environmental assessment survey
 - Take photographs of child's bedroom and home's main living area (environmental remediation assessment)
 - Educate about asthma basics and asthma trigger avoidance
 - Review asthma medications and asthma care plan
 - Administer Asthma Knowledge Quiz
 - Observe MDI technique with either the child or the parent/caregiver
 - Give asthma supplies tailored to environment and show caregiver how to use
-

- Assess possible adverse events
- Review child's medical record for utilization of healthcare services
- Establish care coordination goals and refer to community resources as needed

4.3.3 Home Visit 2

Second home visit is scheduled within 4 weeks of enrollment. Primary care CHW will do the following with the child and caregiver/parent:

- Complete follow-up home environmental assessment
- Educate about types of asthma medications, how they work and how to use them properly
- Review asthma medications and asthma care plan
- Give asthma supplies tailored to environment and show caregiver how to use
- Observe MDI technique with the child or the parent/caregiver
- Assess possible adverse events
- Review child's medical record for utilization of healthcare services
- Review care coordination goals and refer to community resources as needed

4.3.4 Home Visit 3

Third home visit is scheduled within 6 weeks of enrollment. Primary care CHW will do the following with the child and parent/caregiver:

- Complete follow-up home environmental assessment
 - Take photographs of child's bedroom and home's main living area (environmental remediation assessment)
 - Educate about communicating with teachers and family members about asthma
 - Review asthma medications and asthma care plan
 - Observe MDI technique with the child or the parent/caregiver
 - Administer Asthma Knowledge Quiz
 - Assess possible adverse events
 - Review child's medical record for utilization of healthcare services
-

- Review care coordination goals and refer to community resources as needed

4.3.5 Study Visits 2, 3, and 4 (Primary Care Office Visits)

Additional components of Study Visits 2, 3, and 4 will include:

- Coordinate school forms, medications and devices
- Teach asthma care plan
- Review care coordination goals and refer to community resources as needed

4.3.6 Home Visit 4 (12-Month Follow-Up)

- Follow-up environmental assessment
- Take photographs of child's bedroom and home's main living area (environmental remediation assessment)
- Administer Asthma Knowledge Quiz

In between visits:

- Primary care CHW will ensure that caregiver has all forms needed for rescue medication administration at school. Participants attending an intervention school may have rescue and controller medications hand delivered to school nurse through transfer from primary care CHW to school CHW at weekly meetings.

4.3.7 Study Visit 6 (Post 12-Month Follow-Up)

- Administer CHW Caregiver Satisfaction Survey
- Administer Asthma Control Questionnaire
- 2-week parental recall of symptoms, school absences, and work days missed

4.3.8 Unscheduled Visits

Usual care includes the caregivers' ability to make clinical visits for their children whenever they feel that it is necessary. In addition, caregivers may contact the CHW for an unscheduled visit via cell phone for non-clinical issues to assist them in meeting their goals. CHW will assess goals on a case by case basis and make follow-up calls as needed. If the CHW is requested to accompany caregivers for unscheduled visits, the CHW will do their best to accommodate the caregivers' needs. CHWs are expected to contact families within 48 hours after receiving phone messages from families or patients to assess whether a home visit or a primary care office follow-up appointment is needed.

4.4 School Intervention

4.4.1 Community Health Worker Coordination

The primary care CHW will contact the school CHW to identify newly consented children present in each West Philadelphia elementary school participating in the study during weekly team meetings. The primary care CHW will then be responsible for contacting the child's caregiver to arrange a visit for collection of appropriate forms and medications.

4.4.2 School Nurse Coordination

School CHW will:

- Provide a portable locked filing cabinet that can be stored in the school nurse's office for study participants
- Help school nurse with filing medication administration forms (med1 forms) and attaining asthma medications for study participants.

4.4.3 Classroom Environmental Assessments

School CHW will:

- Visit participant classrooms to do an environmental assessment for asthma triggers within the first 2 weeks of enrollment in the study.
- Using environmental assessment findings, advise teacher of appropriate asthma trigger avoidance measures.
- Provide teacher with supplies to assist in decreasing asthma triggers in the classroom. Supplies may include white vinegar and a spray bottle for cleaning, electrostatic dust cloths (dusters), and storage bins. School CHW will notify appropriate school personnel of any pest problems identified in the classroom.

4.4.4 Open Airways for Schools Curriculum

Implementation of the Open Airways for Schools Curriculum will occur over three to six asthma management education sessions.

- The school CHW will conduct Open Airways for Schools classes at least once every semester for children with asthma facilitated by the school nurse or designated school staff by the principal.
- Classes will be separated into sessions by grade.

4.4.5 School Based Asthma Therapy

School Based Asthma Therapy (SBAT) involves the administration of controller or preventive asthma medication at school in addition to rescue asthma medication as needed. School CHW will coordinate with teachers/school administrators for all children that attend a school with the asthma intervention and have a primary CHW. To do this, school CHW will:

- Schedule an initial intake for children receiving SBAT
 - Utilize an MDI checklist for school nurse or school CHW to assess child's ability to self-administer his/her medication
-

- Schedule a time for the child to return to the school nurse's office for daily medication administration.
- Utilize a tracking system for the child's medication use (rescue and controller)

4.5 Rescue Medication Administration

Participants may use asthma rescue medication if there is an exacerbation in his/her asthma symptoms in the school, home and clinic as a part of their usual care.

4.6 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to study procedures. It will be documented whether or not each subject completes the clinical study. If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded in the source documents and on the CRF.

Subjects who become a ward of the state during study participation will continue to have their medical records reviewed, but will no longer participate in study visits or the completion of questionnaires. The state agency assigned legal guardianship of the participant will be asked to provide consent for medical record review of the participant during the study follow-up period. If consent cannot be obtained the participant will be withdrawn.

In the event that a parent or legal guardian regains custody and a participant is no longer a ward of the state, the legal guardian may be approached to provide consent for study participation. Once consent has been obtained, study visits can resume for the duration of the follow-up period.

4.6.1 Early Termination Study Visit

If participants withdraw prior to completing the study, all previously collected data will be stored and used for analysis.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Individual Participant Measures

- Children will be measured for **height and weight** (using standard scales and stadiometers), **blood pressure**, **pulse**, **temperature**, and **pulse oximetry** (SpO₂) at baseline, 3, 6, 9, and 12 months following enrollment. This information may also be abstracted from the medical record.
 - **Pulmonary function tests (spirometry)** will be abstracted from the electronic health record if possible. If spirometry is not completed by the child's healthcare team as a part of usual clinical care, it will be completed by a trained community health worker at baseline, 3, 6, 9 and 12 months post-enrollment. Each recording will be printed out to become a part of the child's medical record. Pulmonary function testing completed for clinical purposes within one month before or after a baseline or
-

follow-up study visit will be abstracted from the medical record if testing is unable to be completed at the time of a study visit.

- Juniper's **Asthma Control Questionnaire** is a validated survey and will be administered by a member of the research team to the parent/caregiver by reading out loud to avoid any literacy barriers. This will be administered at baseline, 3 months, 6 months, 9 months and 12 months
- A home **environmental assessment** will be conducted by a CHW in the living room and child sleeping area to note common triggers such as dust, pests, pets, mold and tobacco smoke measured at Home Visits 1, 2, 3, and 4.
- CAPP's **asthma knowledge survey** will be used to assess knowledge at home visits before, during and after the primary care intervention. This survey may be administered out loud to the parent/caregiver to avoid any literacy barriers.
- CHW will ask parent/caregiver for a **2-week recall of daytime cough or wheeze, nighttime cough or wheeze, missed school days, missed parent workdays at the time of the visit**. This will be recorded on a tracking form in REDCap.
- The **Caregiver Needs Assessment** will be administered to the parent/caregiver at the baseline visit. The needs assessment is a validated instrument that focuses on the caregiver's knowledge about asthma avoidance measures and their comfort level with managing their child's asthma. For participants receiving the primary care intervention, this tool will assist the primary care community health worker with tailoring the educational component of the program to fit the needs of the individual family.
- **Adverse Event Forms** will be completed as needed throughout study participation.

5.2 Group Level Primary care and School Measures

- A REDCap tracking form will be used for documentation of time, date and dose of medication dispensed in **School Based Asthma Therapy**. This information will be collected and recorded by the school CHW.
- A **classroom environmental assessment** form will be completed by the school CHW at baseline and at end of semester for study participant classrooms.
- As a part of the Open Airways for Schools Curriculum, an **Open Airways Quiz** will be administered at the beginning and end of a school asthma management class series.
- Fidelity to the school EBI's will be monitored via observation by study research staff utilizing yes/no completion checklists of core components of each intervention. These checklists include the **MDI checklist**, **OAS lesson plan** and **classroom environmental survey** once each semester. It is expected that **90%** of the core components will be implemented for maintenance of fidelity to the intervention.

5.3 Screening and Monitoring Evaluations and Measurements

5.3.1 Medical Record Review

The following variables will be abstracted from the medical chart.

- Date of birth
-

- Weight
- Height
- Blood pressure
- Pulse
- Temperature
- SpO2 (Pulse Oximetry)
- Zip code of residence
- Gender
- Race/Ethnicity
- BMI
- Pulmonary function test results
- Asthma-related healthcare utilization (hospital, emergency, urgent care visits)

5.3.2 Physical Examination

No physical exam outside of usual care will be conducted in this study.

5.3.3 Vital Signs

Weight will be measured with a standardized scale.

Height will be measured with a standardized stadiometer.

Blood pressure, pulse, temperature and SpO2 will be measured by clinic staff using standard clinical procedures and equipment. This information will be abstracted from the medical record by study staff.

Pulmonary function will be measured using a Morgan Scientific spirometer.

5.4 Efficacy Evaluations

Primary Outcome:

1. Asthma Control

Secondary Outcomes:

1. Asthma Symptom Days
 2. School Attendance
-

3. Utilization of ED/Hospital for Asthma

5.4.1 Diagnostic Tests, Scales, Measures, etc.

Primary Outcome:

- **Asthma control** will be measured with Juniper's Asthma Control Questionnaire at baseline, 3 month, 6 month, 9 month and 12 month study visits. We will assess for changes in the ACQ scores from enrollment to completion of the study.

Secondary Outcomes:

- **Asthma Symptoms** will be measured using a 2 week recall diary at the baseline, 3 month, 6 month, 9 month and 12 month study visits.
- **School Absences** will be measured by school and parental report
- **ED visits and hospitalizations** for an asthma-related cause (ICD-9 493.XX) in the 12 months preceding the start of the study and the 12 months subsequent to study initiation, abstracted from the Epic medical record. We will assess for changes in ED and hospitalization usage following study enrollment.

5.5 Safety Evaluation

Adverse event reports will be collected at each visit. These reports will be reviewed at weekly meetings by the PI to determine if they are a result of the study.

The Funding agency will assemble a DSMB to oversee safety of the interventions.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The primary endpoint is the difference in asthma control between the intervention and the control group.

6.2 Secondary Endpoints

Secondary endpoints will include the following:

- The change in asthma symptom days between the intervention and the control group
- The change in school absences between the intervention and the control group
- The change in ED visits and inpatient hospitalizations for an asthma-related cause between the intervention and the control group.

6.3 Statistical Methods

6.3.1 Baseline Data

Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g. means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender).

6.3.2 Efficacy Analysis

The primary analysis will be based on an intention to treat approach and will include all subjects randomized at Study Visit 1. The primary efficacy endpoint will be the change in asthma control between Study Visit 1 and Study Visit 5. Secondary efficacy endpoints will include the change in asthma symptom days and school absences between Study Visit 1 and Study Visit 5.

6.3.3 Subgroup Analysis: Mediator and Moderator Variables

Baseline variables including asthma control, BMI, school type (public/charter) and demographic characteristics which may serve as moderators of intervention effectiveness will be evaluated through subgroup analyses. These variables will be used to identify subgroups of children that may be more likely to benefit from the study interventions. Mediator variables such as communication between school and primary care and level of participation in school-based asthma therapy will be evaluated to better understand the mechanism of effect of the intervention on the study's primary outcomes.

6.4 Sample Size and Power

The factorial design has enhanced statistical power and can handle cluster randomization of schools. Our statistical methods will also estimate variation in the effect across schools over time. First, linear mixed effects models with random intercepts and slopes for school, and fixed effects for the school-level intervention, time, and time-by-intervention interaction (the estimate of interest) will be applied. Likewise, the main effect for the child-level intervention and a time*intervention interaction term will be included in the model, and variation across multiple measurements on a child within a school will be accounted for by child-level random effects. Second, marginal models using generalized estimating equations will produce robust estimates that adjust for clustering at the school level. Third, assumption-free, randomization-test-based (permutation test) methods do not rely on assumptions of parametric models. We will use conventional levels of statistical significance ($p=0.05$) for all pre-specified comparisons for these aims and shall report all results to confirm consistency of findings and their robustness to model specifications. Variability of the intervention effect across schools will reflect consistency of intervention effects and thus generalizability in new settings. Both mixed effects models and permutation-test methods will estimate variance components. All contrasts noted in specific Aims 1a through 1d are handled with the same modeling specifications. This approach will also be used to account for change over time across schools, and to assess sustainability of the proposed interventions.

Missing data on covariates will be handled using formal multiple imputation as needed. The proposed mixed effects models make limited assumptions of “missing at random” (MAR). To the extent that children are lost to follow-up, we shall include in our models covariates that are associated with the probability of dropout to limit confounding by dropout. We anticipate no school withdrawals, but in case of loss, we will use all data collected until time of dropout. The primary analysis will be “as randomized” (also called intention to treat). Reporting will follow the CONSORT guidelines for randomized studies and cluster randomized designs.

All power estimates are based on custom programmed simulations. The pre-specified contrasts from specific aims 1a, 1b, and 1c, appear in Table 2. All power estimates represent changes over time in the primary outcome (asthma control) in units of standard deviation of change. For translation into clinical terms, the minimally important difference (MID) for children on the Juniper's Asthma Control Questionnaire is 0.5 standard deviation units, which equates to 0.4 units on the questionnaire scale (for children ages 6 to 17 years). Estimates assumed a modest degree of variation in outcomes across schools, which equates to clustering of children within schools. For an overall effect size of 0.5 standard deviation units, we assumed that individual schools would vary from no effect (0.0) to a large effect (1.0 sd units). This degree of variation corresponds to a random cluster (school) effect of 0.025 sd units, and an intraclass correlation coefficient (ICC) of 0.06. With an average of 28 children per school, this variability equates to a design effect (variance inflation factor) of about 2.5. As the table shows, the contrasts for the primary care intervention are powerful to show even small effects, because they are within-cluster comparisons and therefore are influenced if at all only slightly by clustering of children within schools. Across school contrasts, of the effects of the school intervention, remain powerful for MID changes.

Table 2. Power for Contrasts of Interest

Specific Aim	Contrast	Contrast (Table cell)	Stipulated Effect size(sd)			Estimated Power
			P	S	P,S	
1a	S+ v S-	a,b vs c,d	0.5	0.5	0.1	0.90
1a	P+ v P-	a,c vs b,d	0.25	0.25	0.1	0.95
1b	S+P+ v S-P+	a vs c	0.5	0.5	0.1	0.95
1b	S+P+ v S+P-	a vs b	0.35	0.5	0.0	0.88
1b	S- P+ v S+P-	b vs c	0.75	0.25	0.0	0.92
1c	S+P+ v S-P-	a vs d	0.25	0.25	0.1	0.96
1c	S- P+ v S-P-	c vs d	0.35	0.5	0.0	0.90
1c	S+P- v S-P-	b vs d	0.5	0.5	0.1	0.90
20%	Subgroup					
2a	S+ v S-	a,b, vs c,d	0.5	0.6	0.1	0.83
2a	P+ v P-	a,c vs b,d	0.5	0.6	0.1	0.88

P=Primary care effect; S=School Effect; PS= interaction; "+" = , "-" = control

Cells e, f are not included in this table for simplicity and to be conservative.

6.5 Interim Analysis

Interim efficacy or safety analyses not expected.

7 STUDY MEDICATION (STUDY DEVICE OR OTHER STUDY INTERVENTION)

7.1 Description

All medication taken by participating children will be prescribed by their primary care provider.

8 SAFETY MANAGEMENT

8.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

8.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

9 STUDY ADMINISTRATION

9.1 Treatment Assignment Methods

9.1.1 Randomization

Allocation concealment will be preserved by randomly permuted block. This randomization will produce a 2-by-2 factorial design, partly clustered (by school).

TABLE 3		Child-Level Intervention	
		P+	P-
School Level Intervention	S+	A	B
	S-	C	D
	none	E	F

The proposed design results in 6 groups of children. Children who do not attend a participating school will be randomized to the primary care CHW (child-level) intervention or not (groups E and F) and will be followed for the duration of the study. The cells A,B,C will permit comparison of any of the 3 combinations of school and child intervention against the group that has neither (D), and will permit marginal analysis of the effect of the school intervention (A+B vs C+D), and the marginal effect of the primary care intervention

(A+C+E vs B+D+F). We will collect baseline data on children and then follow schools and children over time. This design avoids contamination and interference through cluster randomization, but benefits from added power of a longitudinal analysis. It permits estimation (and testing) of interaction between the school and individual interventions. All randomization schemes will be prepared by the project statistical team and implemented using opaque sealed envelopes or a similar process electronically via REDCap.

9.1.2 Blinding

The PI will be blinded to the intervention/treatment group to the extent possible.

9.1.3 Unblinding

Unblinding will occur if there is an adverse event that warrants investigation or if the DSMB instructs the PI to become unblinded.

9.2 Data Collection and Management

For the study intervention, data will be collected, accessed and stored by the CHWs and study research team. Any paper forms will be stored in a locked cabinets in the Community Asthma Prevention Program's (CAPP) badge-only accessible suite. Data collected using REDCap is accessible only by the CHWs and research study staff. Designated school administrators (i.e. principal), the school nurse and the child's primary care provider will only have access to participant health care information necessary to conduct asthma management in the schools and primary care office, but none of the research data collected by the CHWs and study staff. Information will be kept confidential under HIPPA guidelines and Institutional policies.

We will implement the following:

- A master list containing PHI and subject ID number separate from data forms (paper and electronic) that have only a study ID number.
- The master list and any other files will be password protected and kept on a secure CHOP computer to prevent double enrollments.

CHOP's Department of Biomedical and Health Informatics (DBHi) will work with the research team to extract variables from the EHR, and also provide support for the design and use of the REDCap database.

9.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy. The Investigator and other site personnel will not use such data and records for any purpose other than conducting the study. Hard data will be kept in locked file cabinets in the CAPP suite, and will be destroyed 10 years after the end of the study unless subjects consent to contact regarding future research. Any soft data or electronic data will be password protected and kept on a secure CHOP computer.

9.4 Regulatory and Ethical Considerations

9.4.1 Data and Safety Monitoring Plan

The study sponsor will appoint members to a Data and Safety Monitoring Board. Reporting on study conduct, safety measures, data collection and analysis will be provided to the DSMB.

9.4.2 Risk Assessment

Potential risks directly related to the study are minimal. Children may have difficulty with pulmonary function testing, which may be included as a part of their usual care depending on the child's healthcare team, or collected by a trained CHW. Risks indirectly related to the study, particularly in a group of children where no evidence-based interventions are being conducted may include challenges with asthma management which may lead to ED visits or hospitalizations.

Another risk is the potential breach of confidentiality for participant data. When possible, data will be coded by study personnel through the use of participant identification numbers. Any screening referrals from the community will be faxed to a confidential fax line. In addition, participants could potentially feel discomfort with engaging in any of interventions, as questions may be posed requiring personal information.

9.4.3 Potential Benefits of Trial Participation

Direct benefits: Community Health Workers providing the connection between the home, school and primary care practice may reduce the burden on caregivers and facilitate asthma management for school-aged children. Additionally, as community residents, CHWs are knowledgeable about the public school system and can help parents connect to local resources. Participants will also benefit from asthma management education.

Indirect benefits: This project utilizes a pragmatic, integrated and sustainable design with evidence-based interventions to reduce asthma disparities in poor, minority children. We have engaged stakeholders with experience in the community, school district, health plans and health care systems to implement community and evidence-based interventions. These interventions, if proven successful, will reduce the disproportionate impact of asthma on minority children through the number of missed school days, ED visits and hospitalizations due to asthma exacerbations and also create a sustainable care-coordination model that can be replicated in other communities.

9.4.4 Risk-Benefit Assessment

There are minimal risks due to the possibility of loss of confidentiality and possible discomfort from answering questions. There are significant benefits to be gained through participation in the primary care CHW program. We will, to the best of our capabilities, ensure minimal risks by 1) assigning study identification numbers to patient records and for data collection purposes. Only these numbers will be shared with third parties. 2) The caregiver will always have the option of refusing to answer or participate in any component of the study without change to usual care.

9.5 Recruitment Strategy

We will screen electronic health records to recruit 640 parent-child dyads with children ages 5-13 years old with uncontrolled asthma (evidenced by one or more asthma exacerbations requiring oral steroids -OR- one hospitalization within the past year -OR- two ED visits within the past year) from up to five primary care centers (CHOP CN – Cobbs Creek, CHOP CN - Karabots, CHOP CN – South Philadelphia, The Pediatric and Adolescent Medicine Centers of Philadelphia (PAMCOP) and Federally Qualified Health Centers) who serve families who live in the seven West Philadelphia ZIP codes (19104, 19131, 19139, 19142, 19143, 19151, 19153). In addition, CHOP Emergency Department (ED) will screen electronic health records and refer children for enrollment at the primary care sites when they are seen in the ED. The majority of eligible participants will be identified through medical record review and documented on the screening form completed by the CHW or research assistant in the primary care centers or CHOP ED. A waiver of consent will be used to facilitate this process. If additional information is needed to determine eligibility, the CHW will approach families to see if they are interested in being screened for any missing information on the screening form. The screening form will be reviewed by study staff (SC and PI) to confirm study eligibility.

We will also post flyers in our CHOP primary care centers, CHOP ED, and also in partnering community centers. These flyers will contain the CAPP main phone number and email address for families interested in participating in the study. Community partners can also refer children at community events for study screening by research staff.

The Recruitment Enhancement Core (REC) at CHOP provides assistance with recruitment plan development and may assist us in identifying and contacting potential participants using the Clinical Reporting Unit (CRU), the CHOP Recruitment Registry, social media and internal communication resources. The REC also engages community partners and facilitates outreach on behalf of the research Institute and CHOP research studies.

9.6 Informed Consent/Assent and HIPAA Authorization

For the screening process, a waiver of consent documentation and HIPAA will be used. For children and parents/caregivers interested in the study, they will be given explicit information regarding the purpose and procedures of the program, the family will then be asked if they have any questions. The family will be given a consent form that will be read to them by a member of the study team describing the study procedures, the purpose of the study, that their consent to participate in the study is strictly voluntary, and that should they consent, they have the right to end study procedures at any time. Parents who agree to participate will sign an IRB-approved combined informed consent form and HIPAA authorization on paper using a handwritten signature or on a tablet device using an electronic signature. Consent discussions may be held remotely by phone or through videoconference using a HIPAA-compliant application licensed by CHOP including but not limited to BlueJeans and Skype. For consent discussions held remotely, through video conferencing or by telephone, parents will be provided with a REDCap survey link to the informed consent and HIPAA authorization to review and sign electronically. Alternatively, parents with limited internet access can provide verbal consent for participation. Electronic informed consent forms will be stored and managed in the study's REDCap database. Child

assent will be handled in the same fashion. All participants will receive a copy of the signed informed consent form and HIPAA authorization. The electronic consent form will include the patient and caregiver's typed names and written signatures using a stylus pen. Participants who provide an electronic signature will receive a copy of the signed document by email or a printed copy will be provided at the conclusion of the consent meeting. Participants providing verbal consent will receive a copy of the informed consent and HIPAA authorization and documentation of verbal consent via U.S. postal mail.

9.7 Payment to Subjects/Families

9.7.1 Payments to subject for time, effort and inconvenience (i.e. compensation)

Data will be collected for all individually randomized participants at baseline, 3, 6, 9 and 12 months by the research assistant or primary care CHW in person or by phone. Participants will be compensated \$25 for each visit with data collection at baseline, 3, 6, and 9 months and \$45 for the end of study visit at 12 months.

9.7.2 Gifts

During the study, birthday and holiday cards will be sent by mail to enrolled participants. Annually, a small holiday gift such as a jump rope, sports ball or a similar item valued at no more than \$10 may be provided to each enrolled child.

10 PUBLICATION

Data may be used for scientific papers and presentations at medical conferences. All data is reported in aggregate form and individuals are never identified.

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APPENDIX

- A. Initial Home Environmental Assessment
 - B. Follow-up Home Environmental Assessment
 - C. Initial School Environmental Assessment
 - D. Follow-up School Environmental Assessment
 - E. Care Coordination Goals Form/Tracking Sheet
 - F. Asthma Control Tool
 - G. Asthma Knowledge Quiz (Pre/Post)
 - H. Caregiver Needs Assessment survey
 - I. Caregiver Satisfaction Survey
 - J. MDI checklist
 - K. Paediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ)
 - L. Pulmonary function test data collection form
 - M. Intake Survey
 - N. 3, 6, 9, 12 Month Follow-up Survey
 - O. CARAT Survey
 - P. You Can Control Asthma Curriculum
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