COVER PAGE

Official Title: Reducing Asthma Morbidity in High Risk Minority Preschool Children (Asthma Basic Care (ABC) at Head Start)

NCT01519453

January 26, 2017

Protocol and Statistical Analysis Plan

Johns Hopkins Medicine - eForm A

- **Use the section headings to write the eForm A, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.**
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1. Abstract

a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

Asthma has been identified as the most common chronic disease in early childhood and it places a higher burden on minority groups and the poor. Children ages 0-4 years have been identified as the driving force behind increased rates of hospitalization for children with asthma. Furthermore, black children are approximately 2.5 times likely to have an ED visit or hospitalization than white children. Reflecting this increased risk, the prevalence of asthma among low-income preschool children attending Head Start programs is high, ranging from 14% to 35%. For these reasons, asthma has been identified as a key health risk for Head Start children by the Department of Health and Human Services and the Environmental Protection Agency. Thus, Head Start programs offer a timely and important venue for reaching high-risk, low-income pre-school children and providing asthma education interventions. We therefore propose to draw on our established health and research partnership with Head Start programs in Baltimore City to test the effectiveness of a home-based asthma education intervention (ABC) with demonstrated efficacy. Specifically, we will conduct a randomized clinical trial of a culturally-tailored home-based asthma education intervention combined with a HS-level asthma education program in reducing asthma morbidity among low income minority children compared to a HS-level asthma education program alone. We will enroll 406 HS students aged 2-6 years with caregiver-reported symptomatic asthma from all 16 Baltimore City HS programs. The primary study outcome measure will be symptom free days at six month follow-up. Secondary outcomes include caregiver-reported healthcare utilization for urgent (ED visits and hospitalizations) and non-urgent (primary and specialist care) asthma visits, caregiverreported oral steroid bursts, caregiver-reported asthma control and caregiver quality of life. In addition, at the HS level, we will assess overall HS participation in the HS-level asthma education program and any additional programs or institutional changes that would indicate adoption, implementation and maintenance of asthma education as a core HS health goal and changes in HS staff knowledge, attitudes and practices related to asthma management.

2. Objectives (include all primary and secondary objectives)

Primary Objectives: Assess the relative effectiveness of the ABC intervention combined with Head Start (HS)-level asthma education (ABC group) in improving asthma morbidity compared to HSlevel asthma education alone (Control group) in preschool children with symptomatic asthma. Primary Hypothesis (#1): Participants receiving the ABC intervention will have more symptom free days at the 6-, 9-, and 12-month evaluations when compared with participants in the control group. (#2): Participants receiving the ABC intervention will have reduced morbidity, including decreased urgent care utilization (hospitalizations/ED visits measured by caregiver report as well as insurance payer data), improved quality of life, improved asthma control, and fewer courses of oral steroids, when compared with participants in the Control group at the 6-, 9-, and 12-month evaluations.

Secondary Objectives: Assess the degree to which HS program-level adoption, implementation and maintenance of asthma education activities (stratified as high implementation vs. low implementation) moderates the impact of child-level treatment assignment (ABC vs. Control) on measures of asthma morbidity, including symptom-free days, urgent care, quality of life, asthma control and oral steroids.

Secondary Hypothesis (#3): Participants receiving the ABC home-based intervention combined with high implementation of HS-level asthma education will have reduced asthma morbidity, including decreased urgent care utilization, improved quality of life, improved asthma control, and fewer courses of oral steroids, when compared with participants receiving the ABC intervention in low implementation of HS-level asthma education, or Control group participants at the 6-, 9-, and 12month evaluations. The secondary outcome measures include other measures of asthma morbidity (i.e., ED visits and hospitalizations, oral steroid bursts, asthma control and caregiver quality of life).

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

Previous efficacy studies have suggested that asthma education programs can be effective in improving overall management of asthma for preschool children. Multiple studies have demonstrated that home asthma educational interventions can increase the number of symptom free days, decrease frequency and severity of asthma flares, decrease ED visits and hospitalizations, and improve quality of life. Asthma education interventions have been shown to reduce asthma morbidity across diverse populations, including in preschool age and low-income minority children. Schoolbased asthma programs are a promising strategy for asthma education because of the potential to reach large numbers of children and directly teach them asthma self-management skills. School programs offer the further advantage of being able to deliver asthma education to low-income children who may not be seen for regular asthma medical care. Most of these programs, however, have been conducted in elementary schools and focused on the child's efforts to self-manage and are of limited application in a pre-school age population. In a prior study we found that our **Asthma Basic Care (ABC**) intervention led to significant short-term improvements in symptom free days, along with a greater rate of reduction in courses of oral steroids over 18 months, relative to usual care in low-income, minority children. However, for these promising asthma intervention strategies

to have sustainable public health impact for low-income, minority children, they must be integrated within those medical, educational and social structures that serve these high risk children. We therefore propose to draw on our established health and research partnership with Head Start programs in Baltimore City to test the feasibility of implementing the ABC home-based asthma education intervention with demonstrated efficacy into a Head Start venue.

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

This study is designed to evaluate the effectiveness of a home-based asthma education intervention (ABC) with demonstrated efficacy in combination with a Head Start level intervention (ABC + HS) to improve asthma morbidity compared to a Head Start level intervention (HS Only) containing asthma education implemented in the Head Start Programs. The study design is a two group randomized clinical trial (N=406). Participants will be children with symptomatic asthma enrolled in Baltimore City Head Start Program Sites (age 2-6) and their families. Participants will be recruited from Head Start and randomly assigned to ABC combined with HS asthma education or HS asthma education alone. The ABC intervention is home- asthma education intervention that was tailored, based on our prior research and that of others, to reflect known cultural barriers to effective asthma management among low-income minority families, including underutilization of asthma primary care, overestimation of asthma control, perceptions that asthma is an episodic illness that only needs acute treatment, negative beliefs about controller medications, and environmental risk factors in the home. All intervention visits will be audio-taped. Outcome measures will be collected at 3-, 6-, 9- and 12-months. The primary outcome measure will be symptom free days at six month follow-up. Secondary outcome measures include other measures of asthma morbidity (i.e., ED visits and hospitalizations, oral steroid bursts, asthma control, and caregiver quality of life). In addition, at the Head Start level, we will evaluate over five years the overall HS participation in the HS-level asthma education program and any additional programs or institutional changes that would indicate adoption, implementation and maintenance of asthma education as a core HS health goal and changes in HS staff knowledge, attitudes and practices related to asthma management.

Staff Safety

In order to assure safety for our study team we do the following: (1) All of our study team members are provided with a cell phone to be kept with them at all times. (2) We conduct annual safety training with a member of the police department. (3) We request that our study team members not conduct home visits at night. (4) All study team members are encouraged to request a second team member attend any home visit that makes them feel uncomfortable.

Screening

Potentially eligible families will be identified from Baltimore City Head Start Programs. Specifically, we will distribute an initial screening survey (ISS) to the primary caregiver of all Head Start students (N=4000/year)

enrolled in a Baltimore City Head Start program. This screening questionnaire will assess asthma diagnosis, presence of asthma symptoms as well as questions pertaining to study eligibility. Data from the ISS will be stored without personal identifiers to track Head Start level rates of these variables. Four hundred and six children (ages 2-6 years) whose caregiver reports asthma diagnosis and presence of asthma symptoms will be enrolled in a twelve month study of a home-based asthma education intervention (ABC).

Parents will be asked to complete the Asthma Head Start Initial Screening Survey (ISS). Forms will be sent home with children in informational packets for the family. Each teacher will be given $50 in the form of a gift card as an award for 80% form return for his/her classroom, regardless of recruitment or eligibility status of the students. The ISS has an option that allows the family to refuse to fill out the form but still return it to the teacher. This reward plan is necessary to ensure comprehensive and timely screening of the HS sites. This reward plan has been used by numerous researchers and has been successful in screening up to 98% of children. On the ISS, families will indicate if they give permission to be contacted to determine eligibility and interest in participation in the proposed study. To facilitate recruitment at the Head Start sites, we will be working closely with the HS site Family Service Coordinators (FSCs). They will be assisting us with distribution and completion of the Initial Screening Survey (ISS). They will also be providing student roster information and serve as a communication liaison with the teachers. Therefore we will compensate their time by offering a $50 check for completion of 80% of the forms at their assigned sites, regardless of recruitment or eligibility status of the students. This IRB approved screening approach allowed us to successfully screen 87% of the children during our current study NA_00019089.

Participant Recruitment

Families who report an asthma diagnosis on the ISS who give permission to be contacted will be contacted by phone to confirm eligibility and interest in participation in the proposed study. During this phone contact, eligible families will have the study described in detail and will be informed of the $190 total financial incentive for completing each of the data collection visits. An appointment will be made with interested families to obtain consent and do the baseline assessment in the home. Because of the age of the children, written assent is not possible.

OPTIONAL ABC FAMILY STUDY: During the baseline visit, the consented parent/guardian will be invited to answer an additional survey regarding patterns of health care use and personal health concerns among family members. They will be compensated $50 for the additional time and effort. Parents/ guardians will be asked to nominate up to 5 family members to be recruited to complete the Family Health Questionnaire. Parents will be given IRB approved postcards and/ or emails to pass on to their family members. Each postcard/email will provide an option to respond either by mail (i.e., returning the postcard by mail) or by email (i.e., contact information listed on card or in email). Each postcard/email will have a unique code which links family members to the parent who initially passed them out. For each family member that either returns the postcard or responds by email, the parent who referred the participant will receive compensation of $20. In total, parents who complete the additional family survey and refer up to 5 family members, who subsequently contact the research team, can earn up to $150. Caregivers will be provided the additional compensation regardless of recruitment or eligibility status of the family members.

Family members referred by the initial parent/ guardian who contact research staff will have the study described in detail over the phone and will be informed of the $50 compensation for completing the survey. Oral consent will be obtained prior to the survey will be completed either in the home or over the phone.

Asthma Outreach workers: Interested Asthma Outreach Workers will have the study described to them in detail by a JHARC study team member on an individual basis. Asthma Outreach Workers will be told about the study, given an opportunity to ask questions about participation and informed that participation is voluntary and has no effect on their employment status at Johns Hopkins University. Staff participation consists of Asthma training by JHARC staff and a brief knowledge and satisfaction survey pre and post training.

Randomization

Randomization will occur after baseline data collection and the group assignment will be recorded. Children will be individually randomized to either the ABC + HS intervention or HS intervention alone. Blocked randomization will be used so that staff cannot predict which treatment will follow. We will stratify randomization by Head Start program to control for clustering within Head Start programs.

Baseline and Follow-up Assessments

Baseline measures will be collected prior to intervention delivery. The baseline assessment consists of an environmental home assessment, skills checklist, weight and height of the child and a survey, will be completed in the family's home by a research assistant (RA) before randomization. Families who are unable to locate their spacer or state they do not have a spacer, will be provided one at this time. Participants will receive $50 for completing this home visit.

Follow-up assessments will be completed 3-, 9-, and 12- months and will consist of a survey that will be completed over the phone. Participants will receive $30 for completing these phone visits. 6-month followup assessments will be conducted in the home and consist of an environmental home assessment, skills checklist, weight and height of the child and a survey. Participants will receive $50 for completing this home visit.

Current Medication Treatment Plan (CMTP)

A CMTP for each participant will be obtained from the child's asthma care providers at Baseline and 12 month follow-up vists. The CMTP will contain information about start and end dates for asthma medications as well as drug name, dose and prescribed frequency.

Pharmacy Refill History

Medication refill data will be obtained by faxing all family-identified pharmacies and their pharmacy benefits managers or insurance payer. We will get the refill records for one year before joining the study and following their 12 month phone survey (or 12 months after randomization if the 12 month visit is not completed) .

Health Outcome data

When available, healthcare utilization data will be obtained from insurance payers to validate caregiver report of utilization. This information includes: hospitalizations, ED visits, and PCP visits.

Head Start Staff Assessments

Prior to the delivery of the HS-level asthma education program at a HS program, all staff members (Family Service Coordinators, Teachers, Administrators) at HS centers (N=500) will be asked to complete a survey about knowledge, attitudes and practices related to asthma management. The survey will also include questions about personal knowledge about asthma management and Head Start policies about asthma management, their own health beliefs about asthma management, asthma beliefs about barriers to asthma management, and how often they engage in professional activities related to asthma management either directly with the children or indirectly in parent or staff trainings. The questionnaire will explicitly indicate that survey data will be maintained without personal identifiers and that completion of the survey indicated consent. Staff members who complete and return the survey will receive $10 compensation each year. This survey will also be completed immediately prior to initiation of the HS asthma educational staff workshops and materials distribution and in years 2 and 5. Staff may return the survey to a locked box at the site or by mail (envelope provided). Surveys will be distributed a second time to nonresponders.

Intervention

We propose to conduct a randomized controlled trial of a home-based asthma education intervention for Head Start students, nested within the context of a HS-level asthma education program. We will partner with Baltimore City Head Start to assist them in implementing this HS-level asthma education program across all Head Start programs. We describe below the randomized trial and our role in the HS-level asthma education program.

Control Condition (CC).

All participants who enroll in the trial and are randomized to the control condition will receive (along with all other Head Start students) Head Start-based asthma educational activities and materials. CC participants will be contacted for follow-up assessment at 3, 6, 9, and 12 months.

Intervention Condition (IC).

Participants randomized to the intervention condition will also receive the HS-level asthma education program activities and materials. In addition, participants will receive a culturally-specific home-based asthma education intervention, specifically designed to reflect known cultural barriers to effective asthma management among low-income minority families .Over the course of the intervention the family will receive four weekly home visits (30-45 minutes each; approximately 1-, 2- 3-, and 4- weeks postrandomization) and three quarterly phone sessions (20-30 minutes each, after the completion of each follow-up assessment) by a trained asthma educator. The asthma educator has the knowledge, comfort and experience with the community. The asthma educator overarching goals for intervention are to address known cultural barriers including underutilization of asthma primary care, overestimation of asthma control, perceptions that asthma is an episodic illness that only needs acute treatment, negative beliefs about controller medications, and environmental risk factors in the home. The intervention will begin by

assessing the family's asthma control and management practices. The asthma educator will review the direct, measurable benefits of preventative asthma care, home environmental risk factors, steps to take during an asthma exacerbation, providing low-literacy written asthma education materials and training on using medication devices, if prescribed. The asthma educator will also provide feedback on the child's current level of control following NAEPP guidelines, using a validated asthma control measure. Additionally, the asthma educator will discuss the caregiver's barriers and facilitators to accessing regular asthma care and daily self-management. The caregiver will be encouraged to set a personally relevant asthma goal (e.g., attending a PCP visit, giving the child medicine once a day), and problem solving will be used to collaboratively develop a plan to achieve the goal. A core component of the educational intervention is empowering and supporting caregivers to more effectively communicate with the child's PCP about their child's asthma.. Asthma education will be presented using strategies recommended by the Joint Commission for working with low literacy patient populations. The asthma educator will be trained to use plain language and to avoid medical jargon, and will limit information presented to two or three key elements. The asthma educator will use the "Tell me back/show me" strategy whereby the caregiver is asked to repeat the information provided in his/her own words or demonstrate a skill, and additional teaching is provided until there is full comprehension of the concept. As much as possible the asthma educator will use drawings, models, or diagrams. All intervention visits will be audio-taped. Some families will be asked to have their visits videotaped. If families agree to have their visits videotaped, they will be asked to sign another consent form. If they refuse to have their visits videotaped it will not affect their ability to participate in this study.

"ABC Report". After enrollment, the child's caregiver-identified PCP will be faxed a letter describing the study and informing them of their patient's participation. They will be invited to call the research team if they have any questions. They will be asked to complete the Current Asthma Treatment Plan (CATP) form. The asthma educator may contact the PCP as a part of study interventions; such contacts are integral components of the intervention and reflect the appropriate partnering and inclusion of the physician. After the first intervention session, the asthma educator will prepare the "ABC Report" which will include collected information relevant to asthma management, including: (1) feedback on the child's level of asthma control, medication reconciliation if necessary (e.g., an indication if the medications in the home and family reported regimen do not match the CATP), environmental triggers (from the home assessment), and psychosocial concerns affecting asthma management; and (2) information the asthma educator has provided to the family (e.g., smoking cessation referral). The "ABC Report" will be faxed to the PCP with the family's knowledge and permission.

Asthma Outreach Workers education program

In order to learn what skills work well to train asthma outreach workers we would like to conduct pre-post assessments with our hired asthma outreach workers. We will administer an assessment prior to any training and after training is completed. Training will include didactic lectures, hands-on practice with devices, role plays and supervised intervention sessions. We hope to learn if we are able to effectively train community workers to provide asthma education to families.

HS-level asthma education program

In order to enhance the efficacy, reach, integration and sustainability of the proposed home-based asthma education intervention, we will train and facilitate Head Start staff to implement and deliver the HS-level asthma education program, utilizing existing community resources whenever possible. The HS-level asthma education program will consist of the following four components: 1) bi-annual Staff Training Workshops (for which HS staff will receive continuing education credit), 2) provision of relevant asthma educational materials drawn from public resources, 3) identification and facilitation of community resources relevant for achieving goals, and 4) ongoing expert facilitation of Head Start initiated asthma education activities (e.g. parent workshops, health fairs, newsletters)

a. Study duration and number of study visits required of research participants. The study duration is 12 months for each participant. All participants will complete 5 surveys. The intervention condition will also receive 3 home visits and 4 phone calls. Head Start staff will be offered the opportunity to attend asthma education workshops which contain 8 modules and a postevaluation two times a year.
b. Blinding, including justification for blinding or not blinding the trial, if applicable. N/A
c. Justification of why participants will not receive routine care or will have current therapy stopped.

   All subjects will receive an asthma educational program within the Head Start setting which is not currently provided. Participants in the intervention condition will receive additional intervention.
d. Justification for inclusion of a placebo or non-treatment group.

   Both groups will receive a Head Start level educational intervention, thus there is no nontreatment group. The intervention group will receive additional intervention sessions.
e. Definition of treatment failure or participant removal criteria.

   Any participant can leave the study at any time. Participants will be removed from the study prior to randomization if the baseline assessment is not complete. Treatment failure is defined as subjects not completing the home visits. After the participant is randomized, subjects will not be removed from the study by investigators.
f. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

This study does not provide experimental medical care for the participants but does encourage the families to keep all appointments with the child's PCP. The child's medical care will not be affected if the family ends their participation in the study prematurely. There are no known risks of exiting the study prematurely.

5. Inclusion/Exclusion Criteria

Inclusion:

- Age 2-6 years
- Currently enrolled in Baltimore City HS program
- Physician diagnosis of asthma or reactive airway disease (RAD)

Exclusion:

- Current participation in another respiratory research study
- Families unwilling or unable to participate
- A sibling enrolled in the study
- Non-English speaking
- Plans to move out of the Baltimore area in the next year Living in transitional housing

6. Drugs/ Substances/ Devices N/A

a. The rationale for choosing the drug and dose or for choosing the device to be used.
b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.

Study Statistics

a. Primary outcome variable.
The primary outcome is symptom free days which is a well-recognized, accepted index of asthma morbidity often used to assess the effectiveness of new therapies in children. A measure of SFD is calculated by subtracting the numbers of days and/or nights with asthma symptoms (i.e., cough, wheeze, shortness of breath) in the past month from 30 days. Studies utilizing clinical and education interventions have demonstrated that improvements of 2-3 SFD /month are feasible and clinically meaningful.

b. Secondary outcome variables.
Secondary outcomes include caregiver-reported healthcare utilization for urgent (ED visits and hospitalizations) and non-urgent (primary and specialist care) asthma visits, caregiver-reported oral steroid bursts, caregiver-reported asthma control and caregiver quality of life. We will also collect objective data on healthcare utilization from insurance payers to validate caregiver report. In addition, at the HS level, we will assess overall HS participation in the HS-level asthma education program and any additional programs or institutional changes that would indicate adoption, implementation and maintenance of asthma education as a core HS health goal and changes in HS staff knowledge, attitudes and practices related to asthma management.

c. Statistical plan including sample size justification and interim data analysis.
The power analysis is based on differences in symptom free days between the ABC group and the control group. We expect to recruit 406 total families (203 each group) and anticipate up to 15% of those enrolled will be lost to follow-up for a final sample of 346 families included in the analyses. We chose this sample size because under a variety of scenarios, discussed below, it is considered sufficient to detect a similar increase in symptom free days seen in our previous study. Symptom free days will be assessed at baseline, 3-, 6- 9- and 12-months postrandomization. Choices for treatment effects, variability, associations (to account for the longitudinal nature of the study), and loss to follow up rates were informed by our previous

study, as well as from the literature. The power calculations were obtained using the software package SAS version 9.2 (SAS Institute, Cary NC). We expect that both groups will have a mean (SD) number of symptom free days 23.65 (6.85) in a month at baseline. In our previous study, the ABC group experienced a 23% increase in symptom free days over the no-contact control group at 6 months post-randomization. This application proposes to achieve a similar, if not higher, increase in symptom free days at 6 months. Table 1 gives a summary of the estimated total sample size that we will need to detect effect under different power assumptions (power = 0.8, 0.9) and within-subject association (parameterized as a latent effect inducing correlations of (ρ = 0.5, 0.6, or 0.7). Inspection of the table below reveals that we will have 90% power to detect an approximate 23% increase in symptom free days for the ABC group at 6 months post-randomization.

Table 1

Power = 0.8		Power = 0.9	
ρ	Estimated Total N	ρ	Estimated Total N
0.5	188	0.5	248
0.6	236	0.6	316
0.7	268	0.7	346

Data will be summarized by intervention group (blinded for any interim analyses). Initially we will examine both groups (ABC and Control) for differences in baseline independent/covariate variables (i.e., age, gender, and maternal age). Standard goodness-of-fit tests will be used to determine the approximate normality of the continuous demographic data and response variables under each hypothesis. Data will be transformed as appropriate before hypothesis testing is performed. It is common in prospective studies for a non-trivial fraction of the participants to be lost to follow-up during the course of the study. All outcome analysis will be based upon the intent-to-treat principle (ITT). The sample size calculation and the analytic plan anticipate a 15% loss to follow-up. From a statistical perspective, dropouts can be classified into two major groups: ignorable and non-ignorable. For the former, the probability of dropping out depends upon measured variables, e.g., severity of disease, age and gender. Nonignorable dropouts occur when the probability of dropping out depends upon unobserved quantities, e.g., the outcome that would have been observed had the person not dropped out. We will use statistical methods (weighted Generalized Estimating Equations or likelihood methods) that provide consistent inferences about the intervention effect for ignorable dropout processes. However, all methods of inference can be biased by non-ignorable dropouts. We will conduct sensitivity analyses to determine how extreme the non-ignorable missingness must be to severely compromise the major substantive findings of this research. We will also conduct interclass correlations (ICC) among children recruited from the same HS program for all outcome variables to test if our randomization schema worked. Since we will stratify our randomization by HS program, we anticipate that an equal number of children will receive the

ABC intervention compared to the control. However, if the ICC values indicate a cluster effect, this will be included in our models as nested data models.

Dr. Callaghan-Koru at University of Maryland-Baltimore County will be completing secondary data analysis. UMBC has requested that Johns Hopkins Medicine IRB serve as the site's IRB. De-identified data sets will be sent by Johns Hopkins via HIPAA and JHMI compliant protocols and study participants will not directly interact with UMBC.

d. Early stopping rules.
The DSMB will develop early stopping rules based on their review of the study protocol. Once these rules have been developed they will be shared with the IRB.

7. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency. Parents may be uncomfortable discussing the child's asthma. Some families may experience possible family discord if the asthma management practices change. Asthma educators will be trained to interact with families in a positive, non-judgmental manner that encourages honest communication and a partnership approach to asthma education. Care will be taken to help family members discover ways that they can all work together to better manage the child's asthma.

Maryland law requires us to tell the local or state authorities if we suspect abuse or neglect of a child or dependent adult. If anyone reports that they plan to harm someone, we are required to contact the police. We may also warn the person who is at risk. The caregiver will be informed of the limits of confidentiality during the informed consent process and reminded of this during the first home visit. There are no risks to HS staff completing the staff survey.

b. Steps taken to minimize the risks.
Asthma educators are trained to learn how to clinically address family conflict about asthma practices. The family may refuse to allow the home visits at any time. If this were to happen, the child would continue to be followed and we will categorize him/her as receiving low dose intervention.

c. Plan for reporting unanticipated problems or study deviations.
In the event that any adverse event occurs during the course of the study, the adverse event will be reported to the Johns Hopkins University School of Medicine IRB using the IRB's Protocol Event Report by PI Form with suporting documentation of the adverse event and will also be reported to the study DSMB.

d. Legal risks such as the risks that would be associated with breach of confidentiality.
The only legal risk associated with participating in this study is the breach of confidentiality for the family in disclosing the child's participation in the study or data provided about the child. For confidentialty protection, the identify and personal information of each subject will not be used in communication of the data and each subject will be assigned a unique study number for

identification. All data will be held confidential and stored in locked files, accessible to authorized staff and investigators only. All staff members have completed the IRB certification so they are all aware of the importance of patient confidentiality. All newly hired staff will not be allowed access to any study information until they have completed and passed all IRB human subjects research certification examinations.

e. Financial risks to the participants. N/A

8. Benefits

a. Description of the probable benefits for the participant and for society.
The family may learn strategies to manage asthma in chidlren and thereby reduce moribidities associated with asthma. Study findings may provide evidence on how to improve clinical care to this vulnerable population of young children.

9. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

The child's parent/legal guardian will be given $30 for completing each of the phone surveys and $50 for each home visit, totalling$190. The parent/ legal guardian will receive an additional $50 if they choose to complete the family survey and a $20 incentive for each referral, for a maximum total of $150.

Head Start Staff members will be given $10 for completing each of the staff surveys for a total of $30.

Head Start teachers and family service coordinators (FSCs) will be paid $50 each when they achieve 80% completion rate of the ISS forms for their class (teacher) or classes (FSC)

Interested Family members will receive $50 for completing the Family Health Questionnaire.

10. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them. N/A