Official Title:	Aligning with Schools to Help Manage Asthma (Project ASTHMA)
NCT number:	NCT03032744
Document Type:	Study Protocol and Statistical Analysis Plan
Date of the Document:	7/16/19

Objectives

To improve asthma-related symptoms and lung function through a school-based intervention designed to:

1. Promote chronic medication adherence in children with persistent asthma
2. Facilitate the optimal management of patients based on NAEPP-EPR3 (National Asthma Education and Prevention Program – Expert Panel Report 3) guidelines

Hypotheses

Children with persistent asthma who receive their morning dose of their regularly prescribed twice daily controller medication in school will have reduced asthma-related symptoms and improved lung function compared to those who do not receive their medications in schools

Inclusion Criteria

The study will target children diagnosed with asthma who attend a Buffalo Public School that has a School-based Health Center (SBHC).

Inclusion criteria include:

- A student at one of the targeted schools
- Enrolled for care in the SBHC
- Have a primary care provider other than the advanced practice provider (APP) at the SBHC (If the student does not have a primary care provider, he/she can be referred to practices in the area. They would be eligible for enrollment if they have seen this provider at least once prior to enrollment)
- 4-14 years old
- Have had a physician or APP diagnosed asthma for at least 12 months
- Have active asthma defined as any of the following in the previous 12 months
    - Parent or child talked to a doctor or other health care professional about child's asthma
    - Taken any asthma medications
    - Experienced any asthma symptoms
- Have persistent asthma (based on NAEPP-EPR3 classifications) OR
  ≥ 2 courses of systemic steroids due to asthma in the previous 12 months OR

  ≥ 2 Emergency Department/urgent care visits for asthma in the previous 12 months OR

  ≥ 1 hospitalization for asthma in the previous 12 months

Exclusion Criteria

- Child is already on an appropriate controller medication, and well controlled
- Child who already has plans to leave the current school before the end of the school year UNLESS child will be going to a school participating in Project ASTHMA
- Child has a significant lung or heart disease other than asthma
- Pregnant Teenager
- The child's primary physician has already ordered a controller medication be given to the child every morning at school

Eligibility Screening

1) Initial identification of potential subjects will be through the school nurses and APPs who already know their population of children with asthma that they see for treatment in the SBHC. The school APP at each of the schools currently have a list of students who have asthma. The school APPs are health care providers for the children in their respective schools, and also are members of the study staff. Potential subjects may also be identified by the providers at Niagara Street Pediatrics, Towne Garden Pediatrics, and UBMD Allergy & Immunology Clinics. The study investigators are providers at these clinics. Potential subjects may be identified by the providers at UBMD Lung Center Clinics. Potential subjects can also self-identify by seeing a Project ASTHMA flyer in the school or at 1 of the above clinics.

2) Screening: A screening will be conducted to determine if the prospective participant meets the eligibility criteria. The eligibility criteria will be determined by self-report from the parent. This can either be conducted (1) in person, when the parent/guardian expresses interest to a member of the research team, (2) over the phone, if a parent/guardian calls and/or is called based on their previously expressed interest in participating in the research study. Investigators who are also the prospective participant's provider may call a family who may meet inclusion criteria. If a student does not meet the screening criteria, only their name will be recorded so the study team does not contact the parent of that child again.

3) Enrollment: All of the individuals who meet inclusion criteria will be asked to schedule an enrollment visit. Consent will be obtained from all individuals who attend this session.

Recruitment Methods

1) The school APP, who is also an investigator, will send out letters to the parent of all the known children with asthma at the beginning of the school year to let them know about the study & their potential eligibility. These letters may be sent home with the student, or mailed to the parent. If mailed, the records of the students will be reviewed in order to obtain the parent address. The student's health record may also be reviewed to confirm the asthma diagnosis. The letter will provide the parents with information about the study prior to the APP speaking with them. This letter will also provide contact information for the parent to call the APP or research coordinator for more information about the study.

2) Prescription Drop-off: All of a student's medication for school, including rescue inhalers for asthma, must be hand delivered to the school nurse's office at the beginning of the school year. We plan to have a recruitment flyer, information sheet, and contact sign-up sheet present in the school nurses' offices for parents to see when they arrive. The research coordinator also may be in the school nurses' office to answer parents' questions after they have expressed interest.

3) Phone calls to parents:

    a. If the school APP needs to call a parent because she saw the child in the SBHC (part of their routine care), and the child has asthma, she may let the parent know about Project ASTHMA & ask if the parent is interested in learning more about the study.

    b. Investigators who are also the student's provider, may pre-screen charts to determine if the patient may be eligible for the study. If they are potentially eligible, the investigator-provider may contact the family by phone to ask if they would be interested in participating in the study.

    c. If the APP identifies a student as a potential participant, and they are also a patient of one of the investigators or one of the practices who have provided Project ASTHMA with a letter of support, the potential subjects' provider may also be asked to contact the family regarding the study. In that case, the child's name, school, and individual they last saw in the clinic will be recorded and

shared with the provider either via secure electronic communication or person-to-person communication. The provider may access the individual's medical record in order to find the appropriate phone number and contact the family to ask about their interest in participating in Project ASTHMA. All providers are familiar with the overall study and HIPAA privacy laws.

4) Flyer: Flyers will be placed in the participating schools, Niagara Street Pediatrics, Towne Gardens Pediatrics, the UBMD Allergy & Immunology Clinics, and the Lung Center Clinics so that individuals may also self-identify. It is possible that not all children with asthma in the schools are known to the SBHC, because (1) students and their families must enroll in the SBHC separately from regular school services and can only be seen by the SBHC personnel if they are enrolled in the SBHC, and (2) not all children come to the nurses office when they have asthma symptoms. If parents/guardians express interest in participating in the study and their children are not already enrolled in the SBHC, they will be told that they can participate if they choose to enroll their children in the SBHC. Flyers may also be sent home with the students at the schools who are enrolled in the SBHC and known to have asthma.

5.) If the investigator or another study team member sees a patient in their clinic who may meet the study requirements, and is informed by the patient or family that they attend one of the schools that participates in our study, the study team member may inform the family about the study and provide an information sheet and/or ask for their permission for a member of the study staff to contact them to provide more information about the study.

6.) If the patient is seen at Niagara Street Pediatrics, Towne Garden Pediatrics, or Allergy/Immunology Clinic by a provider who is not a study investigator, and during the course of a clinic appointment this provider notes that the patient has asthma and fits the age range for the study, this provider can give the parent of the patient a study flyer to read. They can ask the parent if the Project ASTHMA research coordinator may contact them. If the parent is interested in hearing more about the study, they will be provided an envelope (addressed to the Project ASTHMA team) with a form for them to complete, giving the study team permission to contact them. After completing the form, the parent will be instructed to place it back in the envelope & seal it. The envelope will be forwarded to the research coordinator.

7.) Lung Center Clinics – Potential study patients may be seen by providers at the Lung Center. If during the course of a clinic appointment, the Lung Center provider notes that a patient has asthma and fits the age range for the study, the Lung Center provider can give the parent of the patient a study flyer to read. They can ask the parent if the Project ASTHMA research coordinator may contact them. If the parent is interested in hearing more about the study, they will be provided an envelope (addressed to the Project ASTHMA team) with a form for them to complete, giving the study team permission to contact them. After completing the form, the parent will be instructed to place it back in the envelope & seal it. The envelope will be forwarded to the research coordinator.

8.) Community Physicians – Physicians who care for children who may attend the target schools, including the physicians who have already provided letters of support for this study, will be given study flyers to give to potential enrollees. Interested parents can contact the research coordinator.

9.) Tabling sessions: Additional school events, such as parent-teacher-conference days or school open houses may also be utilized as recruitment opportunities. If this occurs, the same processes will be used as if the parent presented in the SBHC to drop off medications

Please note that the recruitment strategies are listed in the order in which we intend to use them and preference on how we will recruit. The later options will be used in the event that we do not meet the recruitment goals using the earlier strategies.

Procedures:

1.) Enrollment Visit:
After a potential subject meets the screening criteria, an enrollment visit will be scheduled at the SBHC. If the parent/guardian is unable to come to the SBHC, arrangements will be made for a home visit by the research coordinator to enroll the student. In this situation, the medical questions will be asked by the APP over the phone. The enrollment visit includes many steps, and the medical portion is similar to what would occur if the patient presented to their doctor's office for a visit for their asthma. This visit will include the following listed procedures and should take approximately 1 hour to complete.

a. Parental Permission and child Assent will be obtained

   i. Includes request to contact child's Primary Care Provider

   ii. Includes request to contact child's allergist and/or pulmonologist, if applies

b. History: All of the demographic and history questions will be asked verbally by the individual conducting the assessment and recorded on paper.

   i. Initial Data form

   ii. Asthma Control Test (ACT) Form: The ACT questionnaires are a validated tools used regularly for asthma patients. In addition, the results are included in the NAEPP-EPR-3 Guidelines for the assessment of asthma control for children ≥12. Although this is typically filled out by the parents and children on their own in the clinic setting, the validated process requires an explanation of the questions. In order to ensure that the patients understand all questions as they were designed to be answered, they will be read and explained by the research personnel. Children 4 to 11 have slightly different questions on their ACT form than children 12 and older.

c. MDI Spacer Training & medication training: All patients are to be educated on the use of their controller inhalation medication and their spacer devices. Patients are assessed on how they use the items and then advised on proper technique, why it is important, and what they can improve on in the future. We will also provide the subjects and their parents with printed education material on the proper use of a spacer.

d. Other education: The student subjects and their families will be provided with education on the benefits of daily asthma medication use (using visual aids) and the effects of smoking on asthma.

e. Spirometry breathing test: Spirometry tests are routinely performed by allergy specialists and pulmonologists. The NAEPP-EPR3 recommends this test also be performed in primary care offices to improve the care of patients with asthma, although this practice has still not been widely adapted. It is possible that some of the subjects may have had this test before the study.

   i. The test must be administered and interpreted by trained individuals. The research coordinator will be trained on test administration and interpretation prior to study initiation. The APPs will be trained on test interpretation & how the results affect the child's asthma disease classification. There will be one study designated spirometer and laptop (the spirometer is associated with computer based programming that will be installed on the laptop and be used only for research). These are small, transportable objects that will be easily transported between the schools and the department of Pediatric offices. If unsuccessful in completing the spirometry test, or if the student was not eligible to complete spirometry at the visit (current asthma exacerbation, a significant upper respiratory infection, took a albuterol within 4 hours, took a LABA (Long-acting beta-agonist) in the last 12 hours, or received oral steroids in the past 4 weeks), the spirometry

will not be repeated until the next follow-up assessment. The APPs will assess child's asthma severity based on the NAEPP-EPR-3 Guidelines. The subject's asthma severity will be determined based on the most severe result and NAEPP-EPR3 step-wise guidelines.

f. For students 10 years old and older, both the parent & the student will be asked the questions on the frequency of the students' asthma symptoms, & the agreed upon answer between the 2 of them will be recorded. For students younger than 10 years old, only the parent will be asked these questions.

2.) Eligible students

Students are randomized based on a stratified block randomization (numbered, sealed envelopes with site specific randomizations will be located at each SBHC).

a. Usual care:

   ii. Parents will be given the result of the asthma assessment & be told to have their child follow-up with his/her primary care provider (PCP) for further asthma management.

   iii. The student's PCP will be sent a letter with the student's asthma classification. A copy of this letter will be sent to the child's allergist and/or pulmonologist if applies.

b. Intervention:

   i. Students will self-administer the morning dose of their controller medication under the guidance of the SBHC nurse who will also reinforce proper medication administration technique and home medication adherence. This will start at the time of enrollment and continue until the student's last day of school in June, 2019. Students & their parents will be responsible for administering the evening and non-school day doses of their medication at home. The students will be asked each day they are in the health office if they remembered to take the previous evening's home dose of their medication. Parents will be told at the final 7-month follow-up assessment that they should follow-up with their child's PCP within 1 month after the end of school year.

   ii. If as a result of the asthma assessment the study team determines the student should change their controller medication or change the dose of their controller medication, the PCP or specialist, if applies, will be contacted & a verbal agreement will be documented prior to prescribing the medication. An exception to this would be if the PCP or specialist is the study investigator or part of the study investigator's practice group (Niagara Street Pediatrics & Towne Garden Pediatrics). Another exception would be if the PCP practice has provided Project ASTHMA with a written a letter of collaboration stating they support our medication management decisions and are satisfied with a letter providing them with our management decision after the medication change has been made. A third exception would be if the enrollee is a patient of the allergist who is also a study investigator, in the UBMD Allergy/Immunology Clinics.

   iii. Parents will be given the result of the asthma assessment

   iv. Asthma Action Plan - An individualized Asthma Action Plan will be completed for the student & the study team member will review the directions on the AAP with the parent & the student

   v. The student's PCP will be sent a letter with the student's asthma classification & the recommended step therapy based on NAEPP-EPR3 report. A copy of this letter will be sent to the child's allergist or pulmonologist if applies.

3.) Follow-up visits for all students:

a. Follow-up asthma assessments will be done at 1-, 3- and 5-months after enrollment and a final follow-up assessment at 7-months after enrollment. The 1-month visit may be done up to 2 weeks later. The 3-, 5- and 7-month follow-up visits may be done up to 2 weeks earlier or later. At the 1-, 3- and 5-month follow-ups, students will be seen in the SBHC, complete the patient questions on the ACT form, and have spirometry performed. At the 1-, 3- and 5-month follow-ups, the research coordinator will call the parent/guardian to complete the follow-up data form & the parent questions on the ACT form by phone. At the 7-month final follow-up assessment, both the parent/guardian & student will be seen in the SBHC to complete the final assessment. The final assessment will include the (1) follow-up data form, (2) ACT form (3) the same asthma education given at enrollment, and (4) spirometry testing. If the parent/guardian cannot come to the SBHC to complete the questionnaires, they will be administered by phone by the research coordinator. In this situation, only the student will receive the repeated asthma education.

b. For students 10 years old and older, both the parent & the student will be asked the questions on the frequency of the students' asthma symptoms. Since they will not be together when these questions are asked at the 1-, 3- and 5-month follow-ups (the students will be asked in the SBHC, while the parents will be asked over the phone), the answers may be different. For the purpose of determining the Control Classification, we will use the higher of the 2 answers. If both the parent and the student are present at the final, 7-month follow-up, we will use their agreed upon answers to determine the Control Classification. For students younger than 10 years old, only the parent will be asked the symptom frequency questions at all the follow-up visits.

c. The Research Coordinator will arrange the follow-up visits. Each child may attempt the spirometry test up to 3 times at the follow-up assessments if the initial readings were not interpretable but the research coordinator feels the child may be able to achieve an interpretable curve if repeated on another day. The 1- and 3-month follow-up visits should take about 15 minutes for the student & 10 minutes for the parent/guardian to complete. The final follow-up visit should take about 30 minutes to complete. A letter with the student's results will be sent to the child's PCP after each asthma assessment. A copy of this letter will be sent to the child's allergist or pulmonologist if applies.

4.) Intervention group:

The SBHC APP will write the prescriptions for the controller medication to make sure the child has the medication at home and at school. This type of care is part of the APPs regular job activities.

a. Choice of Medication:

There are 2 categories of controller medications. This includes inhaled corticosteroids (ICS) and combination ICS plus LABA. The medications included in each category include:

Inhaled dosages

(1) Alvesco HFA (FDA approved ≥12 years old)

(2) ArmonAir RespiClick (FDA approved ≥12 yrs old)

(3) Asmanex HFA (FDA approved ≥12 yrs old)

(4) Asmanex Twisthaler (FDA approved ≥4 yrs old)

(5) Flovent Diskus (FDA approved ≥4 yrs old)

(6) Flovent HFA (FDA approved ≥4 yrs old)

(7) Pulmicort Flexhaler (FDA approved ≥6 yrs old)

(8) Qvar Redihaler (FDA approved ≥4 yrs old)

Combination Inhaled Corticosteroid Plus LABA

(1) Advair Diskus (FDA approved ≥4 yrs old)

(2) Advair HFA (FDA approved ≥12 yrs old)

(3) AirDuo RespiClick (FDA approved ≥12 yrs old)

(4) Dulera HFA (FDA approved ≥12 yrs old)

(5) Symbicort HFA (FDA approved ≥6 yrs old)

b. We will be following the NAEPP-EPR3 guidelines on medication drug dosing. Students meeting the criteria for step 2 therapy will be placed on low-dose ICS. Students meeting the criteria for step 3 therapy will be placed on medium dose ICS. Students meeting the criteria for step 4 therapy will be placed on a combination medium dose ICS plus LABA. Students who are followed by an Allergy or Pulmonary specialist & placed on a combination high dose ICS plus LABA by this specialist will be maintained on the same drug.

c. Flovent is the most commonly prescribed inhaled corticosteroid by pediatricians and pediatric subspecialists who manage asthma in our community, and so this will be our preferred drug to use for step 2 and 3 therapy. If the student's insurance does not cover Flovent, we will choose another inhaled corticosteroid based on the drug that is approved by the student's insurance company & has the FDA approval for the age of the child.

d. Advair and Symbicort are the most commonly prescribed combination inhaled corticosteroid plus LABA and so will be our preferred drug to use for step 4 and 5 therapy. If the student's insurance does not cover these drugs, we will choose another inhaled corticosteroid based on the drug that is approved by the insurance company & has the FDA approval for the age of the child. The one exception to this would be Advair HFA which has FDA approval for children 12 years of age and older. Advair Diskus has FDA approval for children 4 years of age and older. Advair HFA and Advair Diskus have the same active ingredients, fluticasone propionate and salmeterol. The only difference is the mechanism of delivery. Although Advair HFA is not FDA approved in children 4 to 11 years of age, the active ingredients and the HFA propellant are FDA approved in children 4 years of age and older. Young children are unable to adequately demonstrate the proper technique to use the Diskus device and get adequate delivery of the drug into their lungs. The Advair HFA uses a metered dose inhaler device, and with the use of a value holding chamber, this is the preferred device to use in young children to ensure adequate delivery of the drug to the lungs. We have obtained an IND exemption to use Advair HFA in this study in children 4 years of age and older.

e. After the initial assessment, all students in the intervention group will fall into 1 of the following categories:

    1. continued on the same controller medication and dose as previously prescribed by their PCP or specialist, if applicable

    2. started on a controller medication at the appropriate step therapy

    3. step-up to a higher step therapy than previously prescribed by their PCP or specialist, if applicable

If #3 applies, the student's PCP or specialist, if applies, will be contacted to obtain verbal agreement for the change in medication and/or dose unless any of the following applies:

i. PCP is from Niagara St Pediatrics or Towne Garden Pediatrics

ii. PCP is from a practice for which Project ASTHMA has a letter of collaboration

iii. Student is a patient of UBMD Allergy/Immunology or Pulmonary

f. Since this is a health services trial, and the student's provider (the SBHC APP, the PCP or the specialist) has determined that the student should be on a controller medication, we will be obtaining the medications from the child's health insurance.

g. Medication Access:

i. Second Controller: The number of inhalers allowed at one time varies by insurance companies. Some insurance companies will only approve 1 inhaler of a daily controller medication per month (1 month's supply) and others will approve up to three inhalers for a three-month supply. This protocol requires the release of three controllers at once - 1 to be kept in the school nurse's office for administration of the morning dose, and 2 to be kept at home for all other doses. By obtaining 3 inhalers at once, the school inhaler will have enough doses for at least 3 months and the 2 home inhalers will have enough doses for 3 months. Once 3 months pass, we can then order another 3 inhalers for the next 3 months.

ii. Insurance Companies: As part of standard care, a prior approval for additional controller medications can be submitted by a provider who determines it is beneficial for their patient to receive his/her medication at school. Since this is a health services trial, the sustainability of the intervention hinges on the successful incorporation of existing systems, including the health insurance system. We therefore feel it is important to use the student's health insurance to supply the medication, as it would be required to do so if the school APP ordered this outside of the study.

iii. Asthma controller medications come in 2 forms, a metered dose inhaler (MDI) and dry powder inhaler (DPI). Young children are unable to use the DPI form well enough to achieve adequate delivery of the drug to their lungs. They therefore require the use of the MDI form with a spacer device. Some insurance formularies only have the DPI. As part of standard care, a prior approval for an MDI controller can be submitted by a provider who determines his/her patient requires this. We will be using this same process in the study.

iv. It is not expected that there will be any added medication cost to the subject's families because (1) our target population is from low-income communities and have managed Medicaid so they do not have co-pays for their medications, and (2) for those families who do have private insurance & must pay a co-pay for their medications, they will still have the same number of co-pays over the course of the intervention because each canister will last more than 1 month.

v. For patients who do not have insurance or their insurance will not allow them to receive more than 1 controller medication within 1 month, we will have some sample medications for their use.

vi. Transport to school: Prescriptions for controller medications will be sent to Oishei's Children's Hospital pharmacy or to the family's preferred pharmacy. The research coordinator will pick up the medications that will be used in the school. If more than

1 controller is filled at once, the research will pick up all medications prescribed and ask the parent to come to the school to pick up the inhalers for home use. If the parent picks up the medications from the pharmacy, they will be responsible for bringing the inhaler that will be used in school to the SBHC.

h. Medication Administration:

i. The APPs, who are also the students' health care provider, will write the order for the controller medication to be given at school. All children in the intervention group will be asked to come to the nurse's office in the morning on school days to take morning dose of their controller medication.

ii. Although it is not often that children with asthma take their daily controller medications at school, the administration of student medications is part of the school nurses' normal responsibility. Under standard school nurses' procedures, medications are delivered to the school (usually by the child's parent) and medication is administered by either the APP or school nurse. Every time a medication is given in the school, it must be recorded in the SBHC medication log. The log is considered a school record, but it is accessible to all members of the SBHC staff. A member of the research team, either the SBHC APP or research coordinator, will use this log to confirm that the individuals in the study received their medications and as part of a process evaluation.

iii. Each morning when the students are given their controller medication, the individual delivering the medicine will also ask if the student took the second (nighttime) dose of their medication the night before & remind them to take their medication at home. The answer to this question is not intended to obtain accurate data points, but will serve as a reminder for children to take their home doses of their controller medication. The answer to this question will not be recorded.

i. Medication change by PCP, allergist, or pulmonologist

i. If at any time during the study period the student's PCP, allergist, or pulmonologist wants the student to step-up in the strength of their asthma controller medication, the student can still stay in the study. The provider making the change would be required to prescribe the controller medication for home & school use.

j. Valve holding chamber (spacer)

i. If the student does not have a spacer device at home, the APP will prescribe 1 for home use. If the student does not already have a spacer device at school, the APP will prescribe 1 for school use & the research coordinator will pick this up from the pharmacy to bring to the school. If the student's insurance will not pay for the 2nd spacer, the student will be provided 1 for school use through study funds.

k. Medication changes at follow-up visits:

i. Any necessary adjustments to controller medication will be done at the time of each of the follow-up assessments. If the child requires a change in medication, they will be given an updated AAP & a study team member will review the directions on it again. All students in the intervention arm will receive a final AAP at the 7-month assessment.

l. Study visit locations: All study visits are expected to take place in the SBHC located in the schools. If the parent or legal guardian is unable to come to the SBHC for enrollment, the research coordinator will conduct a home visit to enroll the student.

m. School changes: Children whose parents report that they plan to move/leave the school before the end of the school year will be excluded from study participation. However, based on the patient demographics and APP experience, we expect that there will be instances where children switch schools due to unexpected moves or other occurrences. If this is the case, the following procedures will be followed:

   i. Usual care group:
   Children will still be asked to follow-up with the study team for their 1-, 3-, 5- and 7-month follow-up visits. In the event that a child in the usual care group leaves the school where they were originally enrolled and does not attend another participating school, they will be asked to return to the original school for their follow-up visits if they still live locally. If the child and parent are unable to come to school for the assessment, we will obtain the asthma health history via the phone or a home visit. This process was approved by the Buffalo Public Schools.

   ii. Intervention group:
   If the child moves to another school that is involved in the study, they can continue as a study participant

   iii. If the child moves to a school that is not currently participating in the intervention, then they will not be able to continue to participate in Project ASTHMA.

n. Other loss to follow-up: If the student is no longer at their school of enrollment and/or we are not able to contact the family and complete the follow-up visits, we will assess the child's medical record to collect the study data points that can be ascertained from the medical record.

o. Asthma Medication Assessments and Management

   i. The SBHC APP serve as both the providers for study patients and the study investigators. They are part of the intervention in the study as well, as they are trained by the Principal Investigator to provide NAEPP-EPR3 guideline-based asthma assessment & management to their patients. This training is not solely for study purposes, but can be applied to study & non-study patients, as well as be applied to their patients after the completion of the study. As the study patient's provider, the SBHC APPs can make asthma assessments and management decisions (prescribe medications), as part of their normal job responsibilities.

   ii. In the event that a SBHC APP/investigator leaves the intervention school, the new SBHC APP will receive NAEPP-EPR3 guideline-based asthma assessment & management training to apply to all her/his patients. Since Project ASTHMA is a health services intervention, our goal is to use the existing health care system in an innovative way to improve the delivery of health care. In providing chronic care management for their asthma patients, the SBHC APPs are performing their normal job responsibilities.

Data Management and Analysis

We expect children in the intervention group to have fewer asthma symptoms and exacerbations than children in the control group. To verify that there are no differences in potential confounders between the two groups, we will use chi-square and t-tests to identify any significant differences in caregiver education and health literacy, children's exposure to second hand smoke, and BMI. We will include any variables for which there are significant group differences in all models. We will conduct both intent-to-treat and as-treated analyses.

Our primary outcome measure is the decrease in frequency of daytime asthma symptoms per week, over a 4-week interval. We will measure asthma symptoms at baseline, 1-, 3- and 7-months, Our secondary outcome variables are scores on the continuous ACT scale. Another secondary outcome measure is improvements in spirometry scores (FEV1/FVC ratio). We will use linear regression to test for differences in at baseline, 1-, 3- and 7-month ACT score controlling for baseline ACT score and any covariates that varied by group. We will repeat similar analyses for FEV1/FVC at baseline, 1-, 3- and 7-months controlling for baseline FEV1/FVC score.

We will also model outcomes for number of courses of oral/parenteral steroids for asthma. We will test negative binomial regression models, individually regressing each of the health care usage variables on group (intervention vs. control). We will control for covariates that vary as a function of group.

All spirometry tests will be interpreted by 1 of the investigators. The allergy specialist on the study team will also evaluate the interpretability of each of the spirometry tests.