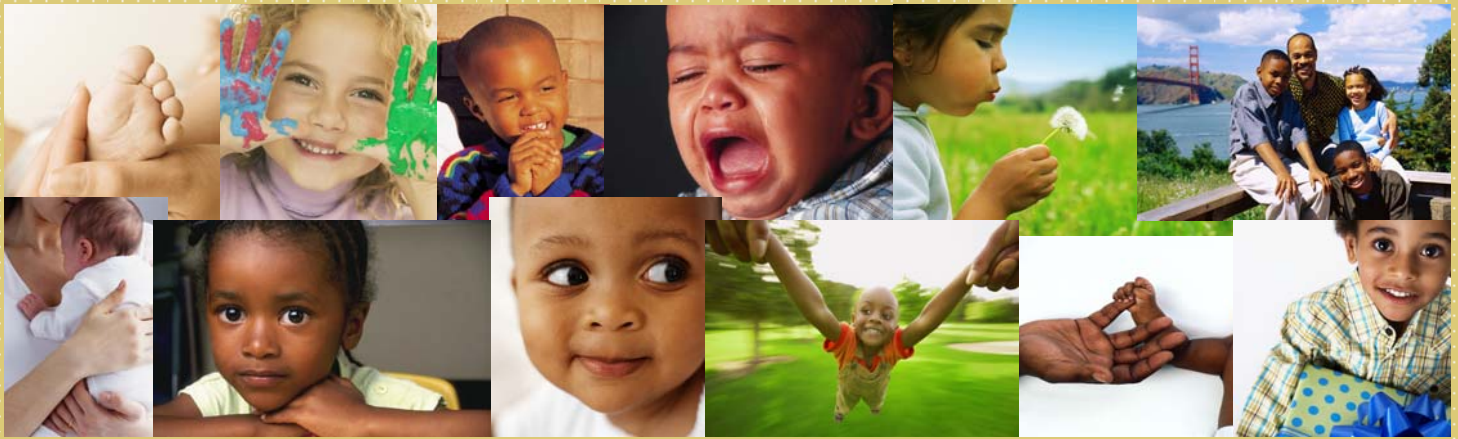


Findings and Recommendations



Sinai's Pediatric Asthma Intervention-2:

Use of Lay Health Educators to Improve
Asthma Management Among
African American Children

June 2004 – August 2006

Sinai Urban Health Institute
and



April 2007

Report on the Findings and Recommendations of

Sinai's Pediatric Asthma Intervention-2: Use of Lay Health Educators to Improve Asthma Management Among African American Children

June 2004-August 2006

Sinai Urban Health Institute &
Sinai Children's Hospital

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TABLE OF CONTENTS

Executive Summary.....	i
Introduction to Sinai's Pediatric Asthma Intervention 2.....	1
Description of the Intervention.....	5
Study Methodology	11
Results.....	17
Lessons Learned & Challenges.....	43
Recommendations	47
Conclusion	53
References.....	57
Appendices	63

LIST OF FIGURES AND TABLES

Figure 1	Summary of the Recruitment and Enrollment Process for PAI-2.....	12
Table 1	Summary of Data Collection Activities.....	13
Table 2	Demographic and Selected Healthcare Characteristics Upon Enrollment into PAI-2	18
Table 3	Asthma-Related Health Resource Utilization in the Baseline Year among those Enrolled into PAI-2.....	19
Table 4	Frequency of Asthma Symptoms, Asthma Attacks, and Activity Limited Days among those Enrolled into PAI-2 as reported at the time of the Baseline Visit.....	19
Table 5	Pediatric Asthma Caregiver's Quality of Life Scores at Baseline.....	20
Table 6	Individual Knowledge Quiz Questions and the Proportion Answering Correctly at Baseline	21
Table 7	Exposure to Cigarette Smoke Reported at Baseline Visit.....	21
Table 8	Most Prevalent Environmental Triggers Identified during Baseline Visit.....	22
Table 9	Most Commonly Reported Triggers (i.e., what triggers the child's asthma) – Baseline.....	22
Table 10	Primary Medication Method among Enrolled PAI-2 Participants	23
Table 11a	MDI Technique Among Children Using an MDI at Baseline	24
Table 11b	DPI Technique Among Children Using a DPI at Baseline	24
Table 12	Proportion of Children Completing Each Educational Visit and the Total Number Completed.....	25
Table 13	Completion and Timeliness of Follow-up Data Collection Among Those Completing the Evaluation Phase	26
Figure 2	Participant Enrollment, Follow-up and Attrition.....	27
Table 14	Symptom Frequency in the Past 2 Weeks (mean) at Baseline vs. 6-month and 12- month follow-up.....	28
Figure 3	Symptom Frequency in Past 2 Weeks - Baseline vs. Average of Follow-up	29
Table 15	Asthma-Related Health Resource Utilization and Activity Limited Days in the Year Prior to and Following the Intervention.....	31
Figure 4	Pediatric Asthma Caregiver Quality of Life Scores at Baseline vs. 6-month and 12- month Follow-ups.....	32
Figure 5	Asthma-Related Knowledge of the Child's Primary Caregiver at Baseline, 2-weeks, 3 months, 6 months and 12 months.....	32
Figure 6	Asthma Management Parental Self-Efficacy of the Child's Primary Caregiver at Baseline, 3 months, 6 months and 12 months.....	34
Table 16	Main Findings of Home Trigger Assessment Related to Cigarette Smoke Exposure and Eight Other Triggers at Baseline, 6-months and 12-months	35
Table 17	Exposure to Common Home Triggers at Baseline, 6-months and 12-months.....	36
Table 18	Primary Method Used in Administering Asthma Medications at Baseline vs. 6 Months.....	37
Table 19a	Proportion Carrying Out Appropriate Steps when Using a Metered-Dose Inhaler among those with a Metered-Dose Inhaler at Baseline vs. 6-month Visit.....	38
Table 19b	Proportion Carrying Out Appropriate Steps when Using a Dry Powder Inhaler among those with a Dry Powder Inhaler at Baseline vs. 6-month Visit	39

Figure 7 Evaluation of Technique Score, Baseline vs. 6 Months39

EXECUTIVE SUMMARY

Rationale:

Asthma affects 12% of children in the United States, with some of the highest rates being reported among inner-city, African American children. Chicago has been shown to be particularly affected by the disease. A tendency to rely heavily on the emergency department (ED) for asthma care has also been documented among disadvantaged populations. As the focus in the ED is on the treatment of acute symptoms, many frequent ED users are not properly medicated or educated on asthma self-management. In addition, poor, minority children living in the inner-city often have other complicating factors in their lives that make it difficult for even an educated caregiver to properly manage their child's asthma.

Mount Sinai Hospital, located in the heart of Chicago's poverty-stricken, primarily African American and Hispanic west side, sees a disproportionately high number of children with asthma each year. Sinai first responded to the pediatric asthma problem that plagues the communities we serve in July 2000, when we initiated our first Pediatric Asthma Intervention (PAI) project. PAI tested the effectiveness of three increasingly intensified approaches combining individualized, one-on-one asthma education with or without case management in improving asthma outcomes among African American and Latino children with asthma. The intervention was carried out by a trained community Lay Health Educator (LHE) in a clinic setting. The most striking finding of PAI is that any intervention seemed to make a difference in the control of asthma exhibited by participants. Participants in all three groups utilized significantly fewer emergency health care services in the year following the initiation of the intervention. Given the degree of improvement in urgent health resource utilization, the approach was also found to be highly cost-effective.

Building upon our experiences with PAI, and the existing literature pertaining to effective asthma interventions with inner-city children, our goal was to design, implement and evaluate an intervention that would educate and empower children with severe asthma and their families, while simultaneously facilitating the establishment of a relationship with a Primary Care Provider (PCP). In 2004, with pilot funding from the Illinois Department of Public Health (IDPH), the Sinai Urban Health Institute (SUHI) and Sinai Children's Hospital were able to implement a project to assess the effectiveness of using Community Lay Health Educators (LHE) in improving asthma management among African American children with severe asthma living in the inner-city.

The project was formally entitled, *The Use of Lay Health Educators to Improve Asthma Management Among African American Children*, but is generally referred to as PAI-2.

Goal:

The pilot project (PAI-2) assessed the effectiveness of using a LHE in reducing asthma morbidity and improving quality of life among children with poorly controlled asthma. Specifically, we aimed to improve asthma management among inner-city African American children with severe asthma and thereby: (1) decrease asthma-related morbidity and (2) improve quality of life.

The Intervention:

The project utilized trained LHEs recruited from inner-city, predominantly African American communities, similar to the target communities, to teach children and their families how to more effectively manage asthma. The education provided to the family was individualized and was provided in the family's home whenever possible.

Two part-time LHEs were recruited from the predominantly African American communities served by Mount Sinai Hospital. The LHE did not need to have any prior experience with asthma. Rather, we were interested in locating individuals with a cultural connection to the target communities and a passion for positively impacting on the lives of the people living within those communities. Once the LHEs were identified, they participated in a 5 day, intensive asthma training class. In addition to the formal sessions, the selected LHEs received further training by working closely with the Pediatric Asthma Educator for Sinai Children's Hospital, who also served as their Supervisor.

Participants were recruited primarily from the ED and inpatient units of Sinai Children's Hospital and also via referrals from community physicians. Eligible children had severe, uncontrolled asthma, were between the ages of 2-16 years, and were African American.

Once trained, LHEs conducted 3-4 home visits during a 6-month period with each participating family, providing individualized asthma education. The LHE also served as a liaison between the family and the medical system, helping to bridge the gap between parents and PCPs. When necessary, the LHE, in consultation with the appropriate Sinai staff, also provided basic case management services.

Study Methodology:

The success of PAI-2 in meeting its goals was evaluated using a pre-post test methodology with each child serving as his/her own historical control. While a randomized controlled trial is the gold standard in evaluation methodology, this was a pilot project with limited funding. Participants were followed for one year post-baseline for evaluation purposes. Data was collected by a Research Assistant at the time of the baseline visit, via monthly phone calls through month 6, and then every two months through month 12. The main outcomes assessed included asthma symptom severity (in the past 2 weeks), frequency of asthma-related emergency health resource utilization, caregiver quality of life, asthma-related knowledge of the caregiver, and the belief (self-efficacy) of the caregiver that he/she is able to manage the child's asthma. In addition, we assessed whether the intervention was effective in decreasing the number of triggers to which the child is exposed, whether medications were being used correctly, and whether families had an Asthma Action Plan that they understood how to use.

Results:

Between November 15, 2004 and July 15, 2005, 70 children were enrolled into the study. Ninety-six percent of enrolled children were insured by Medicaid and 54% lived with a smoker. The average child was 7.3 years old and had visited an ED, been hospitalized or visited a physician for worsening asthma 6.5 times in the year prior to participation. Fifty-eight (82.9%) completed the entire 6-month intervention phase. The outcome analysis was limited to the 50 (71.4%) children who completed the entire 12-month evaluation phase.

Primary Goal 1: Decrease asthma-related morbidity

The findings strongly suggest that our primary goal of decreasing asthma-related morbidity by improving asthma control was met. Specific outcomes examined included four symptom-related variables, asthma exacerbations, wheezing episodes, and urgent health resource utilization. Statistically significant improvements were noted for the majority of examined outcomes. Specifically, approximately two-fold reductions in the frequency of asthma symptoms were noted between the two-weeks preceding the baseline visit and the follow-up period. Urgent health resource utilization also decreased significantly over the follow-up period. For example, ED visits decreased from 3.4 times in the year prior to the study to 0.9 in the year following ($p < 0.05$).

Primary Goal 2: Improve the Quality of Life of the child and the caregiver

Parental Quality of Life is an indicator of the impact of improved asthma control on the family's overall well-being. Parental Quality of Life scores increased significantly from 5.2 (out of a maximum of 7) at the time of enrollment into the intervention to 5.9 ($p < 0.05$) by month 6 and 6.0 ($p < 0.05$) by month 12. Other studies have suggested that changes of this magnitude are associated with clinically significant improvements in outcomes.

Secondary Goals

The project also had four secondary goals (variables on the pathway to successfully meeting the primary goals). Over the follow-up period, improvements were noted for the majority of outcomes utilized in measuring our progress in meeting these secondary goals. Specifically, asthma-related knowledge improved significantly, exposure to asthma triggers in the home decreased (most notably, exposure to secondhand cigarette smoke), medication use improved, and there was a notable increase in the obtainment of Asthma Action Plans.

Lessons Learned & Challenges:

Several important lessons were learned through the process of this pilot intervention. Among the most poignant:

- Having a LHE from the target Community who shares a cultural connection with participants is key in ensuring the acceptability of the intervention and its success.
- When hiring a LHE, one should look for an individual who possesses a true passion for giving back to the community, is willing to take initiative and go the extra mile in ensuring that families have the information and resources they need, and is able to think critically and problem solve.
- Considerable resources need to be spent upfront in training LHEs, and on-going continuing education should be provided. LHEs often need to develop skills beyond asthma and the teaching of asthma (e.g., computer and organizational skills).
- Proper supervision of LHEs is vital to the success of the intervention. The Supervisor should be readily accessible for consultation and needs to be proactive in ensuring the quality of the intervention.
- Home visits help ensure that the most vulnerable of families, and therefore those most in need of intervention, are reached.
- Many children have multiple caregivers. While our goal was to at a minimum educate the primary caregiver of the child, the intervention was most effective when we were able to educate all those involved in the child's care.

The project experienced certain challenges that are important to touch on:

- One of our greatest challenges involved the transient nature of our target population and the instability of their lives.
- Many of the caregivers who participated lived with another family member or friend, and therefore did not have total control over the environment in which they lived.
- Physician buy-in was necessary to make certain aspects of the intervention plausible and effective.
- Many families were seeing multiple physicians (i.e., seeing whichever physician was convenient at the time), and as a result most children did not have an established relationship with one doctor who was managing their asthma.
- The level of cigarette smoke exposure to which children living in the target communities were subjected on a daily basis was extraordinarily high.

Recommendations:

Our findings suggest that LHEs providing one-on-one, individualized asthma education to inner-city African American children with severe asthma may be an effective means of improving knowledge and thereby asthma management and outcomes. While we have not yet completed a formal cost-benefit analysis, the two- to four-fold reductions in urgent health resource utilization between the years prior to and following the intervention combined with the relative low cost of implementing the program strongly suggest this approach will also prove highly cost-effective. We therefore recommend that public funding for models utilizing LHEs be increased, allowing for the testing of the feasibility and effectiveness of the model in a variety of settings, among diverse communities, and with other chronic diseases.

One opportunity to test the approach on a larger level and among diverse communities has been afforded by the IDPH funded initiative entitled *Controlling Pediatric Asthma Through Collaboration and Education (CPATCE)*. As a part of this initiative, the PAI-2 LHE model is being pilot tested in six target areas throughout Illinois which suffer a disproportionate asthma burden. These areas are diverse in terms of urbanicity, race/ethnicity, and socioeconomic status. SUHI and Sinai Children's Hospital have been funded as the coordinating, training and evaluation entities for *CPATCE*. The *CPATCE* initiative has also allowed us to expand our own intervention to encompass more of Chicago's high-risk communities, including the Latino community.

Other recommendations:

- Community clinics in disadvantaged neighborhoods should routinely provide asthma education. The person responsible for providing the education should be someone other than a physician. A nurse, medical assistant or LHE could fill such a role, providing he/she is trained on both asthma management and effective communication.
- Since children with severe, uncontrolled asthma are likely to utilize the ED somewhat regularly, we also recommend that every inner-city ED with a high number of asthmatics consider implementing an asthma program facilitated by a LHE.
- Medicaid and other insurance providers should be encouraged to provide reimbursement for asthma education provided in a clinic, hospital or ED setting by someone other than a physician.
- ED physicians should receive additional training regarding the standard care and treatment of pediatric asthma, and on the NHLBI Guidelines.

- One limitation of the current project is that there was no control group against which the findings could be examined. A randomized controlled trial of a LHE model should be conducted in the near future to more definitively demonstrate the effectiveness of the approach.

Additional recommendations for LHE Supervisors, healthcare providers, further research, community outreach and public policy are included in the body of the Report.

Conclusion:

Our findings suggest that individualized, one-on-one asthma education provided by a trained, culturally competent LHE in the home environment may be an effective means of improving asthma management among inner-city, African-American children with poorly controlled asthma. The pilot study provides evidence of improved asthma outcomes, quality of life and asthma-related knowledge, and of decreased exposure to triggers among families participating in the intervention. Given the degree of improvement in urgent health resource utilization combined with the relative low cost of the intervention, the intervention will likely prove cost effective as well. Nonetheless, further studies with a more stringent study design are needed to affirm our results and assess the model's generalizability.

INTRODUCTION

Rationale:

Several studies have shown that minority children, particularly those living in the inner-city, suffer from high levels of asthma morbidity and mortality.¹⁻⁹ Some of the highest rates have been documented among African American children. Many of these children utilize the emergency department (ED) as their primary source of asthma care.^{3,4,10-13} The focus of asthma management in the ED is usually on the treatment of acute symptoms; therefore, many of these children are not properly medicated. Also, the majority of these children and their families have never been properly educated on appropriate disease management. While the caregivers of children who are seen in the ED or are hospitalized for asthma are encouraged to follow-up with their primary care physician (PCP) in the near future, many do not follow through. Others do not have a PCP. For those who do follow-up with their PCP, the hectic setting of an inner-city physician's office often makes it impossible for the physician to provide them with the education they need regarding the proper management of asthma. In addition, poor, minority children living in the inner-city often have other complicating factors in their lives that make it difficult for even an educated caregiver to properly manage their child's asthma. A team-based, comprehensive approach to the care of children with severe asthma that incorporates proper medical care, comprehensive and reinforced education and case management is clearly necessary.

Chicago is one of the cities hardest hit by the surging asthma epidemic.¹⁴⁻¹⁶ Mount Sinai Hospital, located in the heart of Chicago's poverty-stricken, primarily African American and Latino west side, sees a disproportionately high number of children with asthma each year. Approximately three children seen at Mount Sinai for asthma are black for every one that is Hispanic. Findings from the Sinai Urban Health Institute's (SUHI) *Improving Community Health Survey*¹⁷ suggest that the rates and effects of asthma in the communities surrounding Sinai are immense. The results of the survey revealed extraordinarily high proportions of children with asthma in several of the more disadvantaged and predominantly minority communities surveyed. For example, the proportion of children likely to have asthma (diagnosed or screened positive based on symptoms indicative of asthma) reached 23% in North Lawndale, the nearly entirely non-Hispanic Black community area in which Mount Sinai Hospital is located. In other words, nearly one in four children in the area immediately surrounding Mount Sinai Hospital has asthma. Not only do they have asthma, but the survey also revealed that only 20% of those who have diagnosed symptomatic asthma are on proper medications. Another astonishing finding revealed that nearly half of children with asthma living in North Lawndale were exposed to tobacco smoke on a daily basis. All of these facts combined suggest that the neighborhoods Sinai serves are critically in need of an intervention in managing asthma in children.

These facts along with our prior experiences with the Pediatric Asthma Intervention (PAI) project, a recently completed randomized controlled trial aimed at improving the management of asthma in children served by the hospital, were the motivating factors behind the pilot intervention project described herein. The findings of PAI have been previously published^{18,19} and a report summarizing them can be found on our website (www.sinaiurbanhealthinstitute.org). Briefly, the central hypothesis of PAI was that the most economic and effective path to maximizing the health status of inner city children with asthma is through a process of case specific, one-on-one

reinforced health education combined with case management services. The study participants included children (1-16 years) with asthma who were randomized into three groups: Group One (G1) was provided with a single, one-on-one asthma education session with a trained asthma educator, Group Two (G2) received the same initial education session, but that education was reinforced as needed on a monthly basis (via phone calls), and Group Three (G3) participants received reinforced asthma education with the addition of case management. All participants in each group received an evaluation by a pediatric pulmonologist at their initial visit to ensure proper medical management. Results found that all three groups utilized significantly less emergency health care services in the follow-up year. The magnitude of the declines in utilization averaged across all three groups was enormous: about 81% for hospitalizations, 69% for hospital days, 64% for ED visits, and 58% for clinic visits. Differences in the degree of improvement among the three study groups for these utilization measures were also examined. While there were no significant differences among study groups for 4 of the 5 main outcome measures, G3 participants consistently improved to a greater degree than G1 or G2. Furthermore, the PAI project also proved to be cost-effective. In fact, the G3 intervention, which provided case management services along with reinforced asthma education, resulted in cost-savings of \$4778/patient/year over costs incurred during the baseline year. This translates to \$13.29 saved/\$ spent on the intervention. The findings of the PAI clearly support the utility and cost-benefit associated with providing health education combined with case management services to pediatric patients who are high utilizers of urgent care services.

Building upon evidence concerning the characteristics of children with asthma in the population we serve, the experiences of the PAI^{18,19}, and the existing literature pertaining to effective asthma interventions with inner-city children²⁰⁻²⁶, our goal was to design, implement and evaluate an intervention that would educate and empower children with severe asthma and their families, while simultaneously facilitating the establishment of a relationship with a PCP. In 2004, with pilot funding from the Illinois Department of Public Health (IDPH), the Sinai Urban Health Institute (SUHI) and Sinai Children's Hospital were able to implement a project to assess the effectiveness of using Community Lay Health Educators (LHE) in improving asthma management among African American children with severe asthma living in the inner-city.

The project was formally entitled, *The Use of Lay Health Educators to Improve Asthma Management Among African American Children*, but is generally referred to as PAI-2.

Goal:

To improve asthma management among inner-city African American children with severe asthma and thereby: (1) decrease asthma-related morbidity and (2) improve quality of life. Specifically, we hoped to accomplish the above goals by improving asthma-related knowledge of children's primary caregivers, improving their confidence (i.e. self-efficacy, empowerment) in their ability to properly manage their child's asthma, decreasing the number of triggers to which children are exposed in their homes, increasing the number of children who are on the proper asthma medications and know how to correctly use those medications, and increasing the number of children who have a written asthma action plan that they and their families understand.

Project Overview:

The proper management of asthma requires a combination of access to the right medications, knowing how to correctly use those medications, avoiding triggers, and responding properly when having an asthma exacerbation. A comprehensive approach that aims to improve clinical practice (thereby assuring children are on the proper medications) along with individual self-management knowledge and skills was therefore deemed most appropriate. The pilot project utilized Community Lay Health Educators (LHE) recruited from the inner-city communities targeted by the intervention, to deliver case-specific asthma education in the home environment. The project was coordinated by Sinai Children's Hospital and the Sinai Urban Health Institute.

Two part-time LHEs were hired for this pilot intervention. The LHEs did not need to have any prior experience, as they were trained by our program to teach children and their families how to more effectively manage asthma. Once trained, they would meet with each family 3-4 times over a six month period: once at baseline, once about a month later to reinforce the initial education, once three months post-baseline, and once six months post-baseline. They also followed-up with the families via telephone at least one additional time, and were available for the families to contact as needed. The LHE also served as a liaison between the medical community and the patient. When necessary, the LHE, in consultation with the appropriate Sinai staff, also provided basic case management services.

Our previous experiences with the Pediatric Asthma Intervention^{18,19} and a thorough review of the literature²⁰⁻²⁶ led us to hypothesize that such a comprehensive, coordinated care approach carried out by culturally sensitive LHEs working closely with physicians would prove most effective in improving the management of asthma in the targeted population of inner-city, African American children.

Our success in meeting the project's goals was evaluated, with each child serving as his/her own historical control. Our primary goals were to (1) decrease asthma-related morbidity, and (2) to improve the quality of life of both the child and caregiver. In addition, we assessed whether the intervention was effective in improving the asthma-related knowledge of the child's primary caregiver, improving the caregiver's confidence (i.e., self-efficacy) that they are able to properly manage their child's asthma, decreasing the number of triggers to which the child was exposed, and improving the medical management of the child's asthma.

As the Intervention Phase of the project ended after the 6-month Home Visit, we initially assessed our success in meeting our goals through 6 months of follow-up. We also assessed whether the noted change was maintained through 12 months of follow-up.

DESCRIPTION OF THE INTERVENTION

The project utilized trained Community Lay Health Educators (LHE) recruited from inner-city, predominantly African American communities, similar to the target communities, to teach children and their families how to more effectively manage asthma. The education provided to the family was individualized and was provided in the family's home whenever possible.

The Lay Health Educators: Recruitment & Training:

Two part-time LHEs were recruited from the predominantly African American communities served by Mount Sinai Hospital. These communities include: North Lawndale, East Garfield Park, West Garfield Park and Austin. The LHE did not need to have any prior experience with asthma. Rather, we were interested in locating individuals with a cultural connection to the target communities and a passion for positively impacting on the lives of the people living within those communities. While one can be taught to be an asthma educator provided one has certain core competencies, cultural understanding and perspective cannot be taught. We therefore felt the cultural connection was the most important characteristic in a LHE.

Once the LHEs were identified, they participated in a 5 day, 5 hour per day training class provided by Lenora Coover, RN, MSN-AEC, the founder and President of Pediatric Case Management Services. Lenora has been providing LHE training in the Chicagoland area for several years. Additional community members interested in learning about asthma and potentially serving as LHEs elsewhere in their community were also invited to participate in the training. There were 8 participants all together. The LHEs received a certificate after completing the class.

The curriculum included the basics about asthma pathophysiology, symptoms, triggers and environmental control, management and medications. Significant training was also devoted to the best ways to approach families and keys to successful home visiting. The training was interactive in its nature, with participants engaging in a great deal of discussion and numerous role-playing activities.

In addition to the formal sessions, the selected LHEs received further training by working closely with the Pediatric Asthma Educator for Sinai Children's Hospital, who also served as their Supervisor. As a part of her duties, Sinai's Pediatric Asthma Educator provides one-on-one, comprehensive asthma education to the families of children hospitalized for asthma, and also to those seen in the Pediatric Pulmonology and Allergy specialty clinic. After completing their formal training sessions, the LHEs worked with their Supervisor for approximately two months. For the first month, they mostly shadowed and observed the Supervisor. During the second month, they had the opportunity to provide supervised asthma education in the presence of the Supervisor. During the two-month training period, the Supervisor also did some role playing with the LHEs, and coached them on their teaching style and approach. Finally, the Supervisor accompanied the LHEs to their first few home visits, until she felt confident that they were ready to teach unsupervised.

The training did not end at this point however, but was an on-going process. The LHEs would meet with their Supervisor and Sinai's Pediatric Pulmonologist on a regular basis for continuing education and to reinforce their asthma knowledge and teaching skills.

Recruitment and Enrollment of Participants:

For this pilot intervention, we were interested in recruiting African American children between the ages of 2-16 years who had a previous diagnosis of asthma, and met one of the following criteria:

1. Hospitalized for asthma within the 12 months prior to recruitment
2. Visited the ED for asthma within the 12 months prior to recruitment
3. Had symptoms indicative of moderate persistent asthma.^{27,28}
 - a. Daytime asthma symptoms daily for past 2 months, or
 - b. Nighttime asthma symptoms at least once per week for past 2 months.

Children meeting these criteria were primarily identified via Mount Sinai's ED and inpatient units. Physicians within the target communities were also asked to refer patients who met the study criteria. To be eligible for the study, the onset of asthma symptoms (cough, wheezing, chest congestion, difficulty breathing) had to be at least six months prior to the study enrollment date. Children who had been enrolled in another comprehensive asthma education program within the year prior to being screened for participation were excluded from the study.

The decision to focus heavily on this population of children who utilize emergency services for asthma was made because these children tend to have the most severe symptoms, and are therefore most in need of intervention. It has been documented that primary care is often not being used effectively if at all by inner-city children who are heavy utilizers of the ED.^{3,4,10-13} As such, they are often not properly medicated and have not been educated on proper disease management. They contribute disproportionately to asthma-related health care costs, and therefore helping this group to better control their asthma could result in substantial cost-savings. As over 90% of our pediatric patients are Medicaid insured, the majority of these savings would benefit the Illinois Department of Healthcare and Family Services.

The LHEs were responsible for making initial contact with potential participants and screening them for their eligibility and interest in participating. For those participants who were identified via Sinai's ED or inpatient units, every effort was made to initiate contact within a week of the ED visit or hospitalization, when the memory of the event might be freshest in the caregiver's mind and they might be more receptive to participating. The project's Research Assistant was responsible for routinely using the hospital's Medical Information System to obtain the names and contact information of children who were either seen in the ED or hospitalized for asthma and who met the eligibility criteria. In some cases, the LHE Supervisor would then review the children's medical charts to ensure that they were in fact seen for asthma. The LHE Supervisor was also responsible for obtaining referrals from community physicians and passing the information on to the LHEs.

During the first phone call, the LHE would first inquire as to how the child was doing and whether she could be of any immediate assistance to the family. In the case of children who had been identified because they had been to the ED or had been hospitalized for asthma, the LHE would next determine whether the family has made an appointment with the child's PCP, and if not, would offer assistance in making that appointment. Finally, the LHE would briefly describe the

intervention project to the family, and would determine their eligibility and interest in participating (using the appropriate Recruitment Script in **Appendix 1**). If the child was eligible and the caregiver willing to participate, the LHE would make an appointment with the family for the initial home visit. The project's Research Assistant accompanied the LHE to the first visit, and was responsible for obtaining informed consent and assent (from children 8 years and older). She also asked the family to sign a Health Insurance Portability and Accountability Act (HIPAA) Release of Health Information form. Once all of these forms were understood by the family and signed, the Research Assistant would then collect the identifying and demographic information requested on the "Personal Data Form", as well as all the baseline data (**Appendix 2**) prior to the LHE providing any education. The LHE would benefit from being present during the data collection, as it would allow her to better tailor the education to the particular situation.

The Intervention:

The primary intervention involved **educating the primary caregiver and child on the proper management of asthma**. The LHE would make 3-4 visits over a 6-month period to the participant's home to educate the family about better managing asthma. Generally, the first visit lasted about 60-90 minutes (average time: 88 minutes). During the first 45 minutes or so, the Research Assistant would obtain informed consent and collect the baseline data. The LHE would then offer a 30-45 minute, individualized, intensive asthma education session to the child's primary caregiver. The child was also involved to the level possible given his/her age and level of maturity. This education process was interactive and tailored to the family's unique needs. Our first priority was to address any issues that were of immediate concern to the family. We would try to touch on the following concepts during this session in a format that is easy to understand and culturally sensitive to the family's background:

1. Pathophysiology of asthma
2. Recognition of asthma symptoms and early warning signs of an exacerbation
3. Steps to be taken during an asthma attack
4. Recognition of asthma triggers and their avoidance
5. Concept of quick-relief (i.e., rescue) and long-term controller asthma medications
6. Technique of inhaler and accessory device use
7. Asthma action plan

Written materials were provided to each family as reinforcement of the concepts learned during the session. The last few minutes of the session were devoted to identifying any barriers the family might face in implementing behavioral changes, and helping the family to work through those issues. If appropriate, the LHE would report any needs back to their Supervisor who would then provide case management.

Our initial goal was to go back for a second in-person visit with the family 2-3 weeks after the first. Eighty-eight percent of those completing a 2-week visit did so within a month of the due date. At the time of the 2-week visit, the LHE would first assess the primary caregiver's retention of the information presented during the initial education session by administering the "Asthma Knowledge Quiz" and the "Evaluation of Technique" instruments. The LHE would then reinforce the information that had been presented at the initial visit, and also cover anything that she was not able to cover during the first visit. The average 2-week visit lasted approximately one hour.

The LHE would make two additional home visits: one 3-months following and one 6-months following the initial visit. Besides reinforcing the concepts learned during the initial asthma education sessions, the LHE will strive to identify any barriers to proper management that the family may face during these visits. When appropriate, the LHE, in consultation with her Supervisor and other Sinai staff (e.g., social worker), would also provide basic case management services to the family. Our goal was to have a signed Asthma Action Plan from the participant's PCP prior to the 6-month visit so that we could teach the Plan to the family. The LHE would remain accessible to the family for 12-months following the initial session via telephone. The average 3-month and 6-month visits each lasted about one hour.

The second component of the intervention involved **facilitating the establishment of a relationship with a primary care provider**. The LHE would contact the primary caregiver of eligible children seen in the ED or hospitalized for asthma during the recruitment period, within a week of discharge. The time period was critical, as the memory of the experience would still be fresh in the caregiver's mind and he/she might be more open to following through with an appointment to their primary care physician and meeting with the LHE. The LHE would ask the primary caregiver if they have made an appointment with their PCP, and if they had not, would encourage him/her to do so. If there was a particular barrier that was impeding on the caregiver's ability to make an appointment, the LHE would work with the caregiver to overcome that barrier. If a caregiver indicated that their child does not have a regular doctor, then the LHE would refer the family to one of the six clinics that participated in the physician education piece of the intervention (see below, p. 8).

In a similar manner, the LHE would ascertain whether individuals recruited via the other avenues had been seeing their PCPs appropriately. When they had not, the LHE would offer encouragement and assistance towards doing so.

Finally, the intervention sought to **improve the medical management** of the child's asthma. This goal required the LHE, physicians, and clinic staff to work collaboratively. When we first began the project, we selected six designated study clinics and required that any enrolled participants be patients at one of these six clinics. The six study clinics were selected because they were the clinics that serve the majority of African American children with asthma seen at Sinai's ED, and because they agreed to participate in a physician training program.

The training focused on the optimal medical treatment of asthma in children. It was designed and delivered by Sinai Children's Hospital's Pediatric Pulmonologist. Prior to beginning recruitment for the study, the physicians of each of the six designated study clinics were trained on the proper medical treatment of asthma. He trained the clinic physicians on their roles in effectively treating a child with asthma. The training conformed to the guidelines of the National Heart, Lung and Blood Institute.^{27,28} For example, all physicians were be supplied with a simple set of guidelines to assist them in deciding which controller medication should be prescribed given the severity of the child's asthma and appropriate to the child's age. The importance of a written Asthma Action Plan was also emphasized, and the physician was taught the necessary elements. Finally, physicians were informed as to the role of the LHE and how the LHE might assist them in their work.

A short while after the project began enrolling participants, we realized that many of the children being seen in Sinai's ED or inpatient units had a PCP outside of the six designated clinics. Given we were turning away many children with severe, uncontrolled asthma for this reason, we decided to drop the eligibility criteria requiring that children be a patient at one of the six designated study clinics. Each time a child came into the program with a PCP who we had not yet worked with, the LHE Supervisor would call the PCP to notify them of their patient's enrollment in the program and to introduce them to the project. These PCPs were then sent a letter describing the program and inviting them to refer patients according to the eligibility criteria mentioned above. Because our Pediatric Pulmonologist had not educated these physicians, they were offered the packet of teaching materials used during his education sessions.

One area in which the LHE was of assistance to the PCP was in helping to prepare and teach the Asthma Action Plan. The LHEs were trained on the necessary components of an Asthma Action Plan, and with the information they received from the first two education sessions, would prepare an Asthma Action Plan for the family. They would send the Asthma Action Plan to the physician, along with a letter documenting what had been covered during the first two visits. After having the plan approved by the patient's physician, the LHE would deliver it to the family during her next visit and go through it in detail with the primary caregiver and/or child (as appropriate for age). The LHE, in conjunction with the PCP would revise the Asthma Action Plan as needed throughout the study period.

STUDY METHODOLOGY

Study Design:

The success of PAI-2 in meeting its goals was evaluated using a pre-post test methodology with each child serving as his/her own historical control. While a randomized controlled trial is the gold standard in evaluation methodology, this was a pilot project with limited funding.

The project's primary and secondary goals and the outcome measures associated with each goal are discussed in detail on p.13 below.

As the Intervention Phase of the project ended after the 6-month Home Visit, we initially assessed our success in meeting our goals through 6 months of follow-up. We also assessed whether the noted change was maintained through 12 months of follow-up.

The study took place between November 2004 and December 2006. The Institutional Review Board of the Sinai Health System approved the study initially and at successive annual reviews.

Recruitment and Enrollment Process:

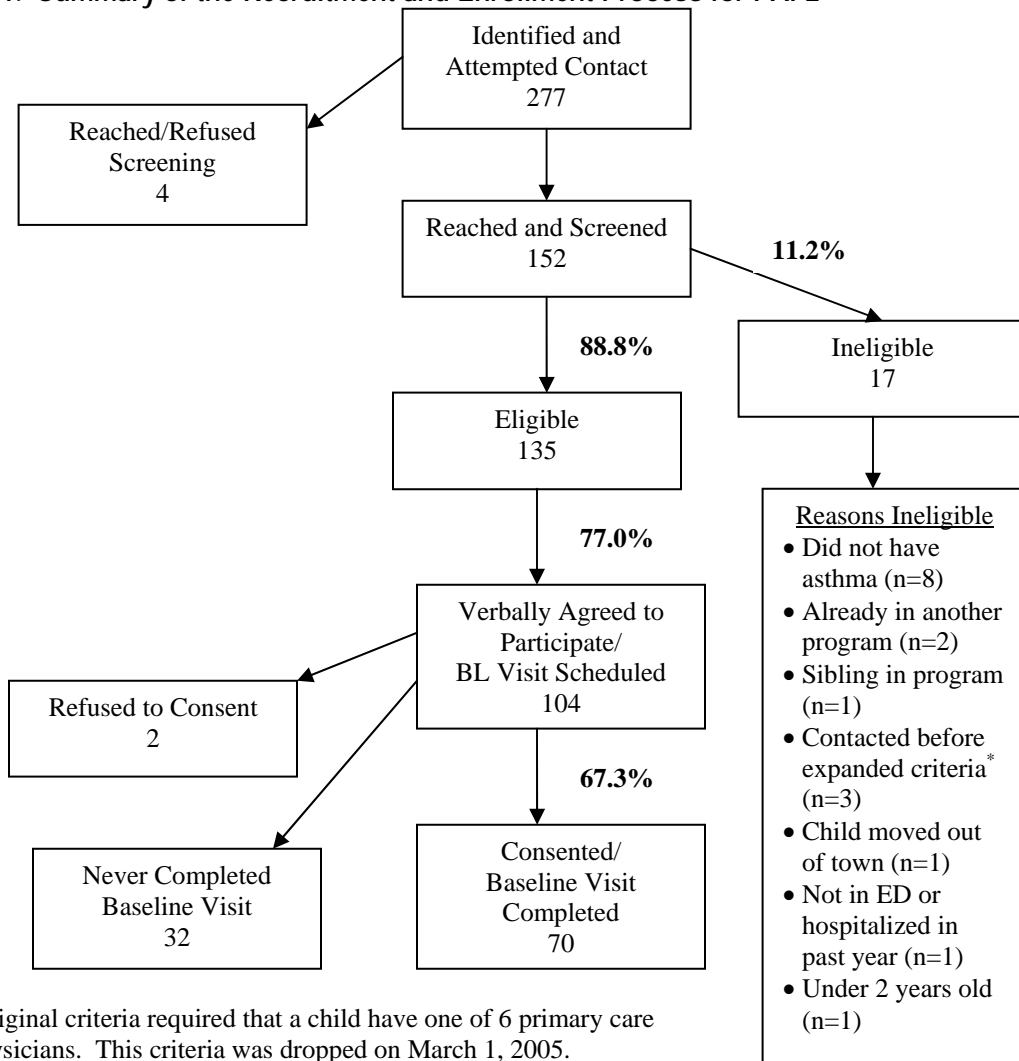
The intervention's eligibility criteria and process are described on p.5 above.

We attempted to contact the primary caregiver of 277 potential participants who were identified through Sinai's ED (n=203), hospital (n=34), and physician referrals (n=40) between November 15, 2004 and July 15, 2005. We were able to get into contact with only 156 of the 277 potential participants (56.3%). Of the 121 that we were not able to contact, 69 (57.0%) could not be contacted due to our having wrong or disconnected phone numbers.

As described on page 7 above, the LHEs were responsible for making initial contact with the primary caregivers of potential participants and screening them for their child's eligibility and their interest in participating. As can be seen in **Figure 1**, of the 156 caregivers contacted, only 4 refused to answer the screening questions. Of the 152 screened, 135 (88.8%) had a child that was eligible per the program's eligibility criteria, of which 104 (77.0%) agreed to an initial meeting with the LHE. Seventy-four percent of those who were eligible but refused to meet with the LHE (n=31) indicated that they were "not interested", providing no further explanation. Among those providing an explanation, responses included that the caregiver did not feel he/she needed education, that the caregiver had limited time, and that the caregiver had undergone some education when the child was hospitalized.

Seventy families (67.3% of those verbally agreeing to participate) completed a Baseline Visit with the LHE, at which time they signed an informed consent form. Only 2 individuals met with the LHE but refused to consent. Thirty-two individuals verbally agreed to participate, but never completed a Baseline Visit.

Figure 1. Summary of the Recruitment and Enrollment Process for PAI-2



Data Collection:

Informed consent was obtained from the primary caregiver of each child during the initial (baseline) appointment. Consent was obtained prior to collecting any data or doing any teaching. The project's Research Assistant was responsible for the majority of the data collection. She accompanied the LHEs to the baseline visit in order to obtain informed consent, the HIPAA waiver to obtain health information, and assent from children 8 years and older, record the identifying and demographic information requested on the "Personal Data Form", and collect the baseline data (all data forms can be found in **Appendix 2**). All data collection was completed prior to the LHE conducting any teaching, so that the data was truly reflective of baseline knowledge and behavior.

The RA collected the remaining data via monthly telephone calls for six months, and then phone calls every two months through 12 months. The instruments were designed and chosen to define the study population, to describe the intervention process, and to assess our success in meeting

our outcome goals. The project's goals were described on p.2. **Table 1** lists the main outcomes to be assessed, the instrument used, and the time points at which the information was obtained.

Table 1: Summary of Data Collection Activities

Purpose/Outcome	Form (s)	Completed by:*	Pre-BL	BL	2-wks	1	2	3	4	5	6	8	10	12
Monitor Recruitment Process	Participant Flow Chart	LHE	x											
Monitor Intervention Process	Participant Log Sheet	LHE	x	x	x	x	x	x	x	x	x			
Demographic Description	Personal Data Sheet	RA		x										
Asthma Related Morbidity	Initial Data Sheet	RA		x										
	Monthly Follow-up	RA				x	x	x	x	x	x			
Caregiver Quality of Life	Pediatric Asthma Caregiver's Quality of Life Questionnaire	RA		x							x			x
Asthma Knowledge	Asthma Knowledge Quiz	LHE/RA		x	x			x			x			x
Self-Efficacy to Manage Asthma	Asthma Management-Parental Self-Efficacy Scale	RA		x				x			x			x
Asthma Triggers	Home/Trigger Assessment	LHE		x				x			x			x
Medications/Proper Use	Initial Data Sheet	RA		x										
	Monthly Follow-up	RA				x	x	x	x	x	x	x	x	x
	Evaluation of Technique	LHE		x	x			x			x			

* RA=Research Assistant; LHE=Lay Health Educator

Outcome Measures:

The project had two over-arching primary goals: (1) to decrease asthma-related morbidity, and (2) to improve the family's quality of life. The following outcome measures were used in assessing the project's success in meeting each:

1. Decrease asthma-related morbidity
 - a. Severity and frequency of asthma symptoms in two weeks prior to data collection time point
 - Assessed at Baseline, Month1-Month 6, Month 8, Month 10, Month 12
 - b. Severity and frequency of asthma exacerbations and wheezing episodes
 - Assessed for year prior to the initiation of the intervention and for the year following the initiation of the intervention
 - c. Asthma-related urgent health resource utilization (ED visits, hospitalizations, and urgent clinic visits)
 - Assessed for year prior to the initiation of the intervention and for the year following the initiation of the intervention
2. Improve the family's quality of life
 - a. *Pediatric Asthma Caregiver's Quality of Life Questionnaire*²⁹
 - Questionnaire captures caregiver's quality of life, which can be used as a proxy for both the child's and the family's quality of life.

- Administered at Baseline, 6 months and 12 months
- Validated questionnaire used extensively in research.
- 13 questions yield an overall Quality of Life Score, an Activity Limitation Sub-score, and an Emotional Function Sub-score
- A change in the quality of life score of 0.5 or more will be considered clinically significant.³⁰

Progress was also monitored toward meeting four secondary goals. The secondary goals are variables that are believed to be on the pathway to helping us realize our primary goals. The secondary goals and related outcome measures were as follows:

1. Improve asthma-related knowledge of the child's primary caregiver
 - a. 10-item Asthma Knowledge Quiz
 - True/False Questions asked in varying order at Baseline, 2 weeks, 3 months, 6 months and 12 months
 - When administered in conjunction with an educational visit, the administration of the questions always preceded any teaching.
 - The Knowledge Quiz was always the first data collection tool administered. This ensured that other forms did not prompt memory and therefore bias the findings around knowledge

2. Improve primary caregiver's confidence (i.e., self-efficacy) that they can properly manage their child's asthma
 - a. *Asthma Management Parental Self-Efficacy Scale*³¹
 - Administered at Baseline, 3 months, 6 months and 12 months
 - Contains 9 questions, 6 of which (#1,3,4,6,7,9) were summed together into a Self-Efficacy score.
 - Certain questions were reverse scored prior to summing (#2,5,6)
 - Maximum score possible is 24.

3. Decrease the number of triggers to which the child is exposed
 - a. Home Trigger Assessment
 - Asks about cigarette smoke exposure, and 9 other triggers (i.e., what "triggers" the child to have an asthma attack)
 - Also assesses the child's personal triggers
 - Administered by LHE at Baseline, 3 months, and 6 months, and by Research Assistant during 12 month phone call

4. Improve the medical management of the child's asthma
 - a. Increase proportion of children who have an Asthma Action Plan that they and their family understand how to use
 - Recorded by LHEs in their notes

 - b. Increase the proportion of children/caregivers who understand their medications and know how to properly use them
 - Evaluation of Technique Form
 - Completed by LHE during each visit after observing the caregiver or child (dependent on age) administering their medications

- Administered at Baseline, 2 weeks, 3 months and 6 months

A more detailed explanation of each outcome measure and the tools used to assess it is presented as each is analyzed in the Report's "Results" section below.

Data Analysis:

Frequencies, means and medians, as appropriate, were calculated for each outcome variable at baseline, and over the follow-up period associated with that outcome. The Outcome Analysis utilized a pre-post design, with each child serving as his/her own historical control. The Outcome Analysis is limited to the 50 children who completed the entire 12-month evaluation phase. Outcomes are presented in the context of our primary and secondary goals. Generally, outcomes are assessed for:

1. Improvement by the end of the 6-month intervention phase
2. Maintained improvement through the 12-month data collection time point

For several outcomes (e.g., symptoms days, attacks, health resource utilization), the variable was a count and not normally distributed. Therefore, non-parametric tests were used to assess whether changes between baseline and follow-up were statistically significant. In cases where the degree of the difference was important, the Wilcoxon Signed-Rank test was used. In situations where the direction but not the magnitude of the difference was important, the sign test was used. These tests are the non-parametric equivalent of the Student's paired t-test.

For all statistical tests, a p-value of 0.05 or less was considered statistically significant. Two-sided tests of hypothesis were used. All statistical analyses were performed using SAS statistical software, version 9.1 (SAS Institute, Inc., Cary, NC).

A more detailed description of the exact methodology and statistical testing utilized for each specific outcome variable is included in the "Results" section.

RESULTS

Description of Enrolled Participants

Demographics and Baseline Characteristics:

Seventy children were enrolled into the project. A summary of the screening, consenting and enrollment process is provided in **Figure 1 (page 12)**.

The baseline characteristics of the enrolled population are shown in **Table 2**. In brief, the study population was exclusively non-Hispanic Black (100%), primarily male (57%), and the overwhelming majority of participants were insured by Medicaid (96%). The average child was just over 7 years old, although half were five years old or younger. Most of the primary caregivers were mothers (91.4%). Sixty-nine percent of caregivers had a high school education or less.

Interestingly, all but two caregivers reported that their child had a Primary Care Physician, and 75% had seen that physician within the past 3 months (**Table 2**). Only 12 of participating children had seen an Asthma Specialist within the past 6 months.

Asthma-related Morbidity:

Given the eligibility criteria, we expected that the average child would have been to the ED at least once in the past year; as is evident in **Table 3**, the average child had actually been to the ED 3.1 times in the past year. In addition, the average child had been to a doctor for worsening asthma symptoms nearly 3 times in the past year. When all urgent health resource utilization was summed together into a single number, the average child had been to the ED, hospitalized, or seen a doctor for worsening asthma symptoms 6.5 times in the past year.

We were interested in recruiting children with severe asthma, but the sample we enrolled had very severe, uncontrolled asthma. The information in **Table 4** illustrates this claim. With regard to asthma symptoms, the period of reference was the two weeks prior to the date of the interview. In the two weeks prior to the baseline health education session, the average child had four days of symptoms and four nights during which asthma disturbed their sleep. The average child experienced six asthma attacks and nearly 13 wheezing episodes in the year prior to enrollment. Finally, children's lives were so affected by asthma that they were unable to carry out their usual activities 10 times in a year.

Table 2. Demographic and Selected Healthcare Characteristics Upon Enrollment into PAI-2 (n=70)

	<u>% or Mean</u>	<u>N</u>
Race/Ethnicity Non-Hispanic Black	100%	70
Gender Male	57.1%	40
Female	42.9%	30
Insurance Medicaid/Kidcare	95.7%	67
HMO/Private	2.9%	2
No Insurance/Self Pay	1.4%	1
Age 2-5 years	50.0%	35
6-12 years	30.0%	21
13-16 years	20.0%	14
Age (mean)	7.3 years	70
Primary Caregiver Mother	91.4%	64
Grandmother	5.7%	4
Sister	1.4%	1
Other Family Member	1.4%	1
Education of Caregiver < High School [‡]	30.8%	20
High School Grad.	38.5%	25
Some College*	29.2%	19
Refused	1.5%	1
Primary Care Physician (PCP) Yes	97.1%	68
No	2.9%	2
Days Since Last Saw PCP[∇] Within the past month	51.5%	35
Within the past 1-3 months	23.5%	16
Within the past year (3-12 months)	23.5%	16
More than 1 year ago	1.5%	1
Asthma Specialist in Past 6 months Yes	17.4%	12
No	82.6%	57

‡ 1 person answered “NCRA-Getting GED now”. Classified her as < HS.

* Includes vocational or business school

∇ Among 68 with PCP

Table 3. Asthma-Related Health Resource Utilization in the Baseline Year among those Enrolled into PAI-2 (n=68)*

	<u>Mean</u>	<u>Median</u>	<u>Range</u>
ED visits	3.1	2	0-25
Hospitalizations	0.7	0	0-6
Hospital Days	2.2	0	0-18
Urgent PCP Visits (worsening symptoms)	2.7	2	0-12
Regular PCP Visits (for asthma)	4.5	3	0-40
Sum of Urgent HRU[⊥]	6.5	4	0-33

*Deleted 2 outliers from analysis.

⊥ Defined as sum of ED, hospitalizations and urgent doctor's visits

Table 4. Frequency of Asthma Symptoms, Asthma Attacks, and Activity Limited Days among those Enrolled into PAI-2 as reported at the time of the Baseline Visit (n=70)

	<u>Mean</u>	<u>Median</u>	<u>Range</u>	<u>N[*]</u>
Symptom free days (past 2 weeks)*	8.3	10	0-14	69
Days w/ daytime asthma symptoms (past 2 weeks)*	4.0	2	0-14	69
Nights sleep disturbed by asthma symptoms (past 2 weeks)*	4.0	2	0-14	69
Days Rescue Med. Used (past 2 weeks)	4.1	3	0-14	70
Asthma Attacks (past 12 months) [⊥]	6.5	4	0-60	69
Wheezing Attacks (past 12 months) ^{⊥⊥}	12.8	5	0-60	66
Days child unable to go to school/ usual activities (past 12 months) ^{⊥⊥⊥}	9.9	7	0-50	69

*One caregiver had answered "don't know".

⊥ Deleted outlier of 96 from analysis. With outlier, mean is 7.7.

⊥⊥ Deleted outliers of 96 from analysis. With outlier, mean is 17.5.

⊥⊥⊥ Deleted outlier of 96 from analysis. With outlier, mean is 11.1.

Sixty-three of the 70 enrolled children (90%) had asthma that would be considered poorly controlled per the National Heart, Lung and Blood Institute standards.^{27,28}

Quality of Life:

The Quality of Life of the child's primary caregiver was assessed at the time of the baseline visit. The instrument, the *Pediatric Asthma Caregiver's Quality of Life Questionnaire*, yields three scores: an Overall score, an Activity Limitation sub-score, and an Emotional Function sub-score. In each case, the maximum possible score is 7. As can be seen in Table 5, baseline quality of life scores were just over 5 for all domains.

Table 5: Pediatric Asthma Caregiver's Quality of Life Scores at Baseline (max score=7)

	<u>Mean</u>	<u>Median</u>	<u>Range</u>	<u>n</u>
Overall Score [⊥]	5.2	5.3	1.4-7	70
Activity Limitation Domain*	5.4	6	1-7	70
Emotional Function Domain**	5.1	4.9	1.2-7	70

⊥Mean of all questions. Maximum score=7, which indicates highest quality of life.

*Mean of questions 2,4,6,8

** Mean of questions 1,3,5,7,9,10,11,12,13

Asthma-related Knowledge:

Asthma-related knowledge of the child's primary caregiver was assessed during the baseline visit, before any teaching occurred. The caregiver was asked a series of 10 True/False questions. At baseline, the average caregiver answered 7.6 of the 10 questions correctly (median=8; range=4-10). Given the high level of cigarette smoke exposure among participants, it was interesting to note that all caregivers accurately reported that exposure to cigarette smoke can worsen asthma symptoms (Table 6). The greatest deficits in knowledge were related to whether or not a child with asthma should engage in physical activity, the proper use of albuterol/rescue medication, the pathophysiology of asthma, and whether steroid inhaler medication use is harmful to children (Table 6).

Parental/Caregiver Self-Efficacy:

Self-efficacy is defined as "the confidence a person feels about performing a particular activity, including confidence in overcoming the barriers to performing that behavior."³² The self-efficacy of the child's primary caregiver to properly manage the child's asthma was assessed at baseline using the *Asthma Management Parental Self-Efficacy Scale*.³¹ The average caregiver scored 19.3 out of 24 possible points at baseline (range=10-24), which was relatively high and allowed little room for improvement (data not shown).

Triggers:

The detrimental affects of cigarette smoke on individuals with asthma have been well established.³³⁻³⁶ Nonetheless, over half of children enrolled into this study lived with someone who smokes (Table 7). One child smoked himself. Furthermore, when caregivers were asked how frequently their child is exposed to second hand cigarette smoke, 60% reported that their child was exposed at least twice a week.

Table 6. Individual Knowledge Quiz Questions and the Proportion Answering Correctly at Baseline (n=70)

<u>Question</u>	<u>Correct Response</u>	<u>% responding correctly</u>
Exposure to cigarette smoke can worsen symptoms of asthma	True	100%
Severity of asthma symptoms may change from one season to another	True	98.6%
Common cold and flu are commonly associated with asthma attacks in children	True	88.6%
Coughing at night can be a symptom of asthma	True	85.7%
Asthma attacks may cause breathing problems, but these attacks are not really dangerous or harmful	False	81.4%
Even on days when my child has no symptoms of asthma, his/her breathing tubes may still be swollen	True	72.9%
Albuterol is a rescue medicine for asthma. It should be given only during times when child has symptoms of asthma	True	67.1%
There is no cure for asthma	True	62.9%
Regular daily use of steroid inhaler medicine for asthma is harmful and should be avoided	False	57.1%
Children w/ asthma should decrease their physical activity to prevent increase in asthma symptoms	False	42.9%

Table 7: Exposure to Cigarette Smoke Reported at Baseline Visit (n=70)

	<u>%</u>	<u>N</u>
How frequently is child exposed to second hand smoke?		
At least once a day	31.4%	22
2-6 days a week	28.6%	20
Once a week	8.6%	6
< once a week/not every week	10%	7
≤ once a month	20%	14
DK/NS	1.4%	1
Child lives with a smoker?		
Yes	54.3%	38
No	42.9%	30
NCRA *	2.9%	2

*Child smokes (n=1); Father smokes but doesn't live with them (n=1)

Table 8 lists the most common asthma triggers found in the home environment during the baseline visit, and the proportion of homes in which the trigger was identified. Table 9 lists the most commonly reported triggers among participants (i.e., what triggers the child's asthma).

Table 8: Most Prevalent Environmental Triggers Identified during Baseline Visit (n=70)

Possible Trigger	%	N
Carpet in some part of home	68.6%	48
Stuffed toys in child's room	44.3%	31
Carpet in child's bedroom	41.4%	29
Damp/moist rooms	38.6%	27
Furry Pets (cats, dogs, etc.)* [‡]	25.7%	18
Roaches in past month?	22.9%	16
Rats/mice in past month?	21.4%	15
Water seepage/leakage	12.9%	9
Visible mold	5.7%	4

*33% of these caregivers reported furry pets as a trigger for their child's asthma.

[‡] 1 NCRA: "child spends half time with father who has pets". This child was placed in the "yes" category for furry pets.

Table 9. Most Commonly Reported Triggers (i.e., what triggers the child's asthma) – Baseline (n=70)

Trigger	% Reporting Trigger for Child's Asthma	N
Weather Changes	94.3%	66
Common Cold/Flu	92.9%	65
Exercise	71.4%	50
Tobacco Smoke	62.9%	44
Dusting/Vacuuming	58.6%	41
Cold Air	52.9%	37
Strong Odors	52.9%	37
Pollens	45.7%	32
Furry Pets	38.6%	27
Strong Emotions/crying	25.7%	18
Air Pollution	15.7%	11
Damp/Musty Areas	14.3%	10
Fireplace/Wood-burning Stove	12.9%	9
Medications	4.3%	3
Birds	2.9%	2

Medical Management:

At the time of the baseline visit, only two children had an Asthma Action Plan that had been signed by their physician. Surprisingly, 48 children (69%) had a controller medication in their homes at the time of the baseline visit. This was higher than we expected per the literature concerning

medication use in urban, minority settings.^{9,37,38} However, it is important to note that this number only reflects whether or not a child had a controller medication in their house at the time of the visit. It says nothing of whether or not that medication was being used on a daily basis, whether the difference between a controller and a rescue medicine was understood by the family, whether the right technique was being utilized, whether the family had the devices needed to optimize administration of the medication, etc. Also, the high rates of asthma hospitalizations and emergency department visits at baseline strongly suggest that medications were not being properly used if at all, even if the prescription had been filled. In fact, as can be seen in **Table 10**, 41% of children who had a metered-dose inhaler (MDI) were using that MDI without a spacer/holding chamber.

Table 10: Primary Medication Method among Enrolled PAI-2 Participants (n=69):

	<u>%</u>	<u>n</u>
MDI Alone	30.4%	21
MDI Alone & DPI	7.3%	5
MDI w/ spacer/HC	17.4%	12
MDI w/ spacer/HC & DPI	5.8%	4
MDI w/ VHC/mask	31.9%	22
DPI	0%	0
Nebulizer Only	4.4%	3
No Meds	1.5%	1
Child Not Present to Demonstrate	1.5%	1

MDI=Metered-Dose Inhaler
DPI=Dry Powder Inhaler
HC=Holding Chamber
VHC=Valved Holding Chamber

The LHE would assess each child's technique in using their medications and rate them on the *Evaluation of Technique* form (**Appendix 2**). Technique was observed and rated separately for MDI and Dry Powder Inhalers (DPI). Among children utilizing a MDI, the following six key areas were assessed on a yes/no scale:

- Appropriately shakes inhaler?
- Appropriate placement of device in mouth/on face?
- Begins each puff separately?
- Appropriate inhalation technique?
- Appropriate breathing technique?
- Tracking inhaler doses appropriately?

A score was then created by adding the number of areas in which the child/caregiver utilized the appropriate technique (maximum possible MDI Score=6). The average child/caregiver who utilized an MDI at baseline could correctly demonstrate 3.3 of the 6 techniques (median: 3.0, range: 0-6).

Table 11.a. shows where technique was most lacking.

The same sort of score was created for children who utilized a DPI at baseline (maximum possible score=4). The average child/caregiver who utilized a DPI at baseline could correctly demonstrate 2.2 of the 4 techniques (median: 2.0, range: 0-4). **Table 11.b.** gives additional details regarding the DPI-specific techniques addressed and the areas where technique was generally lacking.

Table 11.a: MDI Technique Among Children Using an MDI at Baseline (n=64):

	<u>% yes</u>	<u>% N/A</u>
Appropriately shakes inhaler?	64.1%	0%
Appropriate placement in mouth/face?	79.7%	0%
Begins each puff separately?	62.5%	4.7%
Appropriate inhalation technique?	48.4%	0%
Appropriate breathing technique (after inhalation)? *	17.2%	43.8%
Tracking inhaler dose appropriately?	7.8%	0%

*N/A for all children who used HC w/ mask

Table 11.b: DPI Technique Among Children Using a DPI at Baseline (n=9):

	<u>% yes</u>
Appropriate loading of dose prior to use?	77.8%
Appropriate placement in mouth?	66.7%
Appropriate inhalation technique?	44.4%
Appropriate breathing technique (after inhalation)?	33.3%

Implementation of the Intervention & Evaluation Activities (Process Measures)

Intervention:

Ideally, the intervention included four individualized, one-on-one, asthma education sessions carried out by the LHE with the child's primary caregiver (and when age appropriate, with the child as well) within the family's home. These sessions were to occur at the time of enrollment (baseline), 2-weeks, 3 months and 6 months following enrollment. The details of the intervention are highlighted above ("The Intervention", p. 7).

Fifty-eight (82.9%) of the 70 enrolled children completed the entire intervention period (i.e., completed a 6 month home visit).

Table 12: Proportion of Children Completing Each Educational Visit and the Total Number Completed

	All Enrolled (n=70)	Completed Intervention* (n=58)	Completed Follow-up** (n=50)
Visit (% completing)			
Baseline	100%	100%	100%
2 week	80%	88%	88%
3 month	73%	84%	84%
6 month	83%	100%	100%
# of Visits (% completing)			
At least 3 visits	83%	97%	96%
All 4 visits	63%	76%	76%
Average # of Visits (range)	3.4 (1-4)	3.7 (2-4)	3.7 (2-4)

* “Completed Intervention” defined as having participated in at least the Baseline and 6-month Educational Session.

** “Completed Follow-up” defined as having completed the entire 12-month Evaluation Phase

In order to be considered as having completed the intervention, a family had to participate in at least a Baseline and 6-month visit. Our goal was that each family would complete at least 3 visits and, preferably, all four. Of the fifty-eight families who completed the intervention phase, 97% completed at least three visits, and 76% completed all four. The average individual completed 3.7 visits (range: 2-4) (Table 12).

Data collection for evaluation purposes continued for 12-months from the time of the baseline visit (i.e., for six months following the 6-month visit with the family). Fifty participants completed the entire evaluation phase. Of those individuals, 96% met the goal of completing at least 3 visits with the Lay Health Educator, and 76% completed all four. The average individual completed 3.7 visits (range: 2-4) (Table 12).

Evaluation Phone Calls

Of the 58 children who completed the intervention phase, the average child completed 8.6 of the 9 possible data collection follow-ups (range 6-9). Of the 50 children completing the entire evaluation phase, the average child successfully completed 8.98 (range: 8-9). In fact, all but one participant (98%) had completed all 9 follow-up data collection sessions. One person had not completed a Month 5 follow-up (Table 13).

Whenever possible, a follow-up was collected within 2 weeks of the due date. When follow-ups were collected more than 2 weeks after the due date, certain information was not ascertained. Specifically, any questions related to symptom frequency over the past 2 weeks were not asked. The rest of the information could be recalled for the relevant time period. Among those who completed the entire Evaluation Phase, the average follow-up was collected approximately 9 days later than expected. Table 13 shows the timeliness of each follow-up, and the average number of days late.

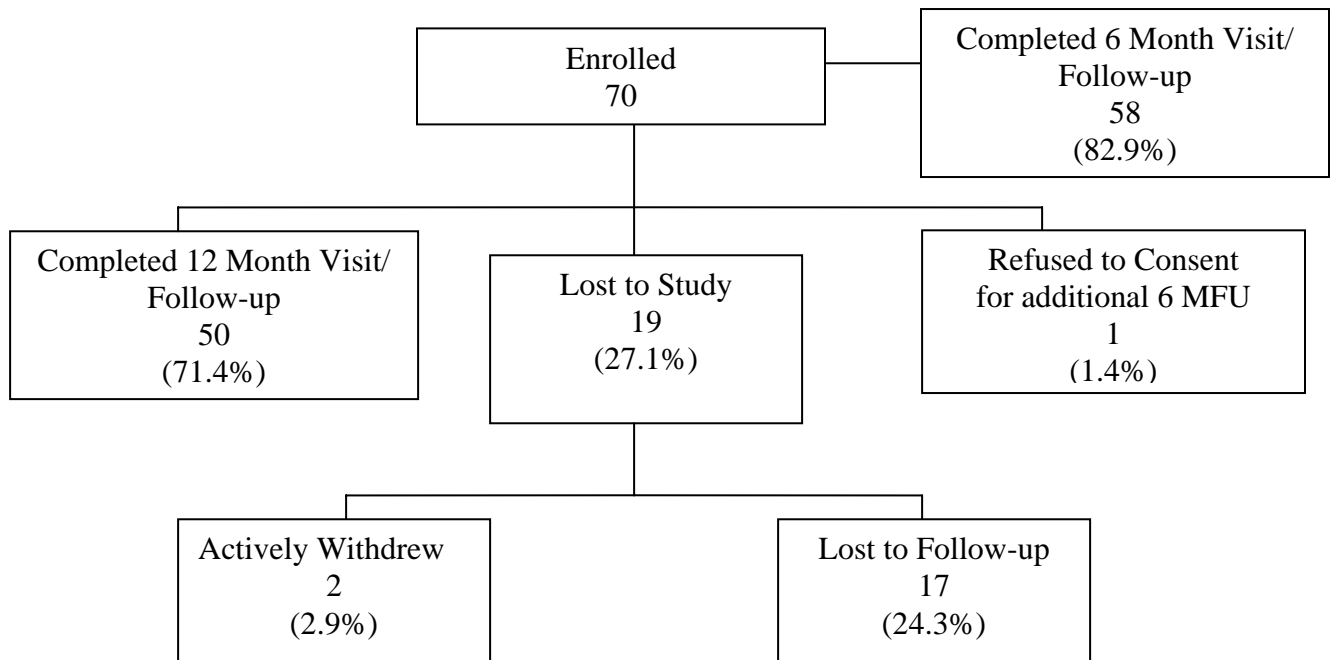
Table 13: Completion and Timeliness of Follow-up Data Collection Among Those Completing the Evaluation Phase (n=50)

Follow-up Call	% Complete Overall	% Complete within 2 weeks of due date	% Complete within 1 month of due date	Average Number of Days Late (range)
Month 1	100%	84%	94%	6.6 (-10-58)
Month 2	100%	80%	96%	12.6 (-12-54)
Month 3	100%	80%	90%	9.3 (-9-78)
Month 4	100%	78%	92%	10.7 (-8-108)
Month 5	98%	86%	96%	7.1 (-13-77)
Month 6	100%	78%	90%	8.5 (-21-48)
Month 8	100%	76%	94%	9.5 (-4-48)
Month 10	100%	74%	92%	9.2 (-2-43)
Month 12	100%	68%	94%	9.0 (-24-55)

Attrition:

Of the 70 participants originally enrolled, 58 (82.9%) completed the final 6-month follow-up visit. Fifty participants (71.4%) completed the 12-month evaluation phone call. We therefore had 20 (28.6% of enrolled) participants who failed to complete the entire 12-month evaluation follow-up period. Of those lost to the study, 2 actively withdrew, 17 were lost to follow-up, and 1 refused to consent for an additional 6 months of follow-up following the 6 month visit (**Figure 2**). A participant was considered lost to follow-up if he/she could not be contacted for 3 consecutive months. While the attrition rate of 28.6% is somewhat higher than desirable, it is not surprising given the target population consisted of inner-city, disadvantaged children and their primary caregivers. The reasons cited for withdrawing from the study included: belief by caregivers that their child “is not sick” or “doesn’t have asthma” (n=1), and feeling that the “study is too much work” (n=1). The three reasons that people were lost to follow-up included: disconnected phone (n=11), family moved and could not be contacted (n=3) and losing contact for 3 or more months (n=5). More specifics on enrollment and attrition are displayed in **Figure 2**.

Figure 2: Participant Enrollment, Follow-up and Attrition.



Participants lost to the study were examined against those completing the study for a number of characteristics and baseline values. The two groups were found to be very similar. In fact, those who completed the study differed from those who did not in only two ways. First, those who were eventually lost to the study were significantly younger than those completing the study (5.1 years vs. 8.2 years, t-test, $p=0.0015$). Second, there was a significant difference in nighttime symptom frequency in the 2 weeks prior to enrollment, with those being lost to the study reporting significantly more nights of symptoms than those completing (6.3 night in past 2 weeks vs. 3.1, t-test, $p=0.0196$). There were no other significant differences. Variables examined for significance included: asthma symptom frequency in the 2 weeks prior to the intervention; average number of asthma exacerbations and wheezing episodes in the year prior to enrollment; urgent health resource utilization in the year prior to enrollment; level of exposure to cigarette smoke and other home triggers; asthma-related knowledge of the child's primary caregiver at baseline; self-efficacy to manage asthma at baseline; and asthma-related quality of life of the child's primary caregiver at baseline. We also assessed whether there was any difference in likelihood of being lost to the study by season of enrollment or by LHE and found no significant differences.

Results by Specific Outcome Measure

The Outcome Analysis is limited to the 50 children who completed the entire 12-month evaluation phase. Outcomes are presented in the context of our primary and secondary goals. Generally, outcomes are assessed for:

1. Improvement by the end of the 6-month intervention phase
2. Maintained improvement through the 12-month data collection time point

Primary Goal 1: Decrease asthma-related morbidity

Several outcomes were used in assessing our success towards the primary goal of decreasing asthma-related morbidity.

Asthma Symptoms

Four symptom-related questions were asked at Baseline, and during each subsequent data collection phone call/visit. In each instance, the period of reference was the 2-weeks prior to the question being asked. Specifically, caregivers were asked about: (1) the number of symptom free days the child experienced; (2) the number of days on which the child experienced symptoms during daytime hours; (3) the number of nights during which asthma symptoms interrupted the child's sleep; and, (4) the number of days on which the child needed to use his/her rescue medicine. The specific questions can be found on the "Initial Data Sheet", questions 1-4 in **Appendix 2**.

In each instance, the number of reported days/nights at the time of the Baseline interview was compared to: (1) the number of days/nights at the time of the 6-month follow-up (**Table 14**); (2) the number of days/nights at the time of the 12-month follow-up (**Table 14**); (3) the average number of reported day/nights per month over the course of the 12 month follow-up period (**Figure 3**). The latter method controls for any seasonal variations in symptoms that may occur.

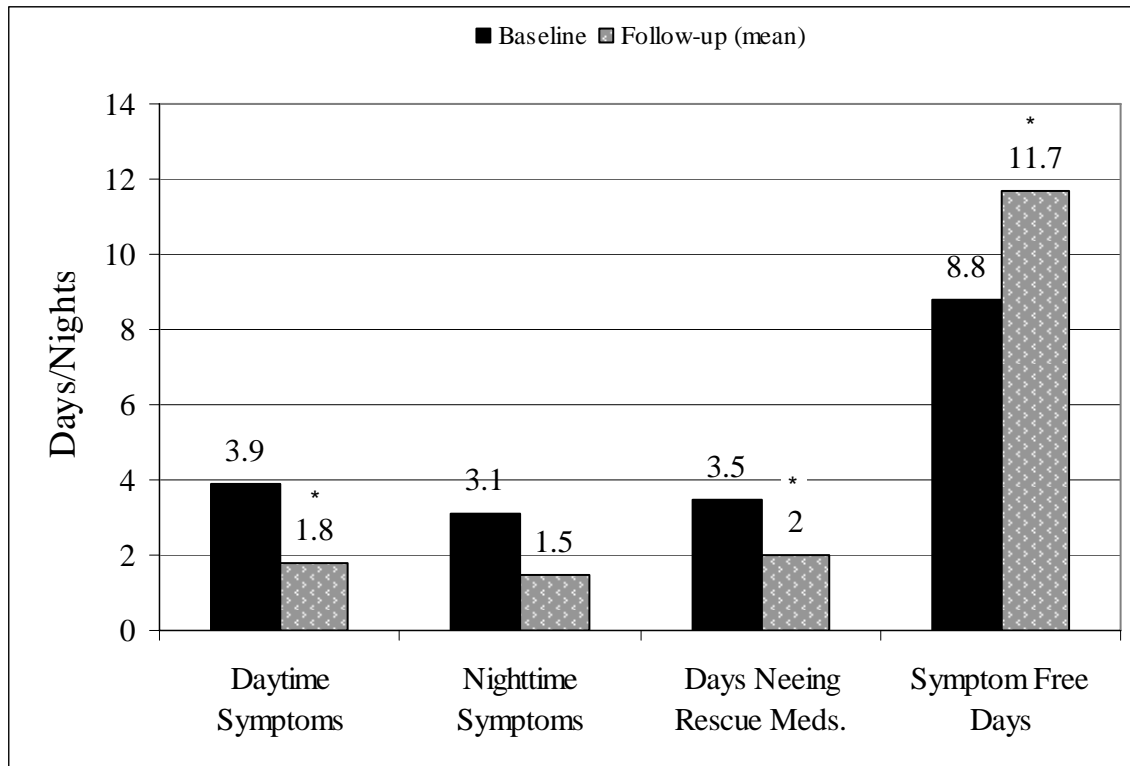
Table 14. Symptom Frequency in the Past 2 Weeks (mean) at Baseline vs. 6-month and 12-month follow-up

	Baseline	Month 6	M6 p-value*	Month 12	M12 p-value*
Daytime Symptoms	3.9	2.1	0.0146	1.7	0.0049
Nighttime Symptoms	3.1	1.7	0.0479	1.8	0.0892
Days Needing Rescue Med.	3.5	1.7	0.0015	2.6	0.0921
Symptoms Free Days	8.8	11.5	0.0013	11.5	0.0024

*Wilcoxon signed-rank non-parametric test used to assess statistical significance

All four symptom-related variables improved significantly in the desired direction between Baseline and the 6-month follow-up. Two of the four noted improvements (daytime symptoms and symptom free days) were sustained at the 12-month follow-up (**Table 14**).

Figure 3. Symptom Frequency in Past 2 Weeks - Baseline vs. Average of Follow-up



*Statistically significant difference ($p < 0.05$) per Wilcoxon signed-rank non-parametric test

When comparing the Baseline symptom frequency with the average over the course of the 12-month follow-up, there were notable improvements for all four variables, with all but nighttime symptoms improving to a statistically significant degree (Figure 3). For example, in the two weeks prior to the baseline visit, the average child experienced 3.9 days of symptoms, while on average over the course of the 12-month follow-up, a child experienced 1.8. This was more than a two-fold reduction when compared to the baseline value (Figure 3).

Asthma Exacerbations and Wheezing Episodes

During the baseline interview, caregivers were also asked about asthma attacks and wheezing episodes in the year prior to the project. Information on asthma attacks and wheezing episodes was collected on every subsequent data collection follow-up. The average number of asthma attacks decreased from 8.9 (range: 0-96) in the year prior to the intervention to 4.0 (range: 0-4) in the follow-up year (Wilcoxon signed-rank test, $p=0.0308$) (data not shown). Wheezing episodes also decreased from 19.6 (range: 0-96) to 11.5 (range: 0-69), but this change was not statistically significant (Wilcoxon signed-rank test, $p=0.4941$) (data not shown).

Asthma-Related Health Resource Utilization and Activity Limited Days

Information on asthma-related health resource utilization and activity-limited days (i.e., number of days on which child was unable to attend school or carry out usual activities because of asthma) was collected retrospectively for one year during the baseline interview, and then prospectively for the 12-months following the initiation of the intervention.

All urgent health resource utilization variables decreased significantly between the baseline and follow-up year. Specifically, the average number of ED visits decreased from 3.4 in the year prior to the intervention to 0.9 in the year following (Wilcoxon signed-rank test, $p < 0.0001$), more than a 3-fold reduction (**Table 15**). Also, when all urgent health resource utilization was summarized into one variable, the average child experienced a 278% decrease in the combination of ED visits, hospitalizations, and urgent-clinic visits between the baseline and follow-up years (6.5 to 2, Wilcoxon signed-rank test, $p < 0.0001$) (**Table 15**).

The number of activity-limited days between the baseline and the follow-up year also decreased significantly from an average of 11.4 at baseline to 6.9 during the course of the follow-up year ($p = 0.0184$) (**Table 15**).

The average number of routine clinic visits was surprisingly at an acceptable level at baseline. It was therefore encouraging that there was no change between the baseline and follow-up year (**Table 15**).

Primary Goal 2: Improve the Quality of Life of the child and the caregiver

We specifically measured the caregiver's quality of life via the *Pediatric Asthma Caregiver's Quality of Life Questionnaire*,²⁹ a validated questionnaire that has been used extensively in research. The tool was administered at the time of the baseline interview and during the 6- and 12-month follow-ups. The tool yields three scores: an Overall Quality of Life Score, an Activity Limitation sub-score, and an Emotional Function sub-score. In each case, the maximum possible score is 7, and a change in score of 0.5 or more has been shown to be clinically significant.

As can be seen in **Figure 4**, the Overall Quality of Life Score of the average caregiver improved from 5.2 at baseline to 5.9 at month 6, a change that is both clinically and statistically significant (Wilcoxon signed-rank test, $p < 0.0001$). The noted improvement in Overall Quality of Life was maintained through 12 months (average score=6.0, Wilcoxon signed-rank test, $p < 0.0001$). Similar statistically and clinically significant improvements were noted for both sub-scores as well (**Figure 4**).

Secondary Goal 1: Improve asthma-related knowledge of the child's primary caregiver

The asthma-related knowledge of the child's primary caregiver was assessed at baseline, 2 weeks, 3 months, 6 months and 12 months. A series of 10 true/false questions were asked to measure asthma-related knowledge. When the tool was administered during a home visit, the questions were asked prior to any teaching being done. The order in which the questions were asked was changed each time in order to ensure that participants were paying attention to each statement and responding based on true knowledge.

Table 15. Asthma-Related Health Resource Utilization and Activity Limited Days in the Year Prior to and Following the Intervention

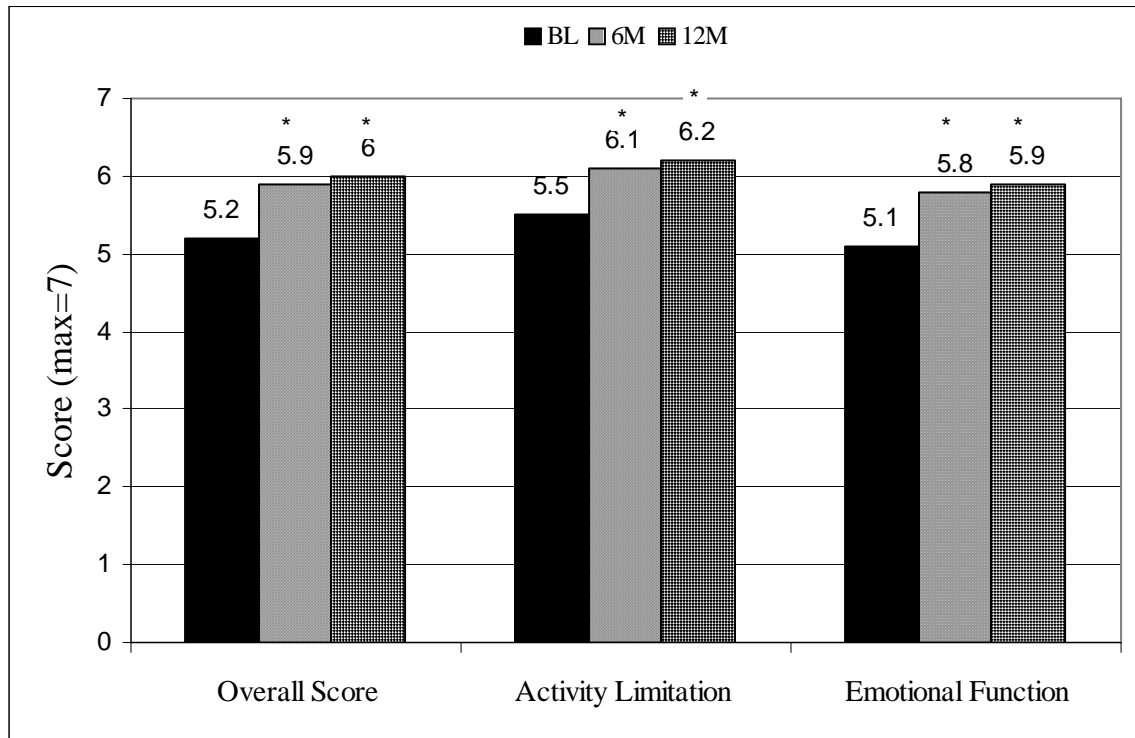
		Baseline Year	Follow-up Year	p-value*
ED Visits	Mean	3.4	0.9	<0.0001
	Median	2.0	0	
	Range	(0-25)	(0-5)	
Hospitalizations	Mean	0.7	0.2	<0.0001
	Median	0	0	
	Range	(0-6)	(0-3)	
Hospital Days	Mean	2.1	0.4	<0.0001
	Median	0	0	
	Range	(0-15)	(0-6)	
Clinic Visits- Urgent**	Mean	2.5	0.9	0.0003
	Median	1.0	1.0	
	Range	(0-12)	(0-8)	
Clinic Visits – Regular	Mean	4.5	3.5	0.9215
	Median	2.5	3.5	
	Range	(0-40)	(0-9)	
Sum of Urgent HRU***	Mean	6.5	2.0	<0.0001
	Median	4.0	1.0	
	Range	(0-33)	(0-12)	
Activity Limited Days	Mean	11.4	6.9	0.0184
	Median	7	3.5	
	Range	(0-96)	(0-29)	

*Wilcoxon signed-rank non-parametric test used to assess statistical significance

** Excluded outlier of 96; n=49

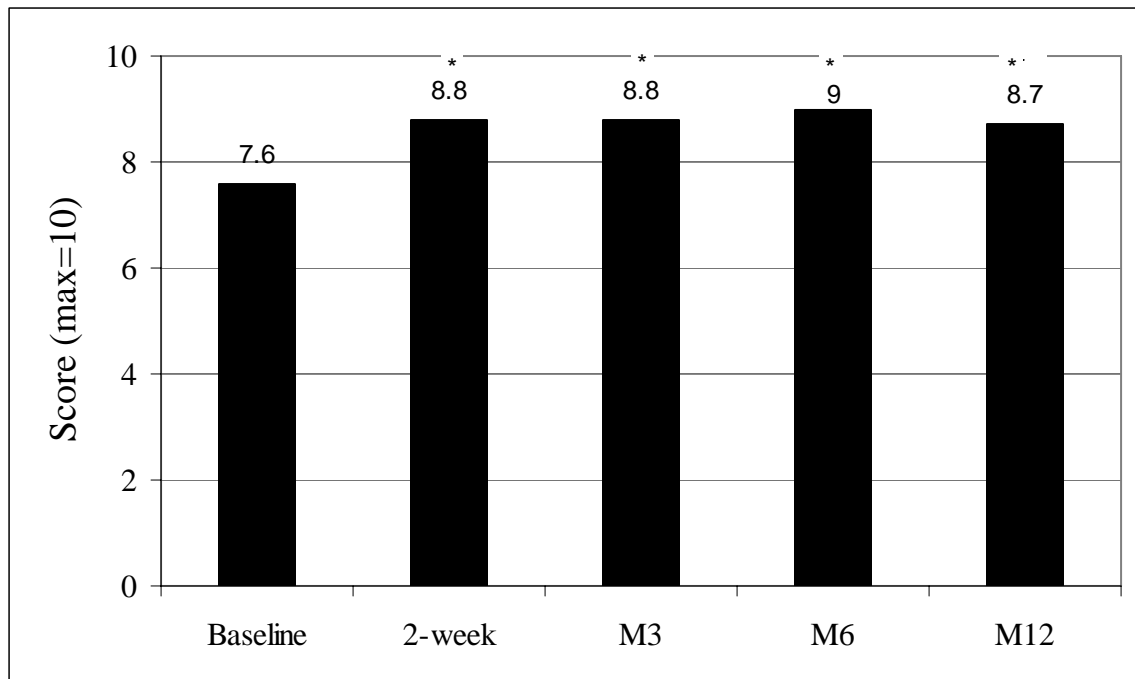
*** Sum of ED visits, hospitalizations, and urgent clinic visits. Excluded outlier of 116; n=49

Figure 4. Pediatric Asthma Caregiver Quality of Life Scores at Baseline vs. 6-month and 12-month Follow-ups



*Statistically significant difference ($p < 0.05$) from baseline score per Wilcoxon signed-rank non-parametric test

Figure 5. Asthma-Related Knowledge of the Child's Primary Caregiver at Baseline, 2-weeks, 3 months, 6 months and 12 months.



*Statistically significant difference ($p < 0.05$) from baseline score per Wilcoxon signed-rank non-parametric test

As can be seen in **Figure 5**, the average number of questions answered correctly improved from 7.5/10 to 9/10 by month 6 ($p < 0.0001$). This improvement in asthma-related knowledge was maintained through month 12.

Knowledge at baseline was considerably higher than we had anticipated, however caregivers consistently struggled with certain questions.

- At baseline, 60.4% of caregivers incorrectly believed that children with asthma should decrease their physical activity to prevent an increase in asthma symptoms. Only 29.8% (sign test, $p = 0.0013$) and 25.0% (sign test, $p = 0.0005$) of caregivers were answering this question incorrectly at 6 months and 12 months respectively.
- At baseline, 43.7% of caregivers believed that the regular daily use of steroid inhaler medicine for asthma is harmful and should be avoided. The proportion asserting this misperception decreased significantly to 17% by month 6 (sign test, $p = 0.0044$). By month 12, only 25% were answering this question incorrectly (sign test, $p = 0.0931$).
- At baseline, 41.7% of caregivers incorrectly believed that there is a cure for asthma. Only 23.4% (sign test, $p = 0.0963$) and 25.0% (sign test, $p = 0.0386$) of caregivers still held this false belief at month 6 and month 12 respectively.

It was encouraging that at the time of the baseline interview, prior to any teaching being done, 100% of caregivers realized that cigarette smoke can worsen symptoms of asthma, and that the severity of asthma symptoms may change from one season to the next. Nearly 90% realized that the common cold and flu are commonly associated with asthma attacks in children.

Secondary Goal 2: Improve primary caregiver's confidence (i.e., self-efficacy) that they can properly manage their child's asthma

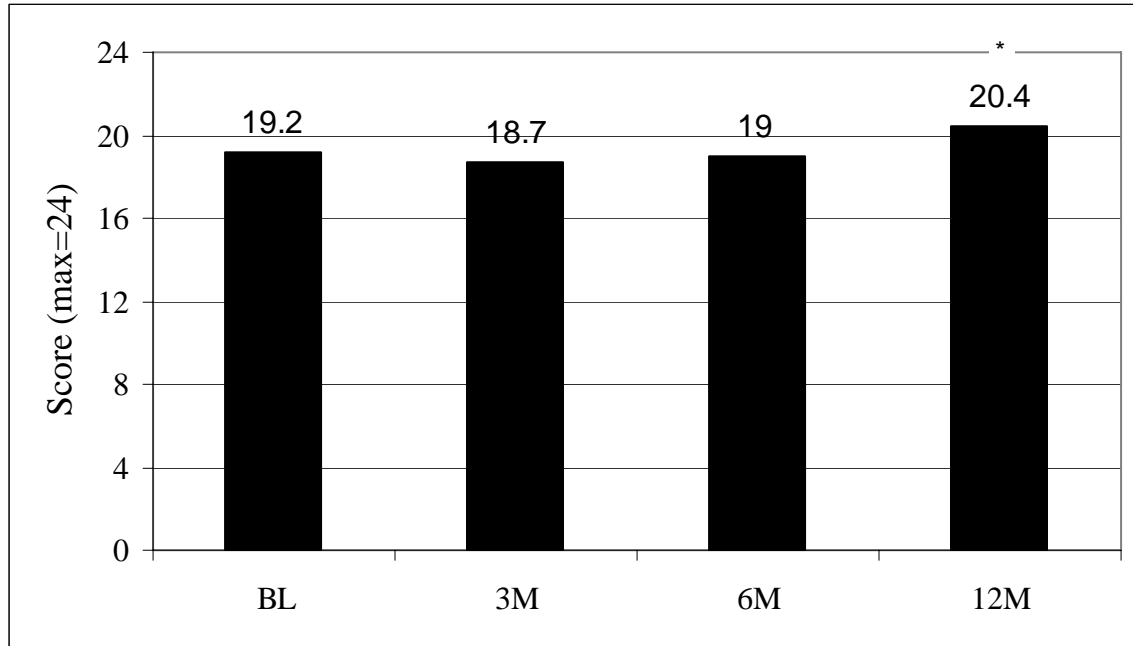
Self-efficacy is a measure of the confidence an individual has in his/her ability to undertake certain actions in managing a prospective situation. We were specifically interested in the primary caregiver's self-efficacy to properly manage his/her child's asthma. Self-efficacy is a personal belief and does not necessarily correlate with actual capabilities. The tool we used to measure self-efficacy is the *Asthma Management Parental Self-Efficacy Scale*.³¹ The tool was administered at baseline, 3 months, 6 months and 12 months. The maximum possible score is 24.

At baseline, the average caregiver scored 19.2 out of a possible 24, a relatively high baseline score. As a result, scores remained essentially constant through the 6-month follow-up, and improved slightly, but significantly to 20.4 by the 12-month follow-up (Wilcoxon signed-rank test, $p = 0.0032$) (**Figure 6**).

There are a few possible explanations for the lack of improvement in self-efficacy scores between the baseline visit and 6-month follow-up visit. For one, several of the questions asked on the *Asthma Management Parental Self-Efficacy Scale* are sensitive in nature. For example, one question asks the respondent how strongly he/she agrees with the statement, "You feel that your child may die during or after an asthma attack". The tool was first administered during our initial visit, before we had established any sort of a relationship with the family. As a result, caregivers may not have been comfortable answering these sensitive questions honestly at baseline leading to an exaggerated baseline score, and making it difficult to detect a change over the course of the

follow-up. Secondly, many of our caregivers had been managing their child's asthma for quite a while. Many also had asthma themselves. It is therefore likely that they were doing what they truly believed to be correct at baseline, but became more aware of their limitations after participating in the intervention. Such a scenario would also lead to exaggerated baseline scores. Finally, it is possible that the tool itself is not sensitive and specific enough to detect a true change.

Figure 6. Asthma Management Parental Self-Efficacy of the Child's Primary Caregiver at Baseline, 3 months, 6 months and 12 months.



*Statistically significant difference ($p < 0.05$) from baseline score per Wilcoxon signed-rank non-parametric test

Secondary Goal 3: Decrease the number of triggers to which the child is exposed

The Home Trigger Assessment was administered by the Lay Health Educator at baseline, 3-months and 6-months, and by the Research Assistant during the 12-month phone call. It inquires about cigarette smoke exposure, as well as 8 other triggers that might be found in the home environment.

Table 16 summarizes the main findings of the Home Trigger Assessment. Three variables describe a child's exposure to second hand cigarette smoke. The proportion of caregivers reporting that their child was exposed to second hand cigarette smoke at least twice a week decreased significantly from 65.9% at baseline to 38.3% and 36.2% at 6-months and 12-months respectively. In fact, by the time of the 12-month follow-up, over half of caregivers reported that their child was exposed to second hand cigarette smoke less than once per week. It is important to note that this information was collected via caregiver report, and there was no biological verification of the information relayed by the caregiver. Therefore, it is difficult to ascertain whether the information is completely accurate, or whether a caregiver's desired situation or impression of what the LHE/Research Assistant wanted to hear may have biased their responses towards reporting less frequent exposure (i.e., social desirability bias). However, at a minimum the decrease in

proxy-reported exposure implies that the message that cigarette smoke exposure is harmful to a child with asthma and should be avoided whenever possible was being internalized by caregivers.

We also noted a slight decrease in the total number of triggers to which a child was exposed in their home environment over the course of the follow-up. Whereas the average child was exposed to 2.4 triggers in their home at the time of the baseline interview, that had decreased significantly to 1.9 by the time of the 12-month follow-up (Table 16). The greatest improvements in individual trigger exposure were related to damp/moist rooms and the presence of rodents in the home (Table 17).

Table 16: Main Findings of Home Trigger Assessment Related to Cigarette Smoke Exposure and Eight Other Triggers at Baseline, 6-months and 12-months.

		BL [^]	6M ^{^^}	p-value*	12M [^]	p-value*
Frequency of exposure to second hand cigarette smoke	At least once a day	34.0%	27.7%	0.0214	17.0%	<0.0001
	2-6 days/week	31.9%	10.6%		19.2%	
	Once/week	8.5%	19.2%		10.6%	
	< once/wk and > once/month	10.6%	17.0%		12.8%	
	< once/month	14.9%	25.5%		40.4%	
Child lives with a smoker^{&}	% yes	62.0%	55.1%	0.2891	46.0%	0.0215
Primary caregiver smokes	% yes	36.0%	36.0%	1.0000	34.0%	1.0000
Total Number of Triggers (max=9)[⊥]	Mean	2.4	2.1	0.0532	1.9	0.0426
	Median	2.5	2.0		2.0	
	Range	(0-6)	(0-6)		(0-5)	

* Wilcoxon signed-rank/sign nonparametric test as appropriate used to assess changes in exposure for individual children between BL and follow-up period assessed.

[^] n=47 for frequency of exposure to second hand cigarette smoke

^{^^} =47 for frequency of exposure to second hand cigarette smoke, and n=49 for “child lives with a smoker”

[&] One child smokes (PA126)

Table 17: Exposure to Common Home Triggers at Baseline, 6-months and 12-months.

Trigger	BL	6M	p-value*	12M	p-value*
Carpet in house (%)	68.0%	58.0%	NS	58.0%	NS
Stuffed toys in child's bedroom (%)	46.0%	30.0%	NS	30.0%	NS
Furry pets (%)	32.0%	28.0%	NS	24.0%	NS
Damp/moist rooms (%)	36.0%	12.0%	0.0169	18.0%	0.0490
Carpet in child's bedroom (%)	38.0%	36.0%	NS	44.0%	NS
Rats/Mice, past month (%)	22.0%	18.0%	NS	4.0%	0.0039
Roaches, past month (%)	24.0%	24.0%	NS	12.0%	NS
Water seepage/ leakage (%)**	14.3%	8.2%	NS	18.4%	NS
Visible mold (%)^	6.3%	8.3%	NS	14.6%	NS
Wood burning stove (%)	0.0%	2.0%	NS	0.0%	NS

*Sign nonparametric test to assess changes in exposure to a particular trigger for individual children between BL and follow-up period assessed. NS="not significant"; p>0.05.

** 2 children missing information (n=48)

^ 1 child missing information (n=49)

Secondary Goal 4: Improve the medical management of the child's asthma

A. Increase proportion of children who have an Asthma Action Plan that they and their family understand how to use

Our final contact with the families for teaching purposes occurred approximately 6 months following our initial visit. It was our goal to have an Asthma Action Plan that had been approved and signed by the child's primary care physician back to every family by the time of the 6-month visit. The LHE would then be able to review the Asthma Action Plan with the family to assure that they understood how to use it. We were able to get a signed Asthma Action Plan to 42 of the 58 children (72.4%) who completed the entire intervention phase. While this was not the 100% we had hoped for, it was a marked improvement from the two children who had an Asthma Action Plan at the time of the baseline visit. This particular outcome required physician cooperation, and our process of obtaining signed Asthma Action Plans improved as our experience working with physicians increased.

B. Increase the proportion of children/caregivers who understand their medications and know how to properly use them.

We were interested in monitoring the degree to which we could modify medication use behaviors. While we found that 69% of children had a prescribed daily controller medication in their home when we made our baseline visit, we also found that the majority of those same children were not using that controller medication appropriately. For example, some were using it on an "as needed" basis, much like they should be using their rescue medication. Some were using the wrong

dosage. Some did not have the devices necessary to properly use an inhaler. For example, several did not perform the steps necessary to make sure they were inhaling the full dosage when using their inhaled medications.

In order to document medication technique, a form was created called the *Evaluation of Technique Form*. This form (**Appendix 2**) was completed during each home visit by the LHE after observing the caregiver or child (as appropriate for age) administering their medications. The LHE would record whether they were following the proper steps for adequate effectiveness depending on the device the family had available or preferred to use.

Table 18 shows the primary techniques used to administer medications at baseline as compared to at the time of the 6-month visit. At the time of the baseline visit, 37.5% of children/caregivers were using a non-optimal medication technique, specifically, a metered-dose inhaler without a spacer/holding chamber. A spacer is a tube that attaches to an inhaler and acts as a reservoir or “holding chamber”. By holding the medication that is released from the inhaler, the spacer makes it easier to breathe in the medication and helps to ensure that the medication gets into the lungs as opposed to being lost into the air or on the back of the mouth. When used properly, a spacer can make an inhaler 20% more effective in delivering medication. It is especially important that people who are using corticosteroid inhalers use a spacer in order to prevent medicine from getting into their mouth and causing an oral yeast infection.

By the time of the 6-month visit, all children who were using a metered-dose inhaler were using a spacer/holding chamber, which resulted in a statistically significant improvement in the proportion of children utilizing an optimal method (**Table 18**).

Table 18. Primary Method Used in Administering Asthma Medications at Baseline vs. 6 Months[‡]

Primary Technique [∇]	Baseline	Month 6	p-value [*]
MDI Alone (%)	28.6%	0.0%	< 0.0001
MDI Alone & DPI (%)	8.9%	0.0%	
MDI w/ Spacer/HC	16.1%	33.9%	
MDI w/ Spacer/HC & DPI	7.1%	19.6%	
MDI w/ VHC & Mask	32.1%	41.1%	
MDI w/ VHC & Mask & DPI	0.0%	0.0%	
DPI only	0.0%	1.8%	
Nebulizer Only (%)	5.4%	0.0%	
Child not present to demonstrate (%)	1.8%	3.6%	

Non-optimal method

[‡] n=56 who had completed a baseline and a 6-month “Evaluation of Technique” form.

[∇] MDI=Metered-Dose Inhaler; DPI=Dry Powder Inhaler; HC=holding chamber; VHC=valved-holding chamber

^{*} Sign non-parametric test used to assess changes in technique from a non-optimal to an optimal method between baseline and 6-month follow-up.

With regard to metered-dose inhaler use, we assessed whether 6 steps were being properly carried out:

1. Appropriately shakes the inhaler prior to use
2. Appropriate placement of device in the mouth or on the face
3. Begin each puff separately, and not together
4. Appropriate inhalation technique after actuation (n/a for MDI with Valved Holding Chamber and Mask)
5. Holds breath for 5-10 seconds after inhalation/face mask kept on until five breaths completed after actuation
6. Tracking inhaler doses appropriately.

As can be seen in **Table 19a**, statistically significant improvements in each of the six areas was noted among those using an MDI between the baseline visit and the 6-month follow-up. The number of steps performed correctly improved significantly from an average of 3.3 of 6 at baseline to 5.3 of 6 by month 6 (Wilcoxon signed-rank test, $p < 0.0001$) (**Figure 7**). In fact, by the month 6 follow-up, over half of the caregivers/children were performing all six steps correctly.

Table 19a. Proportion Carrying Out Appropriate Steps when Using a Metered-Dose Inhaler among those with a Metered-Dose Inhaler at Baseline vs. 6-month Visit

	Baseline (n=52)	Month 6 (n=53)	p-value*
Appropriately shakes inhaler prior to use	63.5%	92.5%	< 0.0001
Appropriate placement of device in mouth/on face	80.8%	98.1%	0.0215
Begins each puff separately	61.5%	92.5%	0.0005
Appropriate inhalation technique	48.1%	88.7%	< 0.0001
Appropriate breathing technique (after inhalation) [∇]	21.2%	54.7%	<0.0001
Appropriate tracking of doses	7.7%	54.7%	< 0.0001

∇ N/A for those using a valved-holding chamber and mask. Includes 22 children at baseline and 24 children at 6-months.

* Sign non-parametric test used to assess changes in proportion performing each step properly between baseline and 6-month follow-up.

Among users of a Dry Powder Inhaler, we assessed whether four steps were being carried out properly:

1. Appropriately loading of a dose prior to use
2. Appropriate placement of device in the mouth
3. Appropriate inhalation technique

4. Holds breath for 5-10 seconds after inhalation/face mask kept on until five breaths completed after inhalation

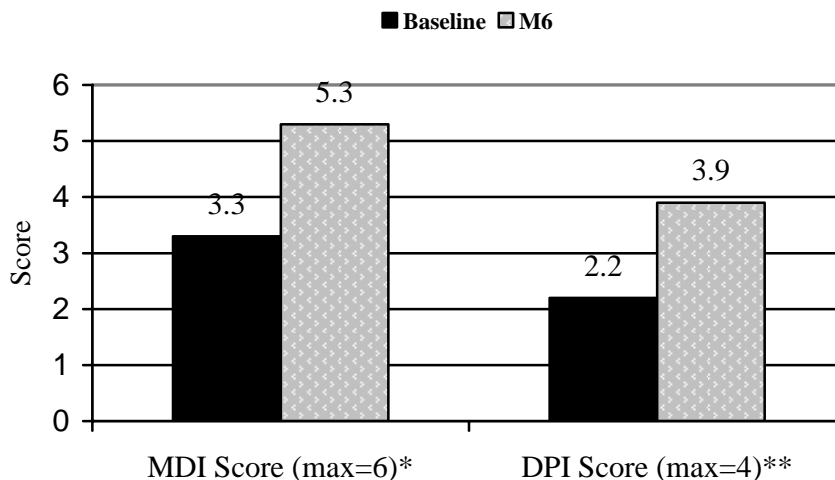
As can be seen in **Table 19b**, improvements were noted in each of the four areas. None of the p-values quite reached statistical significance, but this was probably as a result of the small number of children using this particular technique. The number of steps performed correctly improved to a marginally significant degree from an average of 2.2 of 4 at baseline to 3.9 of 4 by month 6 (Wilcoxon signed-rank test, $p=0.0625$) (**Figure 7**). In fact, by month 6 follow-up, over half of the caregivers/children were performing all four steps correctly.

Table 19b. Proportion Carrying Out Appropriate Steps when Using a Dry Powder Inhaler among those with a Dry Powder Inhaler at Baseline vs. 6-month Visit

	Baseline (n=9)	Month 6 (n=12)	p-value*
Appropriately loads dose prior to use	77.8%	100%	1
Appropriate placement of device in mouth	66.7%	100%	0.5
Appropriate inhalation technique	44.4%	91.7%	0.125
Appropriate breathing technique (after inhalation)	33.3%	100%	0.0625

* Sign non-parametric test used to assess changes in proportion performing each step properly between baseline and 6-month follow-up.

Figure 7. Evaluation of Technique Score, Baseline vs. 6 Months



*Statistically significant difference ($p<0.0001$) from baseline score per Wilcoxon signed-rank non-parametric test.

** Marginally statistically significant difference ($p=0.0624$) from baseline score per Wilcoxon signed-rank non-parametric test.

Cost Benefit Analysis

We intend to implement a cost-benefit analysis intended to estimate the expected savings to the Illinois Department of Healthcare and Family Services (Medicaid administrator) resulting from the intervention approach. Ninety-six percent of study participants were insured by Medicaid, making this approach appropriate.

We are currently working to obtain the necessary cost information from the Illinois Department of Healthcare and Family Services to complete the cost-benefit analysis. *The findings of the cost-benefit analysis will be included in a subsequent report.* Given the degree of improvement in urgent health resource utilization and the relative low cost of implementing the model, we are confident that the model will prove to be highly cost-effective.

Anecdotal Evidence of Success – Case Studies

Every family we encountered was unique and took something a little different away from their experience with the program. Some were appreciative of simply having someone express concern for their child's health and who took the time to answer their questions. Others found themselves learning for the first time what asthma actually is and what it means for their child's physiology.

An interesting trend that emerged over the course of the project was that most parents seemed confident in their abilities to properly manage their child's asthma; specifically to recognize symptoms and to use medications appropriately. In many cases, parents had been dealing with their child's asthma for a very long time (often since birth), and had been doing their best to care for them properly. They believed they were doing everything right and were frustrated that their child was still sick.

While parents generally reported that they were confident in their ability to properly manage their child's asthma, it quickly became clear that this impression was often inaccurate. When we first met with them, the majority of participants did not understand how or when to give medications, nor did they recognize all of the symptoms of an asthma episode (e.g., persistent coughing). These parents were generally surprised to discover that they were doing something incorrectly and were thankful for the knowledge. It was not that these parents were taking asthma lightly, nor that they were careless in caring for their children, but rather that no one has ever taken the time to really teach them how to manage this complicated disease. The majority of the parents we worked with expressed gratitude for what they learned, and were appreciative of the opportunity to better care for their children.

When a child's asthma is properly medicated and under control they gain the freedom to be a normal kid. They can run and play with their peers, sleep through the night, miss fewer days of school and perform better when they are in school. It has been this type of success that we have witnessed over and over again during the course of our program: children being given the opportunity to live normal lives.

Some specific examples will better tell the story.

Case Study 1:

The first case study concerns a 7 year old boy who was diagnosed with asthma shortly after birth. As a result, the mother told us that she has always been concerned about his safety, so she had not allowed him to be very active and play like other children his age. When we first met this patient he was taking Albuterol, whenever needed, and Flovent, 2 puffs once a day. The mother thought that this was how she was supposed to administer Flovent, as that is how she understood the doctor's instructions. The health educator, who is familiar with the medication Flovent (generally given 2 puffs, *twice* a day) asked to see the pharmacy instructions. The Flovent prescription was written as 2 puffs *twice daily*. As a result of this misunderstanding between the doctor and the mother, the child had been receiving only half the medication he needed to control his asthma. His asthma was clearly not under control when we first met him as in the past year he had missed 14 days of school, had been to the ED 4 times, and had difficulty sleeping over half the nights in a typical week.

This mother was extremely grateful that we had approached her with our study program for asthma education. She was thankful that now her child would be able to get the full benefit of his treatment. She has since reported that her son has been doing better. She also reported that his activity level has been substantially improved.

Case Study 2:

The most striking success story is of a different type. It is one of a 16-year-old boy living on the South side of the city. When we first met his mother she was extremely worried about her son's future. He is a competitive sports lover whose main passion is gymnastics. His mother even told us that he gave up a summer trip to Australia that had been offered to only a handful of kids because he would have to miss out on his gymnastics training. He seemed not to be concerned with his asthma and was not convinced that he needed to be.

When we arrived, he had run out of his Albuterol pump, which he should have been using as needed when symptoms arise or when encountering typical triggers. He was also very irregular with the use of his daily controller medication, taking it only when he "needed it". Our experiences have shown us that this is a common misuse of daily controller medications. Because patients do not immediately notice the effects of these long-term drugs and do not understand the physiological effects they have, they often resort to taking them only when they feel sick. This boy reported frequent wheezing and coughing episodes brought on by a number of triggers, exercise being one of them.

The teenager and his mother met with the educator and were taught about the physiology of the disease, the concepts of rescue and controller medications, recognition of symptoms and triggers, and techniques for using the inhaler properly. The importance of using both medications as the doctor had prescribed was particularly stressed. Attempting to get through to the teen, the educator emphasized that his inability to breathe properly could be hindering his performance in sports. At the completion of the session, his mother thanked us profusely. Her son had sat and listened intently for the hour and a half we were there, which was something she often had trouble getting him to do.

When the educator returned for her next visit a few weeks later, this boy proudly showed her a first place gymnastics trophy which he was quick to attribute to the fact that he had been taking his daily controller medication regularly, and had also been taking his Albuterol before competitions, as she had advised. He was able to breathe easily and was not held back by his asthma. He was clearly thrilled about the change.

Case Study 3:

Another remarkable example of success comes from a 15-year-old teenage boy we worked with on the south side of Chicago. The first time we visited with him, his sister and his mother in their home, he expressed frustration with the frequency of his asthma symptoms and the ineffectiveness of his medicine. He is an active kid that was plagued with constant frustration when trying to play basketball and football with his friends. His symptoms were not well controlled prior to beginning the program, and as a result he was frequently kept up at night due to coughing and experienced regular wheezing episodes during the day. He has been amazed to learn that the answer to controlling his asthma (i.e., his medication) was in his hands all along, but that he never understood how to use it. The technique and importance of his daily medication had never been explained to him in a way that he understood and he was frustrated with how useless the medications seemed. Once our educator taught him what asthma meant for his body and how to get the most from his prescribed medications, his life changed.

Every time we have saw or spoke to this young man after the initial education session, he would express disbelief at how much better he felt. It is unfortunate however that for so long he was lacking the tools and the knowledge he needed to properly care for himself and live a normal life.

Such has been the nature of our personal experiences with this asthma intervention. While we have not experienced the same level of success with every single child, generally children and caregivers seem to have gained something valuable from the program, which is reflected in their willingness to continue their participation and their personal comments.

LESSONS LEARNED & CHALLENGES

Lessons Learned

Several important lessons were learned through the process of this pilot intervention. For one, we learned a great deal about what one should look for when hiring a LHE. As mentioned previously, our LHEs were recruited from the same neighborhoods that were targeted by the intervention. They did not need to have any prior experience with asthma or with health education. We also did not require a certain level of education. We felt that having educators with a cultural connection and understanding of the community who could therefore better relate to their clients was more imperative than prior experience. We did in fact find that the community was more welcoming and receptive of our LHEs because they possessed these qualities. Our 83% retention rate through the completion of the 6-month intervention phase substantiates the acceptability of the LHEs by the community.

That said, through our experiences we did learn that there are certain key qualities that one should look for when hiring a LHE. For one, that person must have a true passion for giving back to their community. The LHE needs to be a true advocate for every person with whom he/she works. Secondly, she must be someone who takes initiative and is willing to go the extra mile to assure that a participant has the information and resources necessary to properly care for their child's asthma. Sometimes this means helping the family address issues that are not directly related to asthma, but which impede on the caregiver focusing enough attention on his/her child's asthma. For example, a LHE might assist a family that lives with a relative or friend in finding affordable, quality housing, which will provide the family with greater autonomy and control over the environment in they live. A LHE may also assist a family whose child lacks health insurance in signing up for the All Kids program (Illinois' public health insurance plan for children). The LHE must realize her limitations however, and must be able to discern when she needs to turn an issue over to a social worker or to her supervisor. The LHE should be taught where to go and who to consult in assisting participants with these other issues. Finally, LHEs need to think critically and problem solve. The education provided to each family is specific to that family's unique needs. That means that the LHE needs to be able to take the information they have about asthma, and tailor it appropriately to each situation. The same method and approach will not work with every family. The LHE also needs to know when he/she needs to consult the supervisor and should be proactive in doing so.

We learned a great deal about the process of training LHEs. Our LHEs first participated in a 5 day, 5 hour per day class intended to teach them the basics of asthma pathophysiology, medication use, and triggers. However, their training did not end there. They then shadowed our hospital's experienced Asthma Educator (who also served as their Supervisor) for approximately a month, during which they observed the technique she used in teaching asthma. During this time, they continued to review the material they had learned during the training, to role-play with the Supervisor, and to participate in additional trainings with the hospital's Pediatric Pulmonologist. When the Supervisor felt they were ready to teach, she then shadowed them until she felt they were ready to go out and teach on their own.

LHEs also may need to develop skills beyond asthma and the teaching of asthma. For example, our project's LHEs had little experience with computers when they began working with us. They

needed to use a computer for certain aspects of their job (e.g., preparing letters for physicians) and we therefore had to provide them with basic computer skills training and support. Organizational skills may also be lacking, and some time may need to be spent up front teaching LHEs how to effectively manage a case load. Having a Research Assistant to help with this task was beneficial to our project.

We also learned that proper supervision of LHEs is imperative to the success of the intervention. The Supervisor needs to be readily accessible to the LHEs, so they can consult her whenever they encounter a new situation or need assistance in providing case management. In some cases, the LHEs are resistant to seeking out help and therefore the Supervisor needs to be proactive in checking in with the LHEs to see if they have any concerns or questions. Our Supervisor would review specific cases with the LHEs to assure that they were meeting her expectations. She would also conduct quality assurance checks, contacting random participants to assess their thoughts on the LHEs and the education provided.

Additionally, the establishment of a personal relationship with the family is vital to the intervention's success. We found that home visits by culturally competent LHEs break down barriers and encourage the establishment of a personal relationship. Because the LHE is of a similar culture and often has similar life experiences, a relationship of trust is quickly established. It is because of this success in establishing a personal relationship that we were able to complete the entire 6-month intervention phase with 83% of those enrolled, even though 31% of our families moved at least once during the course of the intervention.

Another interesting lesson that we learned involved the nature of a "family". Our goal was to educate the primary caregiver of the child. However, in many instances the child had several caregivers. For example, the child might live with his/her mother, but may go to his/her aunt's home after school while the mother was at work. It is therefore imperative that all of those caregivers are educated, and that they are encouraged to communicate with one another about their respective roles in managing the child's asthma. An example will illustrate the importance of communication between caregivers. We had a family where the mother and father were living separately from one another, but both had a role in the child's every day care. The child lived with the mother, but spent the afternoon/evening with the father. Both the mother and the father assumed the other was giving the child his daily controller medication and, as a result, the child was hardly ever taking his medication. The LHE was able to facilitate communication between the child's caregivers, thereby resolving the situation.

Finally, we learned that the approach needed to reach teenagers is much different than the approach needed to reach younger children. Clearly a teenager has a different locus of control than a younger child, and therefore the education needs to be mostly aimed towards the teenager with the caregiver present. The approach itself has to target the teen's concerns and/or specific barriers. An approach utilizing Peer Educators may be most effective with this population.

Challenges

The project experienced certain challenges that are important to touch on. One of our greatest challenges involved the transient nature of our target population and the instability of their lives. In fact, 31% of families who completed the entire 6-month intervention had moved at least once in that time interval. This was a challenge for a couple of reasons. First of all, it made it difficult to get a hold of caregivers as phone numbers were regularly changing. However, we had asked for alternative contact information (i.e., the contact information of a family member or close friend) at the beginning of the project, which proved immensely helpful in tracking people down. We were ultimately able to complete the entire 6-month intervention phase with 83% of those enrolled. Secondly, environmental triggers would change as the family's home changed, which meant that we often had to reassess triggers and update the teaching to focus on the current environmental triggers.

Many of the mothers/caregivers we worked with lived with another family member such as a grandmother or an aunt. As a result, they did not have total control over the environment in which they lived. For example, if a young mother was living with her own mother in her mother's home, it was sometimes challenging for the caregiver to request that certain environmental changes be made to accommodate her child.

We were very surprised to find that 97% of caregivers reported that their child had a physician that he/she saw regularly (i.e., a primary care physician). This was inconsistent with the literature suggesting that inner-city children from disadvantaged communities tend to rely on the ED for primary asthma care.^{1,3,37-39} However, as we started contacting doctors to obtain signed Asthma Action Plans, it came to our attention that while families considered one doctor as their child's primary physician, they were not necessarily seeing him/her regularly and were often seeing multiple physicians. The physician they had reported as their child's primary doctor often was not the one who had prescribed the most recent medications. It seemed that many families were going to whichever physician was convenient at the time, and as a result, their child did not have an established relationship with one doctor who was managing their asthma. As part of our intervention, we emphasized the importance of establishing a relationship with one physician and seeing that physician as exclusively as possible.

Another challenge involved the need for physician buy-in to make certain aspects of the intervention plausible and effective. Specifically, before we could provide the family with an Asthma Action Plan, we had to have it approved and signed by their primary care physician. If the physician did not review the Asthma Action Plan, sign it and return it in a timely manner, we could not take it to the family with us during our 6-month visit and discuss it with them. As a result, we were able to get a signed Asthma Action Plan to 42 of the 58 children (72.4%) who completed the entire intervention phase. While this was not the 100% we had hoped for, it was a marked improvement from the two children who had an Asthma Action Plan at the time of the baseline visit. Our process of obtaining signed Asthma Action Plans improved as our experience working with physicians increased.

A final challenge worth mentioning is the level of cigarette exposure to which our target population is subject on a regular basis. Specifically, 54% of enrolled children lived with a smoker, and 60% were exposed to secondhand cigarette smoke at least twice per week. While we tried to

encourage as many caregivers to quit smoking as possible, we were rarely successful. Even if the caregiver was willing to quit smoking for their child's sake, they often were not able to convince other members of their household to do the same. We tried to at least encourage all household members to go outside to smoke, and not to smoke in any car in which the child would ride. However, the level of exposure in the community in general is so high that it is nearly impossible to eliminate exposure to cigarette smoke completely. Findings from SUHI's *Improving Community Health Survey*^{17,40} demonstrate rates of cigarette smoking in North Lawndale (one of the program's target communities) that exceed the national rate by 150% (38.9% of adults in North Lawndale smoke vs. 25.9% of adults nationally). Interestingly, the prevalence of cigarette smoking in North Lawndale is similar to what it was nationally in 1965 (42%).⁴¹ Clearly, cigarette smoke exposure places a large burden on children in these communities with asthma, and may even play into the development of the disease.

RECOMMENDATIONS

General Recommendations

Our findings suggest that LHEs providing one-on-one, individualized asthma education to inner-city African American children with severe asthma may be an effective means of improving knowledge and thereby asthma management and outcomes. While we have not yet completed the formal cost-benefit analysis, the two- to four-fold reductions in urgent health resource utilization between the years prior to and following the intervention combined with the relative low cost of implementing the program strongly suggest this approach will also prove highly cost-effective. We therefore recommend that public funding for models utilizing LHEs be increased, allowing for the testing of the feasibility and effectiveness of the model in a variety of settings, among diverse communities, and with other chronic diseases.

The findings of PAI-2 have led IDPH to fund an expansion of the pilot project described in this report. The initiative is entitled *Controlling Pediatric Asthma Through Collaboration and Education (CPATCE)*, and its overall goal is to improve asthma management among high-risk children in Illinois and thereby reduce asthma-related healthcare expenditure, asthma-related morbidity and mortality. As a part of this initiative, the PAI-2 LHE model will be pilot tested in six target areas throughout Illinois. These six target areas were chosen by IDPH because they have asthma hospitalization rates that exceed the State average (17.6 per 10,000 population), and because they are diverse in terms of urbanicity, race/ethnicity, and socioeconomic status. An asthma consortium within each of the six target areas has been funded to implement the intervention. SUHI and Sinai Children's Hospital have been funded as the coordinating, training and evaluation entities for CPATCE. We are also expanding our own intervention to encompass more of Chicago's high-risk communities, including the Latino community.

CPATCE will provide substantially more data and should the results be consistent with those described herein, will give us more confidence in the effectiveness and generalizability of the approach. For example, PAI-2 was focused exclusively on African American children with severe asthma living in Chicago. We are now testing the same model in Decatur, a considerably smaller urban area about 180 miles southeast of Chicago. We are also testing it in Bureau and Putnam counties, two rural counties with a combined population of about 41,000 people. The pilot phase of the initiative will last approximately 3 years. If implementation proves to be feasible and the final evaluation demonstrates improved asthma outcomes in the six target areas, then this program should be further disseminated throughout the State of Illinois.

The Illinois Department of Healthcare and Family Services has also shown a commitment to improving pediatric asthma management in Illinois through their HealthCare Plus program, a Disease Management program that is being implemented by a selected vendor, McKesson Health Solutions. It is imperative that the effectiveness of this approach be thoroughly evaluated, modified as appropriate, and continued if it is shown to be effective.

Recommendations for Supervisors of LHEs

As outlined in the "Lessons Learned" section above (p.43), this pilot project taught us a great deal about the key qualities that one should look for when hiring a LHE, the process of training a LHE,

and effective supervision. With regard to hiring a LHE, the imperative qualities identified include: a true passion for giving back to and advocating for people living in the community; the ability to take initiative and a willingness to go beyond the call of duty when necessary; resourcefulness combined with an ability to think critically and problem solve. The LHE also needs to be able to recognize when a situation is beyond her area of expertise and must be willing to seek help from her supervisor in such instances. Techniques that will allow one to screen individuals for these key characteristics should be included in the interviewing and hiring process.

The training process utilized by our project is described in detail above ("The Lay Health Educators: Recruitment & Training, p.5). The process needs to be comprehensive. We began with a class intended to teach the basics of asthma pathophysiology, medication use, and triggers. However, that was not enough. The LHEs then shadowed an experienced Asthma Educator for approximately a month. During that month, they also continued to review the material they had learned during the training, to role-play with the Supervisor, and to participate in additional trainings with the hospital's Pediatric Pulmonologist. When the Supervisor felt the LHE was ready to teach, she then shadowed the LHE until she felt the LHE was ready to go out and teach on her own. We eventually developed a process of three supervised home visits combined with a competency evaluation implemented by our project's Medical Advisor (the Pediatric Pulmonologist), prior to allowing the LHEs to teach on their own.

It is also important for a Supervisor to understand that a LHE will likely need to develop skills beyond asthma and the teaching of asthma. For example, our LHEs had little experience with computers. They needed to use a computer for certain aspects of their job (e.g., preparing letters for physicians) and we therefore had to provide them with basic computer skills training and support. Organizational skills may also be lacking, and some time may need to be spent up front teaching LHEs how to effectively manage a case load.

Finally, proper supervision of LHEs is imperative to the success of the intervention. The Supervisor needs to be someone who can be readily accessible for the LHEs to consult whenever they encounter a new situation or need assistance in providing case management. Initially, LHEs may be resistant to seeking out help and therefore the Supervisor may need to be proactive in checking in with the LHEs to see if they have any concerns or questions. Our Supervisor would review specific cases with the LHEs to assure that they were meeting her expectations. She would also conduct quality assurance checks, contacting random participants to assess their thoughts on the LHEs and the education provided.

Recommendations for Providers:

Contrary to our expectations, the majority of our program participants had been to a physician's office for asthma care within the past year. In fact, 97% of caregivers reported that their child had a primary care physician. A large percentage (69%) also had a controller medication in their home. Regardless of this fact, the majority of caregiver's and children (if age-appropriate) did not know how to use their medications properly, did not understand the difference between a controller and a rescue medication, knew little about trigger avoidance, and did not have an Asthma Action Plan. Clearly, either physicians are not spending enough time educating patients on proper asthma management, or the education they are providing is not being understood by patients. Our study cannot decipher which of these situations is most prevalent. However, ideally someone other than

a physician would be responsible for asthma education. In this world of managed care and limited time being allocated for physicians to spend with a patient, it is not realistic that a physician can spend the time necessary to teach a patient how to properly manage asthma and to adequately answer all questions. Someone other than a physician should have primary responsibility for this task, and that person should be trained in both asthma management and effective communication. A nurse, medical assistant or LHE could fill such a role, and both Medicaid and other insurance providers should be encouraged to provide reimbursement for such services.

Secondly, providers must be encouraged to stay up to date with the NHLBI guidelines regarding proper asthma management,^{27,28} to provide referrals to asthma specialists as appropriate, and to prepare an Asthma Action Plan for every patient who has asthma. Our program utilizes a symptom-based Asthma Action Plan which was developed by our Pediatric Pulmonologist. Such a symptom-based Plan was developed based on our Pediatric Pulmonologist's experiences suggesting getting inner-city families to use a peak flow meter on a regular basis can prove nearly impossible.

Since children with severe, uncontrolled asthma are likely to utilize the ED somewhat regularly, we recommend that every inner-city ED with a high number of asthmatics coming through consider implementing some sort of asthma program in their ED. During high volume times, a LHE could institute patient education and provide assistance with follow-up care. Referrals to local primary care providers could be tracked by this LHE and physicians could be contacted regarding their patients who were seen in the ED. Each ED would need to decide whether or not the funding was available to do additional in-home visits with the most severe families encountered. It was definitely our experience that education provided in the home is even more effective than education provided in the clinic, however additional resources are needed for home visits to be plausible. ED physicians could also benefit from receiving additional education from an Asthma Specialist regarding the standard care and treatment of pediatric asthma and NHLBI Guidelines.

At this point it is important to emphasize that no program is without at least initial start up costs. It is imperative that some of the dollars saved at federal, state, or insurance company level be passed on to providers and their institutions for any of these new programs to be successful.

Recommendations for Further Research:

One of the limitations of the current project is that there was no control group against which the findings could be examined. While the findings of the current pilot (based on a before-after model) strongly suggest that LHEs may be an effective means of improving asthma management among inner-city, African American children with severe asthma, the absence of a control group makes it difficult to make definitive assertions about the model's effectiveness. It is therefore our longer term goal to conduct a randomized controlled trial of a LHE model which will more definitively demonstrate the effectiveness of the approach.

Another weakness of the current project concerns the limited target population. The findings of the pilot project therefore suggest that LHEs providing individualized asthma education in a home environment may be an effective means of improving asthma management among African American, inner-city children with severe asthma living in Chicago. We cannot conclude whether this approach would be feasible or effective with Latino or White children living in Chicago for

example. We have no idea whether it might be a feasible approach with children living in a more rural part of the State. Fortunately, CPATCE (described on p.47 above) is affording us the opportunity to test the model in a variety of settings throughout IL.

It would also be useful to test the longer term effectiveness of LHE models. While several studies have suggested that a LHE approach may be an effective means of improving the management of a chronic disease⁴²⁻⁴⁸ none have looked at whether improvements in knowledge, self-efficacy, behaviors and morbidity are maintained over longer time intervals. We are working towards obtaining some data from the Illinois Department of Healthcare and Family Services (the local provider of Medicaid) that would allow us to look at longer term healthcare utilization as an indicator of asthma morbidity over a longer time period.

There is a dire need to improve asthma surveillance in Illinois. There is currently a general lack of information on pediatric asthma prevalence and severity beyond the national level, and in adult asthma prevalence and severity beyond the state level. Such data is imperative so that: (a) available resources can be properly allocated to communities most in need of them, (b) population based efforts can be evaluated for their effectiveness in reducing asthma prevalence and morbidity over time, (c) the environmental triggers associated with asthma can be more clearly delineated and addressed. All existing smaller level data has been obtained via independent, grant funded studies such as Sinai's *Improving Community Health Survey*. A surveillance system for pediatric asthma could draw information from school entrance physicals and from school health records. Such an approach is being considered in New York City. Conversely, a population based telephone survey similar to the Behavioral Risk Factor Surveillance System Survey could be set-up to monitor trends in childhood chronic diseases at a State and local level. Resources should be allocated to the Illinois Department of Public Health to implement a surveillance system.

Given the lack of prevalence data currently available, a lot of information pertaining to areas that experience a disproportionate asthma burden is drawn from hospitalization discharge data. Illinois and Chicago discharge data is based on COMPdata, compiled by the Illinois Hospital Association. Reporting of race/ethnicity and income are not required fields for this dataset, however such information would be invaluable in accurately delineating the burden that minority and disadvantaged individuals experience as a result of asthma. In fact, most large states (e.g., California, New York, Pennsylvania, Massachusetts) do collect information on race/ethnicity. Census tract information would also be helpful in allowing estimates for smaller communities and in measuring the environmental impact of asthma. Currently, the smallest area publicly available is zip code, but as zip codes do not correspond perfectly with census tracts, it is difficult to obtain reliable denominators for smaller geographic areas and thereby accurate rates. In the absence of prevalence information, it is imperative that we be able to obtain more accurate and useful information from the COMPdata set so we can precisely assess the burden of asthma and its contributing factors.

Recommendations for Community Outreach:

The main recommendation surrounding community outreach is simply that the intervention model needs to be tested in a variety of communities, both urban and rural. Fortunately, we have been able to start assessing the feasibility of implementing the project in different community types via the CPATCE grant.

We primarily recruited children into the intervention through our ED and inpatient units and via referrals from community physicians. Such a mechanism works well for us given we are basing the intervention out of a healthcare system. However, other sources for referrals could be utilized as well, including daycares, social service agencies, schools, pharmacies and WIC programs, among others.

While the intervention itself took place in the home environment, and the majority of our referrals did come through health care settings, one of the main intentions of the program was to make a larger impact on asthma within target communities. We therefore also participated in numerous health fairs, did community presentations, hosted World Asthma Day activities at our hospital (inviting the community in to participate in the activities), and provided asthma information to community organizations as requested.

The final recommendation around community outreach involves the molding of the intervention to be more appropriate for teenagers. As mentioned above (see "Lessons Learned", p.43) our experiences suggest that the approach necessary to reach teenagers is much different than the approach needed to reach young children. A teenager is much more autonomous and responsible for his/herself. The education therefore needs to be mostly aimed towards the teenager. Teenagers also tend to be concerned about their image and what their peers will think of them. It may therefore be more effective to recruit teenagers who have asthma and train them to serve as Peer Educators for other teenagers. Such an approach should be tested for feasibility and effectiveness.

Recommendations for Public Policy:

As highlighted throughout, there is a great deal of consistent evidence that asthma education, in conjunction with appropriate medical evaluation and treatment, improves asthma management and outcomes. Lay Health Educators (a.k.a, Community Health Workers, Peer Educators, Promotoras de Salud, etc.) have consistently been shown to improve the management of chronic conditions, including pediatric asthma. SUHI and Sinai Children's Hospital have collaborated on two pediatric asthma interventions, and our experiences clearly reinforce this assertion. The cultural connection that a lay person from the Community brings to a teaching session with a family is invaluable. Also, using LHEs from the community encourages the trust of people living within the community, and boosts the economy of the community by providing jobs, training, and opportunity for community members. Encouraging proactive health behaviors among children and their parents enhances an entire family's quality of life. Developing support systems for people with chronic illnesses and encouraging people to advocate for themselves instills confidence and promotes positive behaviors. The Illinois Department of Public Health and the Department of Healthcare and Family Services have both shown a commitment to improving pediatric asthma management in Illinois by funding Lay Health Educator models. However, it is imperative that these programs and potential expansions of them continue to receive adequate funding.

The fragmentation of health care in the United States is a major deterrent to the implementation of effective disease management programs. By now there are an estimated 50 million people without health insurance in the United States. *This country is the only industrialized nation in the world without a national health care plan.* There is uncontested evidence that lack of such health

insurance is one of the main causes of sickness and death. Certainly this extends to morbidity and mortality due to asthma. We commend Illinois for becoming the first state in the United States to ensure that affordable health insurance is available to all children living in Illinois. However, programs need to be in place that will assist those eligible in applying for these benefits. Also, health insurance is a right that needs to be extended to the entire family. By acting rationally and humanely, and providing health care insurance to all in Illinois, we will at the same time greatly reduce the burden of asthma in the state – and its costs as well.

An additional deterrent to quality asthma medical care being available to residents of our most disadvantaged communities stems from the fact that reimbursement by public insurance for the provision of medical services is unreasonably low. Even though many studies have demonstrated substantial savings to the health care system when appropriate disease management is implemented, there is no mechanism to ensure appropriate medical management is undertaken nor is there any type of incentive for providers to participate. Programs such as the one described herein that demonstrate positive outcomes for patients, cost savings for the health care system, and decreased usage of urgent and emergency care should be identified and implemented appropriately.

To our knowledge, Medicaid does not provide reimbursement for time spent by non-medical staff on patient education. Therefore, attempts are made to provide patient education within the time constraints of a medical appointment. In most instances, having medical staff provide quality education about a chronic disease such as asthma in the limited time they have available amidst their other responsibilities is neither realistic nor practical. A trained LHE can therefore fill a vital gap by providing chronic disease management education in conjunction with a medical facility provided that facility is reimbursed for their services. The findings of our cost-benefit analysis around our first Pediatric Asthma Intervention,¹⁹ along with the dramatic reduction in urgent health resource utilization evidenced in this current intervention, suggest that by reimbursing such services, Medicaid would save money in the long run.

CONCLUSION

The main goal of this study was to examine whether an intervention model utilizing a Lay Health Educator providing individualized asthma education to African American children with severe asthma in the home environment is both feasible and effective. The findings of the process evaluation clearly show that such a model is feasible in an urban environment. Furthermore, the outcome evaluation findings were suggestive of improved asthma control as evidenced by reduced symptom frequency and emergency health resource utilization over the 12-months following the initiation of the intervention. As one poignant example, ED visits decreased about three-fold, from an average of 3.4 times in the year prior to the study to 0.9 in the year following. Pilot participants also had significantly improved asthma knowledge scores, quality of life scores, evidence of decreased exposure to asthma triggers in the home environment, and demonstrated improved technique in using medications following the intervention.

The evidence presented in this report demonstrates that a model that utilizes a culturally competent LHE recruited from the target community to educate families about asthma management is well received by the community. This assertion is further supported by the fact that we were able to complete the entire 6-month intervention phase with nearly 83% of those enrolled, a particularly high retention rate for an urban, disadvantaged population. The benefit that a lay person from the Community brings to a teaching session with a family is invaluable. Asthma information can be taught; culture and experience is more difficult if not impossible to teach.

While the cost-benefit analysis for this particular intervention has not yet been completed, the relatively inexpensive nature of conducting an intervention with LHEs combined with the three to four fold reductions in urgent health resource utilization observed between the baseline and follow-up year, suggest this model will be associated with substantial cost-savings. A separate report with the findings of the cost-benefit analysis will be released in the near future.

There have been a few articles discussing the feasibility of utilizing LHEs in working with the families of children with asthma^{24,26,48}, but only four have included an outcome analysis.^{23,49-51} Krieger et al.^{49,52} found that a high-intensity LHE intervention primarily focused on reducing exposure to indoor asthma triggers in the home was more effective than a lower-intensity (control) intervention in improving pediatric asthma caregiver quality of life and asthma-related urgent health resource utilization among disadvantaged children with persistent asthma living in the Seattle-King County area. The high-intensity intervention included seven home visits consisting of a structured home environmental assessment, devising an environmental action plan, education, social support, and the provision of substantial resources to reduce exposure (e.g., pillow and mattress covers, low-emission vacuums, cleaning kit, referrals to smoking cessation counseling, roach and rodent traps, etc.). LHEs also advocated for improved housing conditions as appropriate. The lower-intensity (control) group received a single visit. While both groups experienced significant improvements from baseline to the one-year follow-up in certain outcomes (symptom days/2 weeks, caregiver quality of life scores, days with activity limitations/2 weeks, and days needing rescue medication/2 weeks), only the high-intensity group improved with regard to urgent health resource utilization. Also, caregiver quality of life and urgent health resource utilization improved to a statistically greater degree in the high-intensity group. While the intervention provided to the high-intensity group, particularly the provision of resources to reduce trigger exposure, may be

difficult to sustain on a larger scale, the findings suggest that while a higher intensity intervention may be more effective, even a low-intensity intervention leads to improved outcomes. It is interesting to note that our intervention was intermediate in intensity between the high and the lower-intensity interventions and noted similar degrees of improvement.

Martin et al.^{50,53} found that Spanish-speaking LHEs from a southside, predominantly Latino Chicago community were effective in reducing exposure to triggers among both adults and children with asthma. There were no statistically significant improvements in any of the other outcomes assessed (asthma severity, health resource utilization, or rescue medication use). However, the intervention provided was limited to a single visit with a pair of LHEs, and the target population included anyone with physician diagnosed asthma, regardless of level of severity. These differences from the study described herein likely contribute to the difference in outcomes.

The Clean Air for Kids® partnership utilized community-based LHEs to provide individualized education on trigger avoidance and asthma management to the families of low-income children with moderate to severe asthma. A varying number of home visits were conducted depending on the needs of the family (mean=2.2 visits occurring over 2-26 weeks). Among families who participated in the evaluation (60 of 197 families who participated in the program) statistically significant improvements were noted in caregiver quality of life, self-reported hospitalizations, and the proportion with an asthma action plan. All participating families indicated having made changes to minimize exposure to asthma triggers. The findings of the evaluation are limited by the fact that a convenience sample of all program participants were used, and those who agreed to participate in the evaluation may have been more motivated to make the changes necessary to improve their child's asthma.

The final study including outcomes was a small pilot (n=23) that utilized a LHE working in conjunction with a health care team (pediatrician, pharmacist and public health nurse) with the goal of providing culturally sensitive support to inner-city children with asthma and their caregivers.²³ The LHE made monthly home visits for six months. Findings were indicative of reductions in hospitalizations, ED visits, and unscheduled clinic visits.

Finally, the literature includes several publications around the use of LHEs with a number of chronic disease management and prevention initiatives. Several published literature reviews have summarized the findings from these studies and drawn conclusions about the effectiveness of CHWs in preventing (primary prevention), identifying (secondary prevention), and managing (tertiary prevention) various chronic diseases.⁴²⁻⁴⁸

Limitations

No summary and conclusion section would be complete without a discussion of the limitations of our study process.

First of all, this was a pilot study with limited funding. As a result, we utilized a pre-post test study design with each child serving as his or her own historical control. The fact that we did not have a control group against which to compare the noted improvements among program participants limits our ability to draw strong conclusions from the data. Without a control group, we cannot definitively conclude that the noted improvements are a result of the intervention itself and not of some other

external factor. However, the magnitude of improvements between the baseline and follow-up year for several of the outcomes combined with the consistency of improvements across the range of outcomes does suggest that the intervention was responsible for at least a portion of the noted improvement.

We also had a limited sample size, with only 50 participants completing the entire 12-month data collection phase of the project. The fact that we saw statistically significant improvements with a relatively small sample size (which makes it more difficult to find statistical significance) lends further credibility to the findings.

Since the study utilized recall for data collection, the ability of the caregivers to remember information may have affected the quality of our data. Limiting the amount of time over which data could be recalled to less than three months minimized bias. When asking about symptoms, we asked about the 2-weeks prior to the date on which the data was being collected. When comparing baseline symptoms to follow-up, we compared the average reported number of days over the past 2-weeks, which should further minimize the effects of recall bias. To further mitigate the potential bias associated with recalled health resource utilization data, we are in the process of obtaining Medicaid data for participants. Once we have this data, we will be able to compare self-reported health resource utilization against claims data for the time period encompassed by the study. We will also be able to assess the longer-term impact of the intervention on asthma control.

The use of recalled data collected by an interviewer also made the data more vulnerable to social desirability bias. Social desirability bias results from the human tendency to seek approval from others and to therefore sometimes report what is perceived as the desirable response as opposed to the true response. Therefore, some of the changes we note especially in behavior may be exaggerated somewhat. For example, a portion of the decline in secondhand cigarette smoke exposure may actually be due to social desirability bias and an increase in knowledge that secondhand cigarette is harmful to children with asthma and should be avoided whenever possible. However, the fact that we had a third party, a research assistant, primarily responsible for collecting the data as opposed to the LHE should have minimized social desirability bias.

Another concern involves the validity of the questionnaires used to gather study related data. There is a general lack of validated tools available to measure asthma-related outcomes. In fact, of the tools utilized only one, *The Pediatric Asthma Caregivers Quality of Life Questionnaire*, had been previously validated. This instrument was validated with the caregivers of children 7-17 years, but has been used with children younger than 7 before.^{49,54} Nonetheless, its content validity (ability to capture all aspects of quality of life) may be compromised when used with the caregivers of younger children, as there are likely issues that are unique to younger children that are not captured by the instrument. As there were no other validated measures available to assess quality of life among the caregivers of young children with asthma, we used this instrument and then analyzed the data stratified by age (2-6 yrs. vs. 7-17 yrs.). No significant differences in scores were noted (data not shown). We are currently undertaking activities intended to validate the Quality of Life tool in younger children, as well as our other tools. If we are able to publish our findings, this will be a great contribution to the asthma literature.

The final limitation involves the limited study population. This study was carried out with African American children with severe asthma living in urban, disadvantaged neighborhoods of Chicago.

The study's findings are therefore not generalizable to other populations. We do not know whether this same model will be feasible and effective in other settings. For example, we cannot conclude from the current pilot study whether this same model would be feasible and effective if used with Latino children living in an urban setting, or with children living in a more rural area.

Conclusion

Our findings suggest that individualized, one-on-one asthma education provided by a trained, culturally competent LHE in the home environment may be an effective means of improving asthma management among inner-city, African-American children with poorly controlled asthma. The pilot study provided evidence of improved asthma outcomes, quality of life and asthma-related knowledge, and of decreased exposure to triggers among families participating in the intervention. Given the degree of improvement in urgent health resource utilization combined with the relative low cost of the intervention, the intervention will likely prove cost effective as well. Nonetheless, further studies with a more stringent study design are needed to affirm our results and assess the model's generalizability.

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APPENDICES

Appendix 1. Recruitment Scripts

Appendix 2. Baseline Data Collection Forms

APPENDIX 1. RECRUITMENT SCRIPTS

Recruitment Script – From Mount Sinai ER or Hospital

Hello. May I talk to the guardian of ___[INSERT CHILD’S NAME] ___. Hi, my name is _____ and I am an asthma educator at Mount Sinai Hospital.

I am working on an asthma education program being conducted by Sinai Children’s Hospital. The purpose is to provide asthma education to the family members of those children with asthma, who have come to the emergency room or had to be hospitalized for their asthma in the last 12 months. Our hospital records suggest that, ___[INSERT CHILD’S NAME] ___ might have been to the hospital for asthma problems in the last 12 months. That’s why I am calling to see if you would be interested in knowing about this program and possibly participating in it. The program is free of cost and asthma education can be provided at your home. Are you interested in knowing about this program?

[IF “YES”, PROCEED WITH THE FOLLOWING. IF “NO”, THANK PERSON FOR THEIR TIME.]

I would first like to ask you a few brief questions to see if your child is eligible for the program. These questions will only take a couple of minutes, and if your child is eligible then I will tell you more about the program. You can then decide if this is something you might be interested in. Can I ask you a few questions?

[IF “YES”, PROCEED WITH THE FOLLOWING QUESTIONS. IF “NO”, THANK PERSON FOR THEIR TIME.]

First, I want to confirm that, ___[INSERT CHILD’S NAME] _ did come to the Emergency room or had to be hospitalized in last 12 months because of Asthma.

[IF “YES”, PROCEED WITH THE FOLLOWING QUESTIONS. IF “NO”, THE CHILD IS NOT ELIGIBLE. THANK PERSON FOR THEIR TIME.]

1. Has a doctor or other health care professional ever told you that your child has asthma?
___ Yes [CONTINUE WITH Q.2]
___ No [CHILD IS NOT ELIGIBLE. END HERE.]
2. Has your child had asthma or the symptoms of asthma for at least 6 months? Symptoms of asthma include coughing, wheezing, chest congestion, and difficulty breathing.
___ Yes [CONTINUE WITH Q. 3.]
___ No [CHILD IS NOT ELIGIBLE. END HERE.]

APPENDIX 1. RECRUITMENT SCRIPTS

3. Does your child have a regular doctor?
___ Yes [CONTINUE WITH Q. 3A.]
___ No [GO TO Q.3B.]
- a. What is the name of your child’s regular doctor? If you do not remember his/her name, could you please tell me the name of the clinic?
_____ [IF
THEY DO NOT HAVE A DOCTOR GO TO 3B. OTHERWISE, GO TO Q.4].
- b. Would you like me to refer you to a doctor who your child could see for his/her asthma?
___ Yes [PROCEED WITH REFERRAL AND GO TO Q.4.]
___ No [CHILD IS NOT ELIGIBLE. END HERE.]
4. Have you or your child been enrolled in any other asthma education program in the last year?
___ Yes [CHILD IS NOT ELIGIBLE. END HERE.]
___ No [CHILD IS ELIGIBLE. CONTINUE WITH SCRIPT.]
5. Do you live in the city of Chicago?
___ Yes [CHILD IS ELIGIBLE. CONTINUE WITH SCRIPT.]
___ No [CHILD IS NOT ELIGIBLE. END HERE.]

Your child is eligible for the project. Let me tell you a little bit about the project so you can decide if you are interested in participating. If you decide to participate, I would meet with you three times over a six-month period to provide you with individualized education on what you can do to help your child better manage his/her asthma. [BREAK] I will do my best to accommodate your schedule. We can have our meetings at your home or we can meet elsewhere. The sessions would last between an hour and an hour-and-a-half. We would also ask you to answer some questions for us at various times during the 6 months. Your answers to these questions would be private, and we would not share them with anyone. These questions will help us determine whether the project is helping you and your child, and whether it is worth offering to others. It is our hope that by participating in the project, you and your child would learn the skills necessary to better manage _____’s [INSERT CHILD’S NAME] asthma.

Does this sound like something you might be interested in?

[IF INTERESTED, SCHEDULE FIRST MEETING TIME AND LOCATION. ALSO, ENCOURAGE POTENTIAL PARTICIPANT TO MEET WITH THEIR CHILD’S DOCTOR BEFORE THAT MEETING (PROVIDE NECESSARY CASE MANAGEMENT TO ASSURE THAT HAPPENS). REMIND CAREGIVER TO HAVE ALL MEDICATIONS AND DEVICES AT MEETING.]

[IF NOT INTERESTED]: Thanks for your time.

APPENDIX 1. RECRUITMENT SCRIPTS

***BREAK:** Ask the caregiver a question to keep her attentive. For example, “How well do you feel your child’s asthma is managed now?”, or “When I say, ‘better manage your child’s asthma’, do you understand what I mean?”.

Recruitment Script – Doctor Referral

Hello – My name is _____ and I am an asthma lay health educator for Sinai Health System.

I received your name from _____ **[INSERT DOCTOR’S NAME]** because your child has asthma. Your child’s doctor believes this asthma may be moderate to severe. I am working with a project to improve asthma management among children and I would like to ask you and your child to participate in this project, which is being conducted by Sinai Children’s Hospital.

I would first like to ask you a couple of questions to see if your child is eligible for the project and to learn how I might be of help to you. These questions will only take a couple of minutes, and if your child is eligible then I will tell you more about the project. You can then decide if this is something you might be interested in. Can I ask you a few questions?

[IF “YES”, PROCEED WITH THE FOLLOWING QUESTIONS. IF “NO”, THANK PERSON FOR THEIR TIME.]

1. Has your child been to the Emergency Room in the past 6 months because of an asthma attack?
 Yes
 No

2. Has your child been hospitalized in the past 6 months because of an asthma attack?
 Yes
 No

3. Does your child experience symptoms of asthma on a daily basis? Symptoms of asthma include coughing, wheezing, chest congestion, and difficulty breathing.
 Yes **[CONTINUE WITH Q.3.A]**
 No **[SKIP TO Q.4]**
 - a. Has your child had daily symptoms of asthma for at least the past 2 months?
 Yes
 No

APPENDIX 1. RECRUITMENT SCRIPTS

4. Does your child experience nighttime asthma symptoms at least once a week?
___ Yes [CONTINUE WITH Q.4.A]
___ No [SKIP Q.4.A.]
- a. Has your child had weekly nighttime symptoms of asthma for at least the past 2 months?
___ Yes
___ No

[IF ANSWERED “YES” TO AT LEAST ONE OF Q.1., Q.2., Q.3.A OR Q.4.A., CHILD MAY BE ELIGIBLE. CONTINUE WITH QUESTIONS. OTHERWISE, CHILD IS NOT ELIGIBLE. END HERE.]

5. Has your child had asthma or the symptoms of asthma for at least 6 months?
___ Yes [CONTINUE WITH Q. 6.]
___ No [CHILD IS NOT ELIGIBLE. END HERE.]
6. Have you or your child been enrolled in any comprehensive asthma education program in the last year?
___ Yes [CHILD IS NOT ELIGIBLE. END HERE.]
___ No [CHILD IS ELIGIBLE. CONTINUE WITH SCRIPT.]

Your child is eligible for the project. Let me tell you a little bit about the project so you can decide if you are interested in participating. If you decide to participate, I would meet with you three times over a six-month period to provide you with individualized education on what you can do to help your child better manage his/her asthma. **[BREAK*]** I will do my best to accommodate your schedule. We can have our meetings at your home or we can meet elsewhere. The sessions would last between an hour and an hour-and-a-half. We would also ask you to answer some questions for us at various times during the 6 months. Your answers to these questions would be private, and we would not share them with anyone. These questions will help us determine whether the project is helping you and your child, and whether it is worth offering to others. It is our hope that by participating in the project, you and your child would learn the skills necessary to better manage _____’s **[INSERT CHILD’S NAME]** asthma.

Does this sound like something you might be interested in?

[IF INTERESTED, SCHEDULE FIRST MEETING TIME AND LOCATION. ALSO, FIND OUT WHEN CHILD LAST SAW HIS/HER DOCTOR. IF APPROPRIATE, ENCOURAGE POTENTIAL PARTICIPANT TO MEET WITH THEIR CHILD’S DOCTOR BEFORE YOUR MEETING WITH THEM (PROVIDE NECESSARY CASE MANAGEMENT TO ASSURE THAT HAPPENS).]

[IF NOT INTERESTED]: Thanks for your time.

***BREAK:** Ask the caregiver a question to keep her attentive. For example, “How well do you feel your child’s asthma is managed now?”, or “When I say, ‘better manage your child’s asthma’, do you understand what I mean?”

APPENDIX 2. BASELINE DATA COLLECTION FORMS

Personal Data Sheet

Participant ID Number: _____

Data Collected by: _____ [INITIALS ONLY]

Date collected: _____ [MM/DD/YYYY]

CONTACT INFORMATION

¹Patient's Name: _____

²Name(s) of Primary Caregiver/s: _____

³Relationship of Primary Caregiver/s to child [CIRCLE CORRECT RESPONSE]:

- a. Mother (biological, adoptive, step)
- b. Father (biological, adoptive, step)
- c. Grandparent
- d. Aunt/Uncle
- e. Sister/Brother (step, foster, half, adoptive)
- f. Other family member
- g. Legal guardian
- h. Foster parent (relative or non-relative)
- i. Other non-relative (specify) _____

⁴Address: _____

⁵City: _____ ⁶State: _____ ⁷Zip: _____

⁸Home Phone: (____)____-____ ⁹Work Phone: (____)____-____

¹⁰Cellular Phone: (____)____-____

¹¹E-Mail address: _____

¹²Preferred Method of Contact: _____

¹³Best Day/Time to Reach Family: _____

ALTERNATIVE CONTACT'S INFORMATION

[I.E., PERSON WHO WOULD KNOW WHERE TO FIND CAREGIVER IF MOVE, ETC.]

¹⁴Name of Alternative Contact: _____

¹⁵Address: _____

¹⁶City: _____ ¹⁷State: _____ ¹⁸Zip: _____

¹⁹Home Phone: (____)____-____ ²⁰Work Phone: (____)____-____

²¹Cellular Phone: (____)____-____

²²E-Mail address: _____

APPENDIX 2. BASELINE DATA COLLECTION FORMS

PRIMARY CARE PHYSICIAN (PCP) INFORMATION

²³Child has a PCP: ___ Yes ___ No [IF YES, ANSWER Q24 AND Q25. IF NO, SKIP TO Q26.]

²⁴If yes, name of PCP: _____

²⁵PCP's Clinic/Office: _____

[SKIP TO Q28]

²⁶If no, name of PCP to which referred: _____

²⁷PCP's Clinic/Office: _____

ASTHMA SPECIALIST INFORMATION

²⁸Has your child seen an asthma specialist in the last 6 months? ___ Yes ___ No [IF YES, ANSWER Q29 AND Q30. IF NO, SKIP TO Q31.]

²⁹If yes, name of asthma specialist: _____

³⁰Asthma specialist's Clinic/Office: _____

DEMOGRAPHIC INFORMATION ABOUT CHILD

³¹Age: _____ ³²Date of Birth: _____ [MM/DD/YYYY]

³³Gender: ___ Male ___ Female

³⁴Insurance [CIRCLE ALL THAT APPLY]:

- a. Medicaid/KidCare/Public Aid
- b. HMO/Private
- c. No Insurance/Self Pay
- d. Other (SPECIFY: _____)
- e. DK/Not Sure
- f. Refused

DEMOGRAPHIC INFORMATION ABOUT PARENT

³⁵Highest level of education completed [CIRCLE APPROPRIATE RESPONSE]

- a. Less than high school
- b. High school graduate
- c. Vocational/Business school
- d. Some college
- e. College graduate
- f. Professional/Graduate degree
- g. No Coded Response Applicable (SPECIFY: _____)
- h. Don't Know
- i. Refused

Date form entered into database: _____ [MM/DD/YYYY]

Data Entry Operator: _____ [INITIALS ONLY]

APPENDIX 2. BASELINE DATA COLLECTION FORMS

Initial Data Sheet

Participant ID Number: _____

Data Collected by: _____ [INITIALS ONLY] Date collected: _____ [MM/DD/YYYY]

SYMPTOMS OF ASTHMA

In the following questions, we are asking you to think back upon your child's asthma symptoms over the past 2 weeks. Symptoms of asthma include coughing, wheezing and shortness of breath.

1. In the past 2 weeks, on how many days has your child had no asthma symptoms? In other words, on how many days has your child gone 24-hours without experiencing any of the symptoms of asthma? _____ [ENTER NUMBER BETWEEN 0-14, OR 98 IF ANSWERED "DON'T KNOW", OR 99 IF "REFUSED"]
2. In the past 2 weeks, on how many days has your child had symptoms of asthma during daytime hours? _____ [ENTER NUMBER BETWEEN 0-14, OR 98 IF ANSWERED "DON'T KNOW", OR 99 IF "REFUSED"]
3. In the past 2 weeks, on how many nights did symptoms of asthma make it difficult for your child to stay asleep? _____ [ENTER NUMBER BETWEEN 0-14, OR 98 IF ANSWERED "DON'T KNOW", OR 99 IF "REFUSED"]
4. In the past 2 weeks, on how many days did your child need to use their quick relief or rescue medicine? _____ [ENTER NUMBER BETWEEN 0-14, OR 98 IF ANSWERED "DON'T KNOW", OR 99 IF "REFUSED"]

SEVERITY OF ASTHMA

In the following questions, we are asking you to think back over the past year. Please answer as accurately as you can.

5. In the past 12 months, how many attacks or episodes of asthma did your child have? _____ [ENTER NUMBER BETWEEN 0-96. IF MORE THAN 96 TIMES, ENTER "96". IF DON'T KNOW, ENTER "98". IF REFUSE, ENTER "99"]
6. In the past 12 months, how many attacks or episodes of wheezing did your child have? _____ [ENTER NUMBER BETWEEN 0-96. IF MORE THAN 96 TIMES, ENTER "96". IF DON'T KNOW, ENTER "98". IF REFUSE, ENTER "99"]
7. In the past 12 months, has wheezing ever been severe enough to limit your child's speech to only one or two words at a time between breathes? [CHECK CORRECT RESPONSE]
 Yes
 No
 No Coded Response Applicable (SPECIFY: _____)
 Don't Know
 Refused
8. During the past 12 months, how many days was your child unable to attend school or carry out usual activities because of asthma? _____ [ENTER NUMBER BETWEEN 0-96. IF MORE THAN 96 TIMES, ENTER "96". IF DON'T KNOW, ENTER "98". IF REFUSE, ENTER "99"]

APPENDIX 2. BASELINE DATA COLLECTION FORMS

In the following questions, we are asking you to think back upon your child's use of health care for asthma over the past year. Please answer as accurately as you can.

APPENDIX 2. BASELINE DATA COLLECTION FORMS

CHILD'S MEDICATION HISTORY

15. Has a doctor ever prescribed any medicine to your child for his/her asthma? **[CHECK CORRECT RESPONSE]**

- Yes
- No
- No Coded Response Applicable (**SPECIFY:** _____)
- Don't Know
- Refused

[IF NO, "DON'T KNOW" OR "REFUSED", SKIP TO Q26. OTHERWISE, CONTINUE WITH Q16]

16. Is your child currently taking any medications for his/her asthma, either regularly or on an "as needed" basis? **[CHECK CORRECT RESPONSE]**

- Yes
- No
- No Coded Response Applicable (**SPECIFY:** _____)
- Don't Know
- Refused

[IF YES, SKIP TO Q18. IF NO, ASK Q17. OTHERWISE, SKIP TO Q24.]

17. Which of the following is the reason why your child is not currently taking any medication for his/her asthma? **[CHECK CORRECT RESPONSE]**

- The doctor told me that my child no longer needs the medicine
- I don't think my child needs the medicine/It doesn't help my child
- My child won't take the medicine
- We have not seen or talked to the doctor recently to obtain a needed refill
- I cannot afford to buy the medicine
- Some other reason (**SPECIFY:** _____)
- No Coded Response Applicable (**SPECIFY:** _____)
- Don't Know
- Refused

[SKIP TO Q.24]

18. Could you please tell me which medications your child is currently taking? **[HAVE THE CAREGIVER BRING THE MEDICATIONS TO YOU IF POSSIBLE]**

- a. Medication 1: _____
Prescribed Strength: _____
Prescribed times per day: _____
Route of Administration: _____ **[SELECT CORRECT NUMBER AND LETTER FROM ATTACHED LIST]**
Actual Use: **[CIRCLE CORRECT RESPONSE]**
i. Regular Use (Times taken per day: _____)
ii. Taken only as needed

- b. Medication 2: _____
Prescribed Strength: _____
Prescribed times per day: _____
Route of Administration: _____ **[SELECT CORRECT NUMBER AND LETTER FROM ATTACHED LIST]**
Actual Use: **[CIRCLE CORRECT RESPONSE]**
i. Regular Use (Times taken per day: _____)
ii. Taken only as needed

APPENDIX 2. BASELINE DATA COLLECTION FORMS

c. Medication 3: _____
Prescribed Strength: _____
Prescribed times per day: _____
Route of Administration: _____ [SELECT CORRECT NUMBER AND LETTER FROM ATTACHED LIST]
Actual Use: [CIRCLE CORRECT RESPONSE]
i. Regular Use (Times taken per day: _____)
ii. Taken only as needed

d. Medication 4: _____
Prescribed Strength: _____
Prescribed times per day: _____
Route of Administration: _____ [SELECT CORRECT NUMBER AND LETTER FROM ATTACHED LIST]
Actual Use: [CIRCLE CORRECT RESPONSE]
i. Regular Use (Times taken per day: _____)
ii. Taken only as needed

19. Does your child always, usually, sometimes or never take the above medications as prescribed by the doctor? [CHECK CORRECT RESPONSE]

- Always
- Usually
- Sometimes
- Never
- No Coded Response Applicable (SPECIFY: _____)
- Don't Know
- Refused

20. If your child does not always take their medications as prescribed by the doctor, why not? _____

[BASED ON THE DATE IN Q14, ASSESS WHETHER THE CHILD HAS SEEN THE PCP SINCE THE INITIATION OF THE INTERVENTION. IF YES, ASK Q21-Q23. ELSE SKIP TO Q24.]

21. Did your child's regular doctor change his/her asthma medications at his/her last appointment? [CHECK CORRECT RESPONSE]
 Yes
 No
 No Coded Response Applicable (SPECIFY: _____)
 Don't Know
 Refused

[IF YES, ASK Q22. ELSE SKIP TO Q24.]

APPENDIX 2. BASELINE DATA COLLECTION FORMS

22. Do you remember or do you still have the medications that your child used to take, before his/her doctor changed them?
- Yes
 - No
 - No Coded Response Applicable (SPECIFY: _____)
 - Don't Know
 - Refused

[IF YES, ASK Q23. ELSE SKIP TO Q24.]

23. Could you please tell me which medications your child was taking before the latest visit with his/her doctor? **[HAVE THE CAREGIVER BRING THE MEDICATIONS TO YOU IF POSSIBLE]**

- a. Medication 1: _____
Prescribed Strength: _____
Prescribed times per day: _____
Route of Administration: _____ **[SELECT CORRECT NUMBER AND LETTER FROM ATTACHED LIST]**
Actual Use: **[CIRCLE CORRECT RESPONSE]**
i. Regular Use (Times taken per day: _____)
ii. Taken only as needed
- b. Medication 2: _____
Prescribed Strength: _____
Prescribed times per day: _____
Route of Administration: _____ **[SELECT CORRECT NUMBER AND LETTER FROM ATTACHED LIST]**
Actual Use: **[CIRCLE CORRECT RESPONSE]**
i. Regular Use (Times taken per day: _____)
ii. Taken only as needed
- c. Medication 3: _____
Prescribed Strength: _____
Prescribed times per day: _____
Route of Administration: _____ **[SELECT CORRECT NUMBER AND LETTER FROM ATTACHED LIST]**
Actual Use: **[CIRCLE CORRECT RESPONSE]**
i. Regular Use (Times taken per day: _____)
ii. Taken only as needed
- d. Medication 4: _____
Prescribed Strength: _____
Prescribed times per day: _____
Route of Administration: _____ **[SELECT CORRECT NUMBER AND LETTER FROM ATTACHED LIST]**
Actual Use: **[CIRCLE CORRECT RESPONSE]**
i. Regular Use (Times taken per day: _____)
ii. Taken only as needed

24. Sometimes children are not able to get medicine when they need it. During the past 12 months, was there any time when your child needed prescription medication for his/her asthma but did not get it right away? **[CHECK CORRECT RESPONSE]**
- Yes
 - No
 - No Coded Response Applicable (SPECIFY: _____)
 - Don't Know
 - Refused

[IF YES, ANSWER Q25. OTHERWISE, SKIP TO Q26]

APPENDIX 2. BASELINE DATA COLLECTION FORMS

25. When you were not able to get your child’s asthma medication right away, what was the most common reason? [CHECK CORRECT RESPONSE]

- You could not afford it
- The pharmacy does not have convenient hours
- You don’t have the time to go get the medicine
- You have a hard time getting a hold of your child’s doctor to get a necessary refill
- You have other children and cannot leave them to go to the pharmacy
- You don’t feel your child really needs the medicine
- Some other reason (SPECIFY: _____)
- No Coded Response Applicable (SPECIFY: _____)
- Don’t Know
- Refused

ALLERGY TESTING

26. Has your child ever undergone allergy testing? [CHECK CORRECT RESPONSE]

- Yes
- No
- No Coded Response Applicable (SPECIFY: _____)
- Don’t Know
- Refused

[IF YES, ASK Q27. ELSE, SKIP TO END]

27.

- a. When was the allergy testing done? If you don’t know the exact date, please give me your best approximation. _____ [MM/DD/YYYY]
- b. What was your child found to be allergic to?

- c. Name of the doctor who ordered the allergy testing and the name of their clinic.

Date form entered into database: _____ [MM/DD/YYYY] Data Entry Operator: _____ [INITIALS ONLY]

APPENDIX 2. BASELINE DATA COLLECTION FORMS

Pediatric Asthma Caregiver's Quality of Life Questionnaire

Participant ID Number: _____

Collected at: ___ Baseline ___ Month 6 ___ Month 12

Data Collected by: _____ [INITIALS ONLY] Date collected: _____ [MM/DD/YYYY]

This questionnaire is designed to find out how you have been during the last week. We want to know about the ways in which your child's asthma has interfered with your normal daily activities and how this has made you feel.

1. During the past week, how often did you feel helpless or frightened when your child experienced cough, wheeze, or breathlessness? Would you say: **[CHECK ONLY ONE RESPONSE]**

All of the time [1]
 Most of the time [2]
 Quite often [3]
 Some of the time [4]
 Once in a while [5]
 Hardly any of the time [6]; or,
 None of the time [7]

2. During the past week, how often did your family need to change plans because of your child's asthma? Would you say: **[CHECK ONLY ONE RESPONSE]**

All of the time [1]
 Most of the time [2]
 Quite often [3]
 Some of the time [4]
 Once in a while [5]
 Hardly any of the time [6]; or,
 None of the time [7]

3. During the past week, how often did you feel frustrated or impatient because your child was irritable due to asthma? Would you say: **[CHECK ONLY ONE RESPONSE]**

All of the time [1]
 Most of the time [2]
 Quite often [3]
 Some of the time [4]
 Once in a while [5]
 Hardly any of the time [6]; or,
 None of the time [7]

APPENDIX 2. BASELINE DATA COLLECTION FORMS

4. During the past week, how often did your child's asthma interfere with your job or work around the house? Would you say: **[CHECK ONLY ONE RESPONSE]**
- All of the time [1]
 - Most of the time [2]
 - Quite often [3]
 - Some of the time [4]
 - Once in a while [5]
 - Hardly any of the time [6]; or,
 - None of the time [7]
5. During the past week, how often did you feel upset because of your child's cough, wheeze, or breathlessness? Would you say: **[CHECK ONLY ONE RESPONSE]**
- All of the time [1]
 - Most of the time [2]
 - Quite often [3]
 - Some of the time [4]
 - Once in a while [5]
 - Hardly any of the time [6]; or,
 - None of the time [7]
6. During the past week, how often did you have sleepless nights because of your child's asthma? Would you say: **[CHECK ONLY ONE RESPONSE]**
- All of the time [1]
 - Most of the time [2]
 - Quite often [3]
 - Some of the time [4]
 - Once in a while [5]
 - Hardly any of the time [6]; or,
 - None of the time [7]
7. During the past week, how often were you bothered because your child's asthma interfered with family relationships? Would you say: **[CHECK ONLY ONE RESPONSE]**
- All of the time [1]
 - Most of the time [2]
 - Quite often [3]
 - Some of the time [4]
 - Once in a while [5]
 - Hardly any of the time [6]; or,
 - None of the time [7]

APPENDIX 2. BASELINE DATA COLLECTION FORMS

8. During the past week, how often were you awakened during the night because of your child's asthma? Would you say: **[CHECK ONLY ONE RESPONSE]**
- All of the time [1]
 - Most of the time [2]
 - Quite often [3]
 - Some of the time [4]
 - Once in a while [5]
 - Hardly any of the time [6]; or,
 - None of the time [7]
9. During the past week, how often did you feel angry that your child has asthma? Would you say: **[CHECK ONLY ONE RESPONSE]**
- All of the time [1]
 - Most of the time [2]
 - Quite often [3]
 - Some of the time [4]
 - Once in a while [5]
 - Hardly any of the time [6]; or,
 - None of the time [7]
10. During the past week, how worried or concerned were you about your child's performance of normal daily activities? Would you say: **[CHECK ONLY ONE RESPONSE]**
- Very, very worried or concerned [1]
 - Very worried or concerned [2]
 - Fairly worried or concerned [3]
 - Somewhat worried or concerned [4]
 - A little worried or concerned [5]
 - Hardly worried or concerned [6]; or,
 - Not worried or concerned [7]
11. During the past week, how worried or concerned were you about your child's asthma medications and side effects? Would you say: **[CHECK ONLY ONE RESPONSE]**
- Very, very worried or concerned [1]
 - Very worried or concerned [2]
 - Fairly worried or concerned [3]
 - Somewhat worried or concerned [4]
 - A little worried or concerned [5]
 - Hardly worried or concerned [6]; or,
 - Not worried or concerned [7]

APPENDIX 2. BASELINE DATA COLLECTION FORMS

12. During the past week, how worried or concerned were you about being overprotective of your child? Would you say: **[CHECK ONLY ONE RESPONSE]**

- Very, very worried or concerned [1]
- Very worried or concerned [2]
- Fairly worried or concerned [3]
- Somewhat worried or concerned [4]
- A little worried or concerned [5]
- Hardly worried or concerned [6]; or,
- Not worried or concerned [7]

13. During the past week, how worried or concerned were you about your child being able to lead a normal life? Would you say: **[CHECK ONLY ONE RESPONSE]**

- Very, very worried or concerned [1]
- Very worried or concerned [2]
- Fairly worried or concerned [3]
- Somewhat worried or concerned [4]
- A little worried or concerned [5]
- Hardly worried or concerned [6]; or,
- Not worried or concerned [7]

Child was present during completion of this form (LEAVE BLANK IF NO)? _____

Date form entered into database : _____ [MM/DD/YYYY]

Data Entry Operator: _____ **[INITIALS ONLY]**

ROUTE OF MEDICATION ADMINISTRATION

1. ORAL
2. NEBULIZER
 - a. BY FACE MASK
 - b. BY MOUTH PIECE
 - c. BLOW-BY ON FACE
3. METERED DOSE INHALER
 - a. DIRECTLY INTO MOUTH
 - b. OPEN SPACER
 - c. VALVED HOLDING CHAMBER
 - d. VALVED HOLDING CHAMBER WITH MASK
4. DRY-POWDER INHALER
 - a. DISKUS
 - b. TURBUHALER
 - c. AEROLIZER
 - d. DISKHALER

APPENDIX 2. BASELINE DATA COLLECTION FORMS

Asthma Knowledge Quiz

Participant ID Number: _____
Collected at: ___ Baseline ___ 2 Weeks ___ Month 3 ___ Month 6 ___ Month 12
Data Collected by: _____ [INITIALS ONLY] Date collected: _____ [MM/DD/YYYY]

- | | True | False |
|---|-------------|--------------|
| 1. Common cold and flu are commonly associated with asthma attacks in children. | _____ | _____ |
| 2. Exposure to cigarette smoke can worsen symptoms of asthma. | _____ | _____ |
| 3. Even on days when my child has no symptoms of asthma, his/her breathing tubes may still be swollen. | _____ | _____ |
| 4. Children with asthma should decrease their physical activity to prevent increase in asthma symptoms. | _____ | _____ |
| 5. Albuterol is a rescue medicine for asthma. It should be given only during those times when the child has symptoms of asthma. | _____ | _____ |
| 6. Asthma attacks may cause breathing problems, but these attacks are not really dangerous or harmful. | _____ | _____ |
| 7. Coughing at night can be a symptom of asthma. | _____ | _____ |
| 8. There is no cure for asthma. | _____ | _____ |
| 9. Regular daily use of steroid inhaler medicine for asthma is harmful and should be avoided. | _____ | _____ |
| 10. Severity of asthma symptoms may change from one season to another. | _____ | _____ |

Date form entered into database: _____ [MM/DD/YYYY]
Data Entry Operator: _____ [INITIALS ONLY]

APPENDIX 2. BASELINE DATA COLLECTION FORMS

Pediatric Asthma Management Parental Self-Efficacy Scale

Participant ID Number: _____

Collected at: ___ Baseline ___ Month 3 ___ Month 6 ___ Month 12

Data Collected by: _____ **[INITIALS ONLY]** Date collected: _____ **[MM/DD/YYYY]**

I will read you a series of statements. For each, please tell me whether you strongly agree, agree, disagree or strongly disagree with the statement.

1. You feel certain/confident that you can respond when your child begins to show symptoms of an asthma attack. **[CHECK ONLY ONE RESPONSE]**
 - ___ Strongly Agree [4]
 - ___ Agree [3]
 - ___ Disagree [2]
 - ___ Strongly Disagree [1]
 - ___ Don't Know [8]

2. You feel burdened because your child has to take medications on a daily basis. **[CHECK ONLY ONE RESPONSE]**
 - ___ Strongly Agree [4]
 - ___ Agree [3]
 - ___ Disagree [2]
 - ___ Strongly Disagree [1]
 - ___ Don't Know [8]

3. You feel capable in using the medicines appropriately. **[CHECK ONLY ONE RESPONSE]**
 - ___ Strongly Agree [4]
 - ___ Agree [3]
 - ___ Disagree [2]
 - ___ Strongly Disagree [1]
 - ___ Don't Know [8]

4. You know when your child's medications are not working. **[CHECK ONLY ONE RESPONSE]**
 - ___ Strongly Agree [4]
 - ___ Agree [3]
 - ___ Disagree [2]
 - ___ Strongly Disagree [1]
 - ___ Don't Know [8]

APPENDIX 2. BASELINE DATA COLLECTION FORMS

5. Your child feels different from other children his/her age. **[CHECK ONLY ONE RESPONSE]**
- Strongly Agree [4]
 - Agree [3]
 - Disagree [2]
 - Strongly Disagree [1]
 - Don't Know [8]
6. You feel that your child may die during or after an asthma attack. **[CHECK ONLY ONE RESPONSE]**
- Strongly Agree [4]
 - Agree [3]
 - Disagree [2]
 - Strongly Disagree [1]
 - Don't Know [8]
7. You feel capable in managing an acute asthma attack of your child. **[CHECK ONLY ONE RESPONSE]**
- Strongly Agree [4]
 - Agree [3]
 - Disagree [2]
 - Strongly Disagree [1]
 - Don't Know [8]
8. You feel where you live affects your child's asthma. **[CHECK ONLY ONE RESPONSE]**
- Strongly Agree [4]
 - Agree [3]
 - Disagree [2]
 - Strongly Disagree [1]
 - Don't Know [8]
9. You feel capable in communicating with doctors/school authorities regarding your child's asthma. **[CHECK ONLY ONE RESPONSE]**
- Strongly Agree [4]
 - Agree [3]
 - Disagree [2]
 - Strongly Disagree [1]
 - Don't Know [8]

Date form entered into database: _____ [MM/DD/YYYY]

Data Entry Operator: _____ **[INITIALS ONLY]**

Source: Telleen, Sharon (2000). Use of Child Health Services by Latino Families in Chicago. Final Report. Maternal and Child Health Bureau, HRSA Grant Number: MCJ 17080.

APPENDIX 2. BASELINE DATA COLLECTION FORMS

Home/Trigger Assessment

Participant ID Number: _____
Month: ___ Baseline ___ Month 3 ___ Month 6 ___ Month 12
Data Collected by: _____ [INITIALS ONLY] Date collected: _____ [MM/DD/YYYY]
Assessment done: ___ at family's home ___ elsewhere via caregiver's report

1. How frequently is your child exposed to second hand cigarette smoke? **[CHECK CORRECT RESPONSE]**
 - ___ At least once a day
 - ___ 2-6 days a week
 - ___ Once a week
 - ___ More than once a month, but not every week
 - ___ Once a month
 - ___ Less than once a month
 - ___ No Coded Response Applicable (SPECIFY: _____)
 - ___ Don't Know
 - ___ Refused

2.
 - a. Do you smoke? **[CHECK CORRECT RESPONSE]**
 - ___ Yes
 - ___ No
 - ___ No Coded Response Applicable (SPECIFY: _____)
 - ___ Don't Know
 - ___ Refused

 - b. Does anyone who lives in your home smoke? **[CHECK CORRECT RESPONSE]**
 - ___ Yes
 - ___ No
 - ___ No Coded Response Applicable (SPECIFY: _____)
 - ___ Don't Know
 - ___ Refused

TRIGGERS

3. Which of the following seems to trigger your child's asthma? **[CHECK ALL THAT APPLY]**
 - ___ cold air
 - ___ changes in weather/humidity/temperature
 - ___ exposure to tobacco smoke
 - ___ common cold/flu
 - ___ exercise, running or playing
 - ___ smoke from a fireplace or wood-burning stove
 - ___ cats, dogs, or other furry pets
 - ___ birds
 - ___ strong odors (perfumes, paints, cleaners)
 - ___ air pollution
 - ___ house dusting/vacuuming
 - ___ damp, musty areas

APPENDIX 2. BASELINE DATA COLLECTION FORMS

- pollens
- medication (SPECIFY: _____)
- other (SPECIFY: _____)

Environmental History

4.

a. Do you have any pets? [CHECK CORRECT RESPONSE]

- Yes
- No
- No Coded Response Applicable (SPECIFY: _____)
- Don't Know
- Refused

[IF YES, ANSWER Q4B. ELSE SKIP TO Q5.]

b. Which pets do you have? [CHECK ALL THAT APPLY]

- cat (How many? _____)
- dog (How many? _____)
- bird (How many? _____)
- other furry pet (SPECIFY: _____)

5. Has anyone seen roaches in your home in the past month? [CHECK CORRECT RESPONSE]

- Yes
- No
- No Coded Response Applicable (SPECIFY: _____)
- Don't Know
- Refused

6. Has anyone seen rats or mice in your home in the past month? [CHECK CORRECT RESPONSE]

- Yes
- No
- No Coded Response Applicable (SPECIFY: _____)
- Don't Know
- Refused

7. Which of the following rooms in your home are carpeted? [CHECK ALL THAT APPLY]

- no room in the house is carpeted
- child's bedroom
- living room
- other (SPECIFY: _____)

8. Does your child have any stuffed toys in his/her bedroom? [CHECK CORRECT RESPONSE]

- Yes
- No
- No Coded Response Applicable (SPECIFY: _____)
- Don't Know
- Refused

APPENDIX 2. BASELINE DATA COLLECTION FORMS

9. Does your child have allergy proof covers for any of the following: **[CHECK ALL THAT APPLY]**

- mattress
- box spring
- pillow

10. Do any of the rooms in your home feel moist or damp? **[CHECK CORRECT RESPONSE]**

- Yes
- No
- No Coded Response Applicable (**SPECIFY:** _____)
- Don't Know
- Refused

11. Is there visible mold in any part of your home? **[CHECK CORRECT RESPONSE]**

- Yes
- No
- No Coded Response Applicable (**SPECIFY:** _____)
- Don't Know
- Refused

12. Is there water leakage or seepage in any part of your home? **[CHECK CORRECT RESPONSE]**

- Yes
- No
- No Coded Response Applicable (**SPECIFY:** _____)
- Don't Know
- Refused

13. Do you have a wood-burning stove or a fireplace in your home that you use? **[CHECK CORRECT RESPONSE]**

- Yes
- No
- No Coded Response Applicable (**SPECIFY:** _____)
- Don't Know
- Refused

Date form entered into database: _____ **[MM/DD/YYYY]**

Data Entry Operator: _____ **[INITIALS ONLY]**

APPENDIX 2. BASELINE DATA COLLECTION FORMS

Evaluation of Technique of Use of Asthma Inhalers and Devices

Participant ID Number: _____

Month: ___ Baseline ___ 2 Weeks ___ Month 3 ___ Month 6

Data Collected by: _____ [INITIALS ONLY] Date collected: _____ [MM/DD/YYYY]

[ASSESS EACH CHILD/CAREGIVER'S TECHNIQUE, IF APPROPRIATE FOR THAT PARTICULAR CHILD (I.E. CHILD HAS AN MDI WITH A SPACER/HOLDING CHAMBER)]

MDI ALONE:

1. Appropriately shakes the inhaler prior to use. ___ Yes ___ No
2. Appropriate placement of device in the mouth. ___ Yes ___ No
3. Begins each puff separately, and not together. ___ Yes ___ No ___ N/A
4. Appropriate inhalation technique after actuation. ___ Yes ___ No
5. Holds breathe for 5 to 10 seconds after inhalation. ___ Yes ___ No ___ N/A
6. Tracking inhaler doses appropriately. ___ Yes ___ No

MDI WITH SPACER/HOLDING CHAMBER:

7. Appropriately shakes the inhaler prior to use. ___ Yes ___ No
8. Appropriate placement of device in the mouth. ___ Yes ___ No
9. Begins each puff separately, and not together. ___ Yes ___ No ___ N/A
10. Appropriate inhalation technique after actuation. ___ Yes ___ No
11. Holds breathe for 5 to 10 seconds after inhalation. ___ Yes ___ No ___ N/A
12. Tracking inhaler doses appropriately. ___ Yes ___ No

MDI WITH VALVED HOLDING CHAMBER AND MASK:

1. Appropriately shakes inhaler prior to use. ___ Yes ___ No
2. Appropriate placement of device on the face. ___ Yes ___ No
3. Begins each puff separately, and not together. ___ Yes ___ No ___ N/A
4. Face mask kept on until five breaths completed after actuation. ___ Yes ___ No
5. Tracking inhaler doses appropriately. ___ Yes ___ No

APPENDIX 2. BASELINE DATA COLLECTION FORMS

DRY POWDER INHALERS:

1. Appropriate loading of a dose prior to use. Yes No
2. Appropriate placement of device in the mouth. Yes No
3. Appropriate inhalation technique. Yes No
4. Holds breathe for 5 to 10 seconds after inhalation. Yes No

Date form entered into database: _____ [MM/DD/YYYY]

Data Entry Operator: _____ [INITIALS ONLY]

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